The Commonwealth of Massachusetts
William Francis Galvin - Secretary of the Commonwealth

Apostille

(Convention de la Haye du 5 Octobre 1961)

1. Country: United States Of America

This Public Document

2. Has been signed by: Ayako Muto

3. Acting in the capacity of: Notary Public

4. Bears the seal/stamp of: Ayako Muto

Whose commission expires on: 06/28/2030

Certified

5. At: Boston, Massachusetts 6. The: March 11, 2026

7. By: The Secretary of Commonwealth

8. No.: 2810031

9. Seal/Stamp: *(Great Seal of the Commonwealth)*

10. Signature:

William Francis Galvin
Secretary of the Commonwealth

Prepared By: DDasousa

2026-07-22 10:05:56.224342-03

Boston Scientific

300 Boston Scient
Marlborough, MA
www.bostonscienti

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March 4, 2026

To Whom It May Concern,

This is to certify that, pursuant to an International Distributorship Agreement between Boston Scientific Corporation., with a principal business address of 300 Boston Scientific Way, Marlborough, MA 01752 USA ("BSI") and manufacturing locations detail below, and the party to the agreement identified immediately below as "Distributor", Distributor is authorized to make offers or bids, solicit orders, import, conclude sales, register with government offices, and perform all necessary functions for sales of the Boston Scientific products in the territory of Paraguay.

JACK FACK S.R.L. ("Distributor")

Reclus #288, entre Guido Spano y Andrade
Asuncion, Paraguay
Tel: 59521600865
FAX: 59521612314
E-mail: quirno@jackfack.com.py
Attn: Quirno Codas Thompson

Boston Scientific Corporation manufactures its products at manufacturing sites owned and operated by companies within the Boston Scientific Group, as well as at certain qualified third-party manufacturing sites operating under OEM (Original Equipment Manufacturer) agreements.

The authorized manufacturing sites are listed below:

A quien corresponda,

Esto certifica que, conforme a un Acuerdo Internacional de Distribución entre Boston Scientific Corporation, con dirección comercial principal en 300 Boston Scientific Way, Marlborough, MA 01752 USA ("BSI") y ubicaciones de fabricación detalladas a continuación, y la parte del acuerdo identificada inmediatamente como "Distribuidor", el Distribuidor está autorizado para hacer ofertas, participar de licitaciones, solicitar pedidos, importar, concluir ventas, registrarse en oficinas gubernamentales y realizar todas las funciones necesarias para la venta de los productos de Boston Scientific en el territorio paraguayo.

JACK FACK S.R.L. ("Distribuidor")

Reclus #288, entre Guido Spano y Andrade
Asuncion, Paraguay
Tel: 59521600865
FAX: 59521612314
E-mail: quirno@jackfack.com.py
Attn: Quirno Codas Thompson

Boston Scientific Corporation fabrica sus productos en sitios de fabricación propios y operados por empresas dentro del grupo Boston Scientific, así como en ciertos centros de fabricación de terceros cualificados que operan bajo acuerdos OEM (*Original Equipment Manufacturer*).

Los sitios de fabricación autorizados se detallan a continuación:

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Boston Scientific

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American Medical Systems Inc.
10700 Bren Road West Minnetonka, MN 55343, USA.

Amphenol Alden Products Company
C/O Amphenol PCD Shenzhen, Building 21 1st Liao Keng Industrial Zone, Shi Yan Street Bao An District, Shenzhen China 518108.

AMPHENOL ALDEN PRODUCTS COMPANY
Parque Industrial Dynatech, Ave. Severiano Talamante No. 6-B Hermosillo, Sonora 83170, MEXICO.

Amphenol DC Electronics
1870 Little Orchard St. – San Jose, California, 95125, USA

Anrei Medical (HZ) CO, LTD
NO. 3 AVE, 8, HEDA HANGZHOU, CHINA

APOLLO ENDOSURGERY COSTA RICA S.R.L.
Edificio 13.3, Zona Franca Coyol, Alajuela 20113, Costa Rica.

ARMOR PLAST LTD
235 B Bommasandra Industrial Area, Bangalore Karnataka 560099 India.

Assut Europe S.P.A.
Zona Industriale, Magliano Dei Marsi, L'Aquila AQ I-67062, Italy.

Availmed S.A. de CV
C.Industrial Lt.001 Mz.105, No. 20905 Int.A Col.Cd, Industrial, Tijuana, Baja California 22444, Mexico.

B. Braun US Device Manufacturing LLC
901 Marcon Boulevard, Allentown, PA 18109-9341, USA.

Benchmark Electronics, Inc.
4065 Theurer Blvd., Winona, MN 55987, USA

Boston Scientific Belo Horizonte (BHM) site (ACURATE Industria e Comercio Ltda)
3445 Avenida General David Sarnoff Lote 02 Quadra 31A Cidade Ind, Contagem, Minas Gerais (MG), Brasil.

Boston Scientific Corporation
100 Boston Scientific Way, Marlborough, MA 01752 USA

Boston Scientific Corporation
150 Baytech Drive San Jose, CA 95134 USA

Boston Scientific Corporation
2546 First Street, Propark, El Coyol, Alajuela, Costa Rica

Boston Scientific Corporation
300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA

Boston Scientific Corporation
302 Parkway Global Park, Heredia, Costa Rica

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Boston Scientific Corporation
4100 Hamline Ave. N. St. Paul, Minnesota 55112, USA

Boston Scientific Corporation
doing business as Boston Scientific Corporation, Marina Bay Customer Fulfillment Center
500 Commander Shea Boulevard, Quincy, MA 02171, USA

Boston Scientific Corporation
780 Brookside Drive, Spencer, Indiana 47460, USA

Boston Scientific Corporation
doing business as Boston Scientific Puerto Rico LLC.
N° 12 RD N° 698, Dorado, PR USA 00646.

Boston Scientific Corporation
Two Scimed Place, Maple Grove, MN 55311, USA

Boston Scientific Corporation
2775 Matheson Blvd E, Mississauga, Ontario, CANADA L4W 4P7

Boston Scientific Corporation
Zona Franca La Lima, Cartago, Cartago, COSTA RICA 30106

Boston Scientific Ecublens (ECU) site (Symetis S.A)
11 Chemin de la Venoge, 1024, Ecublens, Suiza.

Boston Scientific Limited
Ballybrit Business Park, Galway, Irlanda.

Boston Scientific Limited
Business & Technology Park, Model Farm Road Cork, Ireland.

Boston Scientific Limited
Cashel Road, Clonmel, Co.Tipperary, Ireland.

Boston Scientific Medical Device (Malaysia) SDN BHD
PMT 741, Persiaran Cassia Selatan 1, Taman Perindustrian Batu Kawan, 14110 Bandar Cassia, Pulau Pinang, Malaysia.

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop, Valencia, CA 91355, USA

BWXT Medical Ltd.
447 March Road, Ottawa, Ontario, K2K 1X8, Canada.

C.R. Bard, Inc.
289 Bay Rd. – Queensbury, NY 12804, USA

Cable Connection Inc.
1035 Mission Court, Fremont, CA 94539, USA

Cardiac Pacemakers, Inc., a subsidiary of Boston Scientific Corporation
4100 Hamline Avenue North, St. Paul, MN 55112, USA

Carrio Cabling Corporation

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Boston Scientific
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2455 Executive circle, Colorado Springs, CO USA 80906

CEA Medical Manufacturing Inc
1755 Merchants Ct, Colorado Springs, CO 80916 USA.

CenterPoint Systems LLC
3338 W Parkway Blvd West Valley City, UT 84119 USA

COOPERSURGICAL INC
95 Corporate Drive, Trumbull, CT 06611, USA

COSMAN MEDICAL LLC
22 TERRY AVE, BURLINGTON, MA 01803, USA

Creation Technologies Ltd.
8977-8999 Fraserton Court, Burnaby, British Columbia V5J 5H8, Canada.

Creganna Medical
400 metros este de Holcim, Zona Industrial Felxipark Bodega G6, San Rafael, Alajuela, Costa Rica 20108.

Creganna Tactx Medical
Parkmore West, Galway, Ireland.

Dedicated Computing LLC
N26W23880 Commerce Circle – Waukesha, Wisconsin –53188 – USA

Enercon Technologies
25 Northbrook Dr., P.O. BOX 665 Gray, ME 04039, USA

FMD. Co., Ltd.
1-166 Shimoobari, Nakashima, Komaki, Aichi 485-0051, Japan.

GCX Corporation
26 Spur Dr., El Paso, TX 79906, USA

Greatbatch Medical
2300 Berkshire Lane North, Minneapolis, MN 55441, USA

Greatbatch Medical, S. de R.L. de C.V.
Boulevard Hector Teran Teran #20120, Ciudad Industrial Tijuana, Baja California, 22444, México.

Hemoteq AG
Adenauerstrasse 15, 52146, Würselen, Germany.

Heraeus Medical Components, SRL
Parque Industrial Zona Franca La Lima Guadalupe Building 29 Cartago, Cartago COSTA RICA 30106.

Jabil Circuit Shanghai, LTD
600 Tian Lin Road, Shanghai, Shanghai 20022, China.

Lake Region Medical
340 Lake Hazeltine Drive, Chaska, MN 55318. USA

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Lake Region Medical Limited
Butlersland, New Ross, Co. Wexford, Ireland.

LEAD-LOK, INC
doing business as Nissha Medical Technologies
814 Airport Way, Sandpoint, ID, USA 83864

Light Guide Optics International
Celtniecibas Street 8 Livani. LATVIA

LINEMASTER SWITCH CORP.
29 PLAINE HILL RD, WOODSTOCK, CT 06281 USA

Lumenis Ltd.
Yokneam Industrial Park, Hakidma Street 6 P.O.B. #240, Yokneam 2069204, Israel.

Merit Medical Systems, Inc
14646 Kirby Drive, Houston, Texas, USA 77407

Micropace Pty Ltd
41/159 Arthur Street, Homebush West, NSW 2140, Australia

MICROTEK DOMINICANA S.A.
Las Americas Free Zone Park, Km 22, Autopista Las Americas, Santo Domingo
Santo Domingo 11606, República Dominicana.

Nicolay GMBH
Graf-Zeppelin-Strasse 21, Nagold, Baden-Wurttemberg, Alemania 72202

NISSHA MEDICAL TECHNOLOGIES SAS
23-25 Boulevard de la Paix, Cergy, Val- d'Oise 95800, France.

Nissha Medical Technologies Limited
Torbay Business Park, Woodview Road, Paignton Devon, TQ4 7HP, United Kingdom.

NOLATO CONTOUR
660 Vandeberg St Baldwin, WI USA 54002.

Northgate Technologies Inc.
1591 Scottsdale Courthouse, Elgin, IL USA 60123.

Nypro DR LLC (operating as Jabil Healthcare)
Carretera Sanchez Km 18.5, Parque Industrial de ITABO, Haina, San Cristobal, Republica Dominicana.

Phillips-Medisize Costa Mesa LLC
3545 Harbor Boulevard, Suite 150, Costa Mesa California, 92626, USA

Plexus Corp.
2400 Millbrook Drive, Buffalo Grove, IL 60089, USA

Plexus Electrónica S. de R.L. de C.V.
Paseo del Norte N° 4640, Parque Tecnológico de Guadalajara, Zapopan, Jalisco, México 45010.

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Boston Scientific

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Proxy Biomedical Ltd.
Coilleach, Spiddal, Galway, Galway, Ireland.

Quasar Medical (Singapore) Pte Ltd.
8 Admiralty Street, #07-10 Admirax Building Singapur 757438.

Scapa Tapes North America, LLC
2565 Bertelkamp Lane, Knoxville, TN 37931, USA

SMC LTD, Santa Rosa
3250 Brickway BLVD, Santa Rosa, CA, 95403, USA

Statice SA
9 rue Thomas EDISON BESANCON, Franche-Comte France 25000

Stellartech Research Corp.
560 Cottonwood Dr. Milpitas, CA 95035, USA

Stockert GmbH
Boetzinger Strasse 31, Freiburg, Baden-Wuerttemberg, Alemania 79111

SWEMCO
1215 N. Church Street, Moorestown, NJ 08057, USA

Teleflex Medical de México S. de R. L. de C.V.
Av. Industrias N° 5954, Parque Industrial Finsa Nuevo Laredo, Tamaulipas, México 88275.

Teleflex Medical.
Unit 7, 8 & 9 - Annacotty Business Park – Annacotty Co. Limerick - Ireland.

Togo Medikit Co., LTD.
17148-6, Aza Kamekawa, Oaza Hichiya, Hyuga City, Miyazaki Prefecture 883-0062 Japan.

VENITI, Inc.
4025 Clipper Court, Fremont, CA 94538, USA

Venusa de Mexico S. de R.L. de C.V.
Calle Hertz 1525, Parque Industrial Antonio J. Bermudez Ciudad Juarez, Chihuahua 32470 Mexico.

Viant AS&O Holdings, LLC
45 Lexington Drive Laconia, NH 03246 USA

Viant Medical, Inc
5079 33rd St SE, Grand Rapids, MI 49512, Estados Unidos.

Adrienne Bishop

Adrienne Bishop
Director, Global Regulatory Affairs Operations
Boston Scientific Corporation

300 Boston Scientific Way
Boston Scientific Corporation
Marlborough, MA 01752 USA

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Commonwealth of Massachusetts
County of Middlesex } ss.

On this 4th of March 2026 before me, the undersigned notary public, personally appeared Adrienne Bishop, proved to me through satisfactory evidence of identification, which was US Passport to be the person whose name is signed on the preceding or attached document, and acknowledged to me that (he/she) signed it voluntarily for its stated purpose.

Ayako Muto Notary Public
My commission expires: June 28, 2030

Ayako Muto
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
June 28, 2030

REGISTRO UNIFICADO NACIONAL
DIRECCIÓN GENERAL DE REGISTROS ESPECIALES
SECCIÓN REGISTRO PÚBLICO DE COMERCIO

DENOMINACIÓN JACK FACK S.R.L.

MATRICULA Nº 8539 ACTO: Distribución
BAJO EL Nº 1 FOLIO Nº 1 SERIE: Contrato
Nº 15648372 FECHA 13-4-26 HORA: 13:42:51

PODER JUDICIAL
REGISTRO UNIFICADO NACIONAL
SECCION REGISTRO PUBLICO DE COMERCIO

LIC. GERARDO RAUL BENITEZ
Jefe Interino

Adrienne B.
Director, Gl
Boston Scien

JACK FACK S.R.L.

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Lote Nº 1 - Item 1 al 18

DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

CERTIFICADO DE REGISTRO SANITARIO

Dispositivos Médicos, Materiales Cortopunzantes y Equipo de Protección Individual

La Dirección Nacional de Vigilancia Sanitaria, autoriza el Registro Sanitario del producto más abajo descripto, cumpliendo la misma con los requisitos y las legislaciones vigentes en la República del Paraguay según Código Sanitario Ley N°836/80,Ley N°6788/2021, Ley N°4659/12, Resolución S.G. N°669/16 y demás legislaciones vigentes.

Certificado N°: **DM-001153-02** Vencimiento: **10-10-2027**
Denominación Comercial: **CATÉTER DE DILATACIÓN PARA ACTP – EMERGE**
Denominación Genérica/Código ECRI: **CATÉTERES, PARA ANGIOPLASTIA, CON DILATACIÓN POR BALÓN, PARA PERFUSIÓN CORONARIA 17-521**
Clase: **CLASE IV**

Marca: **BOSTON SCIENTIFIC**
Material de Composición: **REVESTIMIENTO HIDROFÍLICO ZGLIDE™.EL REVESTIMIENTO ZGIIDE SE SITUA DESDE LA SALIDA DE LA GUFA HASTA CASI LA SECCION PROXIMAL DE LA CINTURA DEL BALON.HIPO-TUBO REVESTIDO DE PTFEMATERIAL DEL BALÓN OPTILEAPCONDICIÓN DE ESTERILIDAD MD/MÉTODO DE ESTERILIZACIÓN: ESTÉRIL / ÓXIDO DE ETILENO**
Accesorios: **UNA (1) PINZA DE HIPOTUBO CLIPIT**
Presentación: **BOLSA DE CABECERA COMPUESTA POR UNA BOLSA LAMINADA DE POLIETILENO/NYLON CON UNA TIRA TYVEK EN CAJA X 1 UNIDAD**
Plazo de Vida Útil: **32 MESES MR2 AÑOS PARA OTW**
Condición de Venta: **VENTA EXCLUSIVA A PROFESIONALES E INSTITUCIONES SANITARIAS**

Titular: **JACK FACK S.R.L**
Director Técnico: **SILVA GONZÁLEZ NORMA CONCEPCIÓN**
Elaborador Producto Final: **TWO SCIMED PLACE, MAPLE GROVE NM 55311, ESTADOS UNIDOS** por **BOSTON SCIENTIFIC CORPORATION**
Elaborador Producto Final: **PMT 741 PERIARAN CASSIA SELATAN 1 -14110 BANDAR CASSIA, PALAU PINANG, MALASIA** por **BOSTON SCIENTIFIC MEDICAL DEVICE (MALAYSIA) SDN BHD**

Asunción 17 de Octubre de 2023.

LAURA PATRICIA PEREZ VILLAVERDE

Firmado digitalmente por LAURA PATRICIA PEREZ VILLAVERDE
Fecha: 2023.10.17 12:05:55 -03'00'

JACK FACK S.R.L.

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DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

Certificado N°: **DM-001153-02** Vencimiento: **10-10-2027**
Denominación Comercial: **CATÉTER DE DILATACIÓN PARA ACTP – EMERGE**
Denominación Genérica/Código ECRI: **CATÉTERES, PARA ANGIOPLASTIA, CON DILATACIÓN POR BALÓN, PARA PERFUSIÓN CORONARIA 17-521**

ANEXO

Modelos

EMERGE™ MONORAIL™ PTCA DILATATION CATHETER
H7493919308120 EMERGE MONORAIL 8MM X 1.20MM /
H7493919308150 EMERGE MONORAIL 8MM X 1.50MM /
H7493919308200 EMERGE MONORAIL 8MM X 2.00MM /
H7493919308220 EMERGE MONORAIL 8MM X 2.25MM /
H7493919308250 EMERGE MONORAIL 8MM X 2.50MM /
H7493919308270 EMERGE MONORAIL 8MM X 2.75MM /
H7493919308300 EMERGE MONORAIL 8MM X 3.00MM /
H7493919308320 EMERGE MONORAIL 8MM X 3.25MM /
H7493919308350 EMERGE MONORAIL 8MM X 3.50MM /
H7493919308370 EMERGE MONORAIL 8MM X 3.75MM /
H7493919308400 EMERGE MONORAIL 8MM X 4.00MM /
H7493919312120 EMERGE MONORAIL 12MM X 1,20MM /
H7493919312150 EMERGE MONORAIL 12MM X 1.50MM /
H7493919312200 EMERGE MONORAIL 12MM X 2.00MM /
H7493919312220 EMERGE MONORAIL 12MM X 2.25MM /
H7493919312250 EMERGE MONORAIL 12MM X 2.50MM /
H7493919312270 EMERGE MONORAIL 12MM X 2.75MM /
H7493919312300 EMERGE MONORAIL 12MM X 3.00MM /
H7493919312320 EMERGE MONORAIL 12MM X 3.25MM /
H7493919312350 EMERGE MONORAIL 12MM X 3.50MM /
H7493919312370 EMERGE MONORAIL 12MM X 3.75MM /
H7493919312400 EMERGE MONORAIL 12MM X 4.00MM /
H7493919315120 EMERGE MONORAIL 15MM X 1.20MM /
H7493919315150 EMERGE MONORAIL 15MM X 1.50MM /
H7493919315200 EMERGE MONORAIL 15MM X 2.00MM /
H7493919315220 EMERGE MONORAIL 15MM X 2.25MM /
H7493919315250 EMERGE MONORAIL 15MM X 2.50MM /
H7493919315270 EMERGE MONORAIL 15MM X 2.75MM /
H7493919315300 EMERGE MONORAIL 15MM X 3.00MM /
H7493919315320 EMERGE MONORAIL 15MM X 3.25MM /
H7493919315350 EMERGE MONORAIL 15MM X 3.50MM /
H7493919315370 EMERGE MONORAIL 15MM X 3.75MM /

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

H7493919315400 EMERGE MONORAIL 15MM X 4.00MM /
H7493919320120 EMERGE MONORAIL 20MM X 1.20MM /
H7493919320150 EMERGE MONORAIL 20MM X 1.50MM /
H7493919320200 EMERGE MONORAIL 20MM X 2.00MM /
H7493919320220 EMERGE MONORAIL 20MM X 2.25MM /
H7493919320250 EMERGE MONORAIL 20MM X 2.50MM /
H7493919320270 EMERGE MONORAIL 20MM X 2.75MM /
H7493919320300 EMERGE MONORAIL 20MM X 3.00MM /
H7493919320320 EMERGE MONORAIL 20MM X 3.25MM /
H7493919320350 EMERGE MONORAIL 20MM X 3.50MM /
H7493919320370 EMERGE MONORAIL 20MM X 3.75MM /
H7493919320400 EMERGE MONORAIL 20MM X 4.00MM /
H7493919330200 EMERGE MONORAIL 30MM X 2.00MM /
H7493919330220 EMERGE MONORAIL 30MM X 2.25MM /
H7493919330250 EMERGE MONORAIL 30MM X 2.50MM /
H7493919330270 EMERGE MONORAIL 30MM X 2.75MM /
H7493919330300 EMERGE MONORAIL 30MM X 3.00MM /
H7493919330320 EMERGE MONORAIL 30MM X 3.25MM /
H7493919330350 EMERGE MONORAIL 30MM X 3.50MM /
H7493919330370 EMERGE MONORAIL 30MM X 3.75MM /
H7493919330400 EMERGE MONORAIL 30MM X 4.00MM /
H7493919408120 EMERGE MONORAIL PUSH 8MM X 1.20MM /
H7493919408150 EMERGE MONORAIL PUSH 8MM X 1.50MM /
H7493919412120 EMERGE MONORAIL PUSH 12MM X 1.20MM /
H7493919412150 EMERGE MONORAIL PUSH 12MM X 1.50MM /
H7493919415120 EMERGE MONORAIL PUSH 15MM X 1.20MM /
H7493919415150 EMERGE MONORAIL PUSH 15MM X 1.50MM /
H7493919420120 EMERGE MONORAIL PUSH 20MM X 1.20MM /
H7493919420150 EMERGE MONORAIL PUSH 20MM X 1.50MM /
EMERGE™ OVER-THE-WIRE PTCA DILATATION CATHETER
H7493919508120 EMERGE OTW 8MM X 1,20MM /
H7493919508150 EMERGE OTW 8MM X 1.50MM /
H7493919508200 EMERGE OTW 8MM X 2.00MM /
H7493919508220 EMERGE OTW 8MM X 2.25MM /
H7493919508250 EMERGE OTW 8MM X 2.50MM /
H7493919508270 EMERGE OTW 8MM X 2.75MM /
H7493919508300 EMERGE OTW 8MM X 3.00MM /
H7493919508320 EMERGE OTW 8MM X 3.25MM /
H7493919508350 EMERGE OTW 8MM X 3.50MM /
H7493919508370 EMERGE OTW 8MM X 3.75MM /
H7493919508400 EMERGE OTW 8MM X 4.00MM /

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DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

H7493919512120 EMERGE OTW 12MM X 1,20MM /
H7493919512150 EMERGE OTW 12MM X 1.50MM /
H7493919512200 EMERGE OTW 12MM X 2.00MM /
H7493919512220 EMERGE OTW 12MM X 2.25MM /
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H7493919512270 EMERGE OTW 12MM X 2.75MM /
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H7493919512370 EMERGE OTW 12MM X 3.75MM /
H7493919512400 EMERGE OTW 12MM X 4.00MM /
H7493919515120 EMERGE OTW 15MM X 1.20MM /
H7493919515150 EMERGE OTW 15MM X 1.50MM /
H7493919515200 EMERGE OTW 15MM X 2.00MM /
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H7493919515250 EMERGE OTW 15MM X 2.50MM /
H7493919515270 EMERGE OTW 15MM X 2.75MM /
H7493919515300 EMERGE OTW 15MM X 3.00MM /
H7493919515320 EMERGE OTW 15MM X 3.25MM /
H7493919515350 EMERGE OTW 15MM X 3.50MM /
H7493919515370 EMERGE OTW 15MM X 3.75MM /
H7493919515400 EMERGE OTW 15MM X 4.00MM /
H7493919520120 EMERGE OTW 20MM X 1,20MM /
H7493919520150 EMERGE OTW 20MM X 1,50MM /
H7493919520200 EMERGE OTW 20MM X 2.00MM /
H7493919520220 EMERGE OTW 20MM X 2.25MM /
H7493919520250 EMERGE OTW 20MM X 2.50MM /
H7493919520270 EMERGE OTW 20MM X 2.75MM /
H7493919520300 EMERGE OTW 20MM X 3.00MM /
H7493919520320 EMERGE OTW 20MM X 3.25MM /
H7493919520350 EMERGE OTW 20MM X 3.50MM /
H7493919520370 EMERGE OTW 20MM X 3.75MM /
H7493919520400 EMERGE OTW 20MM X 4.00MM /
H7493919530200 EMERGE OTW 30MM X 2.00MM /
H7493919530220 EMERGE OTW 30MM X 2.25MM /
H7493919530250 EMERGE OTW 30MM X 2.50MM /
H7493919530270 EMERGE OTW 30MM X 2.75MM /
H7493919530300 EMERGE OTW 30MM X 3.00MM /
H7493919530320 EMERGE OTW 30MM X 3.25MM /
H7493919530350 EMERGE OTW 30MM X 3.50MM /
H7493919530370 EMERGE OTW 30MM X 3.75MM /

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

H7493919530400 EMERGE OTW 30MM X 4.00MM /
H7493919608120 EMERGE OTW PUSH 8MM X 1.20MM /
H7493919608150 EMERGE OTW PUSH 8MM X 1.50MM /
H7493919612120 EMERGE OTW PUSH 12MM X 1.20MM /
H7493919612150 EMERGE OTW PUSH 12MM X 1.50MM /
H7493919615120 EMERGE OTW PUSH 15MM X 1.20MM /
H7493919615150 EMERGE OTW PUSH 15MM X 1.50MM /
H7493919620120 EMERGE OTW PUSH 20MM X 1.20MM /
H7493919620150 EMERGE OTW PUSH 20MM X 1,50MM /
NC EMERGE™ MONORAIL™ PTCA DILATATION CATHETER
H7493927606200 NC EMERGE MR OUS 6MM X 2.00MM /
H7493927606220 NC EMERGE MR OUS 6MM X 2.25MM /
H7493927606250 NC EMERGE MR OUS 6MM X 2.50MM /
H7493927606270 NC EMERGE MR OUS 6MM X 2.75MM /
H7493927606300 NC EMERGE MR OUS 6MM X 3.00MM /
H7493927606320 NC EMERGE MR OUS 6MM X 3.25MM /
H7493927606350 NC EMERGE MR OUS 6MM X 3.50MM /
H7493927606370 NC EMERGE MR OUS 6MM X 3.75MM /
H7493927606400 NC EMERGE MR OUS 6MM X 4.00MM /
H7493927606450 NC EMERGE MR OUS 6MM X 4.50MM /
H7493927606500 NC EMERGE MR OUS 6MM X 5.00MM /
H7493927608200 NC EMERGE MR OUS 8MM X 2.00MM /
H7493927608220 NC EMERGE MR OUS 8MM X 2.25MM /
H7493927608250 NC EMERGE MR OUS 8MM X 2.50MM /
H7493927608270 NC EMERGE MR OUS 8MM X 2.75MM /
H7493927608300 NC EMERGE MR OUS 8MM X 3.00MM /
H7493927608320 NC EMERGE MR OUS 8MM X 3.25MM /
H7493927608350 NC EMERGE MR OUS 8MM X 3.50MM /
H7493927608370 NC EMERGE MR OUS 8MM X 3.75MM /
H7493927608400 NC EMERGE MR OUS 8MM X 4.00MM /
H7493927608450 NC EMERGE MR OUS 8MM X 4.50MM /
H7493927608500 NC EMERGE MR OUS 8MM X 5.00MM /
H7493927608550 NC EMERGE MR OUS 8MM X 5.50MM /
H7493927608600 NC EMERGE MR OUS 8MM X 6.00MM /
H7493927612200 NC EMERGE MR OUS 12MM X 2.00MM /
H7493927612220 NC EMERGE MR OUS 12MM X 2.25MM /
H7493927612250 NC EMERGE MR OUS 12MM X 2.50MM /
H7493927612270 NC EMERGE MR OUS 12MM X 2.75MM /
H7493927612300 NC EMERGE MR OUS 12MM X 3.00MM /
H7493927612320 NC EMERGE MR OUS 12MM X 3.25MM /
H7493927612350 NC EMERGE MR OUS 12MM X 3.50MM /

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DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

H7493927612370 NC EMERGE MR OUS 12MM X 3.75MM /
H7493927612400 NC EMERGE MR OUS 12MM X 4.00MM /
H7493927612450 NC EMERGE MR OUS 12MM X 4.50MM /
H7493927612500 NC EMERGE MR OUS 12MM X 5.00MM /
H7493927612550 NC EMERGE MR OUS 12MM X 5.50MM /
H7493927612600 NC EMERGE MR OUS 12MM X 6.00MM /
H7493927615200 NC EMERGE MR OUS 15MM X 2.00MM /
H7493927615220 NC EMERGE MR OUS 15MM X 2.25MM /
H7493927615250 NC EMERGE MR OUS 15MM X 2.50MM /
H7493927615270 NC EMERGE MR OUS 15MM X 2.75MM /
H7493927615300 NC EMERGE MR OUS 15MM X 3.00MM /
H7493927615320 NC EMERGE MR OUS 15MM X 3.25MM /
H7493927615350 NC EMERGE MR OUS 15MM X 3.50MM /
H7493927615370 NC EMERGE MR OUS 15MM X 3.75MM /
H7493927615400 NC EMERGE MR OUS 15MM X 4.00MM /
H7493927615450 NC EMERGE MR OUS 15MM X 4.50MM /
H7493927615500 NC EMERGE MR OUS 15MM X 5.00MM /
H7493927615550 NC EMERGE MR OUS 15MM X 5.50MM /
H7493927615600 NC EMERGE MR OUS 15MM X 6.00MM /
H7493927620200 NC EMERGE MR OUS 20MM X 2.00MM /
H7493927620220 NC EMERGE MR OUS 20MM X 2.25MM /
H7493927620250 NC EMERGE MR OUS 20MM X 2.50MM /
H7493927620270 NC EMERGE MR OUS 20MM X 2.75MM /
H7493927620300 NC EMERGE MR OUS 20MM X 3.00MM /
H7493927620320 NC EMERGE MR OUS 20MM X 3.25MM /
H7493927620350 NC EMERGE MR OUS 20MM X 3.50MM /
H7493927620370 NC EMERGE MR OUS 20MM X 3.75MM /
H7493927620400 NC EMERGE MR OUS 20MM X 4.00MM /
H7493927620450 NC EMERGE MR OUS 20MM X 4.50MM /
H7493927620500 NC EMERGE MR OUS 20MM X 5.00MM /
H7493927620550 NC EMERGE MR OUS 20MM X 5.50MM /
H7493927620600 NC EMERGE MR OUS 20MM X 6.00MM /
H7493927630200 NC EMERGE MR OUS 30MM X 2.00MM /
H7493927630220 NC EMERGE MR OUS 30MM X 2.25MM /
H7493927630250 NC EMERGE MR OUS 30MM X 2.50MM /
H7493927630270 NC EMERGE MR OUS 30MM X 2.75MM /
H7493927630300 NC EMERGE MR OUS 30MM X 3.00MM /
H7493927630320 NC EMERGE MR OUS 30MM X 3.25MM /
H7493927630350 NC EMERGE MR OUS 30MM X 3.50MM /
H7493927630370 NC EMERGE MR OUS 30MM X 3.75MM /
H7493927630400 NC EMERGE MR OUS 30MM X 4.00MM /

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Lote Nº 3 - Item 1 al 6
Lote Nº 109 - Item 1
Lote Nº 110 - Item 1
Lote Nº 112 - Item 1
Lote Nº 125 - Item 1

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DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

CERTIFICADO DE REGISTRO SANITARIO

Dispositivos Médicos, Materiales Cortopunzantes y Equipo de Protección Individual

La Dirección Nacional de Vigilancia Sanitaria, autoriza el Registro Sanitario del producto más abajo descripto, cumpliendo la misma con los requisitos y las legislaciones vigentes en la República del Paraguay según Código Sanitario Ley N° 836/80, Ley N° 6788/2021 y demás normativas vigentes.

Certificado N°: **DM-002508-02** Vencimiento: **10-07-2032**
Denominación Comercial: **INTRODUCTOR DE VAINA PRELUDE**
Denominación Genérica/Código ECRI: **INTRODUCTORES DE CATÉTERES 10-678**
Clase: **CLASE IV**

Marca: **MERIT MEDICAL**
Material de Composición: **ETFEPOLIPROPILENOPOLICARBONATOSILICONAACERO INOXIDABLEMÉTODO DE ESTERILIZACIÓN: OXIDO DE ETILENOSE PRESENTAN EN KIT Y CONTIENE LO SIGUIENTE; • UN INTRODUCTOR DE VAINA• UN DILATADOR DE VASOS• UNA GUÍA METÁLICA INTRODUCTORA • UNA AGUJA**
Accesorios: **NO POSEE**
Presentación: **ENVASE PRIMARIO: BOLSA DE TYVEK/NYLONENVASE SECUNDARIO: CAJAS DE CARTONUNIDADES DE VENTA: CAJAS POR 1 UNIDAD, CAJAS POR 5 UNIDADES Y CAJAS POR 20 UNIDADES**
Plazo de Vida Útil: **3 AÑOS**
Condición de Venta: **VENTA EXCLUSIVA A PROFESIONALES E INSTITUCIONES SANITARIAS**

Titular: **JACK FACK S.R.L**
Director Técnico: **DÍAZ VILLANUEVA MARÍA LOURDES**
Elaborador Producto Final: **1600 WEST MERIT PARKWY, SOUTH JORDAN, UT. USA 84095, ESTADOS UNIDOS** por **MERIT MEDICAL SYSTEMS, INC.**

Asunción 03 de Febrero de 2025.

JORGE ILIOU SILVERO
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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

Certificado N°: **DM-002508-02** Vencimiento: **10-07-2032**
Denominación Comercial: **INTRODUCTOR DE VAINA PRELUDE**
Denominación Genérica/Código ECRI: **INTRODUCTORES DE CATÉTERES 10-678**

ANEXO

Modelos
PRELUDE SHEATH INTRODUCERS;
PSI-4F-11-035 /
PSI-5F-11-035 /
PSI-6F-11-035/
PSI-7F-11-035 /
PSI-8F-11-035/
PSI-5F-11-038 /
PSI-6F-11-038 /
PSI-7F-11-038 /
PSI-8F-11-038 /
PSI-4F-11 /
PSI-5F-11 /
PSI-6F-11 /
PSI-7F-11/
PSI-8F-11 /
PSI-4F-23-035 /
PSI-5F-23-035 /
PSI-6F-23-035 /
PSI-7F-23-035/
PSI-8F-23-035 /
PSI-5F-23-038 /
PSI-6F-23-038 /
PSI-7F-23-038 /
PSI-8F-23-038 /
PSI-4F-23 /
PSI-5F-23 /
PSI-6F-23 /
PSI-7F-23 /
PSI-8F-23//
PRELUDE PRO SHEATH INTRODUCERS;
PRO-4F-11-035 /
PRO-5F-11-035 /
PRO-6F-11-035 /
PRO-7F-11-035 /

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PRO-8F-11-035 /
PRO-5F-11-038 /
PRO-6F-11-038 /
PRO-7F-11-038 /
PRO-8F-11-038 /
PRO-4F-11 /
PRO-5F-11 /
PRO-6F-11 /
PRO-7F-11 /
PRO-8F-11///

- PRELUDE ACT SHEATH INTRODUCERS;

PSI-4F-11-035ACT /
PSI-5F-11-038ACT /
PSI-6F-11-038ACT /
PSI-7F-11-038ACT /
PSI-8F-11-038ACT /
PSI-4F-11ACT /
PSI-5F-11ACT /
PSI-6F-11ACT /
PSI-7F-11ACT /
PSI-8F-11ACT//
PRELUDE SHORT SHEATH INTRODUCERS;
PSS-5F-4-018MT/
PSS-6F-4-018MT /
PSS-7F-4-018MT /
PSS-8F-4-018MT /
PSS-5F-4-035MT/
PSS-6F-4-035MT /
PSS-7F-4-035MT /
PSS-8F-4-035MT /
PSS-5F-4-038MT /
PSS-6F-4-038MT /
PSS-7F-4-038MT /
PSS-8F-4-038MT /
PSS-5F-4MT /
PSS-6F-4MT/
PSS-7F-4MT /
PSS-8F-4MT //
PRELUDE NEEDLE SHEATH INTRODUCERS ;
PSI-4F-11-018 /
PSI-4F-11-018-NT4/

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

PSI-4F-11-025 /
PSI-4F-23-018NT4 /
PSI-4F-11-23-018NT7 /
PSI-4F-7-018 /
PSI-4F-7-018NT4 /
PSI-4F-7-025/
PSI-5F-11-018/
PSI-5F-11-018-NT4/
PSI-5F-11-025 /
PSI-5F-23-018NT4 /
PSI-5F-11-23-018NT7 /
PSI-5F-7-018/
PSI-5F-7-018NT4 /
PSI-5F-7-025 /
PSI-6F-11-018/
PSI-6F-11-018-NT4/
PSI-6F-11-025 /
PSI-6F-23-018NT4 /
PSI-6F-11-23-018NT7 /
PSI-6F-7-018 /
PSI-6F-7-018NT4 /
PSI-6F-7-025 /
PSI-7F-11-018 /
PSI-7F-23-018NT4/
PSI-7F-7-018 /
PSI-5F-11-035-18G /
PSI-6F-11-035-18G/
PSI-7F-11-035-18G /
PSI-8F-11-035-18G /
PSI-5F-11-038-18G /
PSI-6F-11-038-18G /
PSI-7F-11-038-18G /
PSI-8F-11-038-18G /
PSIP4F11018NTPD/
PSIP4F11018SS/
PSIP4F7018NTPD/
PSIP4F7018SS/
PSIP5F11018NTPD/
PSIP5F11018SS/
PSIP5F7018NTPD/
PSIP5F7018SS/

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY | PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

PSIP6F11018NTPD/
PSIP6F11018SS/
PSIP6F7018NTPD/
PSIP6F7018SS//
PRELUDE PRO + NEEDLE SHEATH INTRODUCERS;
PRO-4F-11-018NT7/
PRO-5F-11-018NT7/
PRO-6F-11-018NT7/
PRO-7F-11-018NT7/
PRO-5F-11-038-18G/
PRO-6F-11-038-18G//
PRELUDE IDEAL TM HYDROPHILIC SHEATH INTRODUCER;
PID4F7018NTPD/
PID7F11018SS/
PID5F23021SC/
PID5F7018NTPD /
PID4F11021SC/
PID6F23021SC/
PID5F23021PW/
PID6F7018NTPD/
PID5F11021SC/
PID7F23021SC/
PID7F23021PW/
PID6F23021PW/
PID4F11018SC/
PID6F11021SC/
PIDSF23021SSC/
PID4F11025PW/
PIDSF11018SC/
PID7F11021SC /
PID6F23021SSC /
PID5F11025PW/
PID6F11018SC /
PID5F11021SSC /
PID4F11021PW/
PID6F11025PW/
PID7F11018SC /
PID6F11021SSC/
PID5F11021PW/
PID7F11025PW/
PID4F11018NTPD /

JACK FACK S.R.L.

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

PID4F16021SC /
PID6F11021PW/
PID4F16025PW/
PID5F11018NTPD /
PID5F16021SC/
PID7F11021PW /
PIDSF16025PW /
PID6F11018NTPD/
PID6F16021SC /
PID4F16021PW /
PID6F16025PW/
PID7F11018NTPD /
PID7F16021SC /
PID5F16021PW/
PID7F16025PW/
PID4F11018SS/
PID5F16021SSC/
PID6F16021PW/
PID4F11021SSC/
PID5F11018SS /
PID6F16021SSC/
PID7F16021PW /
PID4F16021SSC/
PID6F11018SS/
PID4F23021SC/
PID4F23021PW /
PID4F23021SSC/
PID5F11021SSC20G /
PID7F11021SSC/
PID7F16021SSC /
PID7F23021SSC/
PID6F11021SSC20G//
PRELUDE EASE TM HYDROPHILIC SHEATH INTRODUCER;
PHR4F11018NTPD/
PHR4F7018SC /
PHR5F7018SC /
PHR6F11025PW/
PHR4F11018SC /
PHR5F11018NTPD /
PHR6F11018NTPD /
PHR6F11035SC/

JACK FACK S.R.L.

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DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

PHR4F11021PW/
PHR5F11018SC/
PHR6F11018SC/
PHR6F23021SC/
PHR4F11021SC/
PHR5F11021PW /
PHR6F11021PW/
PHR6F7018SC/
PHR4F11025PW/
PHR5F11021SC /
PHR6F23018NT/
PHR7F11018SC/
PHR4F16018NT /
PHR5F11018SS/
PHR6F23021PW/
PHR7F11021SC/
PHR4F16021SC/
PHR5F7018NTPD/
PHR6F16018NT/
PHR7F11035SC/
PHR4F16025PW /
PHR5F11025PW/
PHR6F16021SC /
PHR7F16018NT/
PHR4F11018SS /
PHR5F16018NT /
PHR6F16025PW /
PHR7F16021SC/
PHR4F11021SCSN /
PHR5F16021SC /
PHR5F11021SCSN /
PHR7F23018NT/
PHR4F7018NTPD /
PHR5F16025PW/
PHR6F11021SCSN /
PHR7F23021SC/
PHR4F23018NT /
PHR5F23018NT /
PHR6F7018NTPD/
PHR4F11018SSSN/
PHR4F23021PW /

JACK PACK SRL

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PHR5F23021PW /
PHR6F11018SS /
PHR5F11018SSSN/
PHR4F23021SC /
PHR5F23021SC /
PHR6F11021SC /
PHR6F11018SSSN/
PHR5F11021SSC /
PHR6F11021SSC /
PHR5F23021SSC /
PHR6F23021SSC/

RELUDE MARKER TIP SHEATH INTRODUCERS;
PSI-4F-23-035MT /
PSI-5F-23-035MT /
PSI-6F-23-035MT /
PSI-7F-23-035MT /
PSI-8F-23-035MT /
PSI-5F-23-038MT /
PSI-6F-23-038MT /
PSI-7F-23-038MT /
PSI-8F-23-038MT /
PSI-4F-23MT /
PSI-5F-23MT /
PSI-6F-23MT /
PSI-7F-23MT /
PSI-8F-23MT//

PRELUDE SHEATH INTRODUCER DILATOR;
PD4F035/
PD7F038/
PSD6F035-8CM/
PD5F038/
PD8F038/
PSD7F035-8CM/
PD6F038/
PSD5F035-8CM/
PSD8F035-9CM///

PRELUDE SHEATH INTRODUCER OCTURADOR:;
OBT-4F-11/
OBT-6F-11/
OBT-4F-23/

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DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

OBT-6F-23/
OBT-5F-11/
OBT-7F-11/
OBT-5F-23/
OBT-7F-23//

JORGE ILIOU SILVERO
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LOTE Nº 6, 7, 12, 13, 16, 17, 20, 21, 37 - ITEM 1

DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

CERTIFICADO DE REGISTRO SANITARIO

Dispositivos Médicos, Materiales Cortopunzantes y Equipo de Protección Individual

La Dirección Nacional de Vigilancia Sanitaria, autoriza el Registro Sanitario del producto más abajo descripto, cumpliendo la misma con los requisitos y las legislaciones vigentes en la República del Paraguay según Código Sanitario Ley N° 836/80,Ley N° 6788/2021, Ley N° 4659/12, Resolución S.G. N° 669/16 y demás legislaciones vigentes.

Certificado N°: **DM-001103-02** Vencimiento: **05-10-2028**
Denominación Comercial: **ALAMBRE GUÍA INQWIRE**
Denominación Genérica/Código ECRI: **ALAMBRES GUÍA 11-925**
Clase: **CLASE IV**

Marca: **MERIT MEDICAL**
Material de Composición: **ESTRUCTURA DE ACERO INOXIDABLE, CON COBERTURA CONTÍNUA INTERNA DE PTFE (POLITETRAFLUORUROETILENO), Y CON COBERTURA OPCIONAL DE HEPARINA.**
Accesorios: **N/A**
Presentación: **CAJAX1UNIDADCAJAX5UNIDADESCAJAX10 UNIDADES**
Plazo de Vida Útil: **3 AÑOS**
Condición de Venta: **VENTA EXCLUSIVA A PROFESIONALES E INSTITUCIONES SANITARIAS**

Titular: **JACK FACK S.R.L**
Director Técnico: **SILVA GONZÁLEZ NORMA CONCEPCIÓN**
Elaborador Producto Final: **PARKMORE BUSINESS PARK WEST, GALWAY, IRLANDA** por **MERIT MEDICAL IRELAND, LTD** Fabricado para **MERIT MEDICAL SYSTEMS, INC**

Asunción 05 de Octubre de 2023.

JORGE ILIOU SILVERO
Firmado digitalmente por JORGE ILIOU SILVERO
Fecha: 2023.10.05 09:17:47 -03'00'

JACK FACK

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DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

Certificado N°: **DM-001103-02** Vencimiento: **05-10-2028**
Denominación Comercial: **ALAMBRE GUÍA INQWIRE**
Denominación Genérica/Código ECRI: **ALAMBRES GUÍA 11-925**

ANEXO

Modelos

INQWIRE GUIDE WIRES PTFE COATED::

6500-11 0.035" (0.89 MM) 150 CM (59") 1.5 MM J-TIP
6500-31 0.035" (0.89 MM) 80 CM (31.5") 1.5 MM J-TIP
6609-13 0.035" (0.89 MM) 180 CM (71") 1.5 MM J-TIP
6609-33 0.035" (0.89 MM) 260 CM (102") 1.5 MM J-TIP
6647-11 0.035" (0.89 MM) 145 CM (57") 3 MM J-TIP
6676-A1 0.018" (0.46 MM) 150 CM (59") STRAIGHT TIP
6676-B3 0.018" (0.46 MM) 180 CM (71") STRAIGHT TIP
6676-C1 0.021" (0.53 MM) 150 CM (59") STRAIGHT TIP
6676-D3 0.021" (0.53 MM) 180 CM (71") STRAIGHT TIP
6676-G1 0.018" (0.46 MM) 150 CM (59") STRAIGHT TIP
6676-H1 0.018" (0.46 MM) 80 CM (31.5") STRAIGHT TIP
6677-71 0.035" (0.89 MM) 150 CM (59") STRAIGHT TIP
6677-B1 0.035" (0.89 MM) 150 CM (59") 3 MM J-TIP
6678-71 0.035" (0.89 MM) 150 CM (59") 1.5 MM J-TIP
6678-81 0.035" (0.89 MM) 180 CM (71") 1.5 MM J-TIP
6680-11 0.035" (0.89 MM) 150 CM (59") STRAIGHT TIP
6680-23 0.035" (0.89 MM) 260 CM (102") STRAIGHT TIP
6680-31 0.038" (0.97 MM) 150 CM (59") STRAIGHT TIP
6680-43 0.038" (0.97 MM) 180 CM (71") STRAIGHT TIP
6680-51 0.035" (0.89 MM) 100 CM (39.4") STRAIGHT TIP
6680-61 0.035" (0.89 MM) 80 CM (31.5") STRAIGHT TIP
6680-71 0.035" (0.89 MM) 180 CM (71") STRAIGHT TIP
6682-21 0.032" (0.81 MM) 150 CM (59") 3 MM J-TIP
6682-41 0.035" (0.89 MM) 150 CM (59") 3 MM J-TIP
6682-E1 0.025" (0.64 MM) 150 CM (59") 3 MM J-TIP
6682-K1 0.018" (0.46 MM) 150 CM (59") 3 MM J-TIP
6682-L3 0.018" (0.46 MM) 180 CM (71") 3 MM J-TIP
6682-M1 0.021" (0.53 MM) 150 CM (59") 3 MM J-TIP
6682-N3 0.021" (0.53 MM) 180 CM (71") 3 MM J-TIP
6682-R1 0.035" (0.89 MM) 200 CM (79") 3 MM J-TIP
6684-41 0.035" (0.89 MM) 150 CM (59") 3 MM J-TIP TC
6689-11 0.035" (0.89 MM) 150 CM (59") 15 MM J-TIP
6689-A1 0.035" (0.89 MM) 150 CM (59") 15 MM J-TIP

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DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

6690-41 0.035" (0.89 MM) 150 CM (59") STRAIGHT TIP
6693-41 0.035" (0.89 MM) 150 CM (59") 3 MM J-TIP
6693-61 0.038" (0.97 MM) 150 CM (59") 3 MM J-TIP
6693-71 0.035" (0.89 MM) 150 CM (59") 3 MM J-TIP
6693-A1 0.035" (0.89 MM) 150 CM (59") 1.5 MM J-TIP
6694-21 0.035" (0.89 MM) 150 CM (59") 6 MM J-TIP
6695-31 0.035" (0.89 MM) 260 CM (102") STRAIGHT TIP
6697-11 0.032" (0.81 MM) 125 CM (49") 3 MM J-TIP/ STRAIGHT
6697-21 0.032" (0.81 MM) 150 CM (59") 3 MM J-TIP/ STRAIGHT
IQ35F100J15 0.035" (0.89 MM) 100 CM (39.4") 15 MM J-TIP
IQ35F150B 0.035" (0.89 MM) 150 CM (59") STRAIGHT TIP
IQ35F150BC 0.035" (0.89 MM) 150 CM (59") STRAIGHT TIP
IQ35F150BST 0.035" (0.89 MM) 150 CM (59") STRAIGHT TIP
IQ35F150J15 0.035" (0.89 MM) 150 CM (59") 15 MM J-TIP
IQ35F150J1O5 0.035" (0.89 MM) 150 CM (59") 1.5 MM J-TIP
IQ35F150J1O5RS 0.035" (0.89 MM) 150 CM (59") 1.5 MM J-TIP
IQ35F150J1O5S 0.035" (0.89 MM) 150 CM (59") 1.5 MM J-TIP/ STRAIGHT
IQ35F150J3 0.035" (0.89 MM) 150 CM (59") 3 MM J-TIP
IQ35F150J3F 0.035" (0.89 MM) 150 CM (59") 3 MM J-TIP
IQ35F150J3S 0.035" (0.89 MM) 150 CM (59") 3 MM J-TIP/ STRAIGHT
IQ35F150J3SHD 0.035" (0.89 MM) 150 CM (59") 3 MM J-TIP/ STRAIGHT
IQ35F150J6 0.035" (0.89 MM) 150 CM (59") 6 MM J-TIP
IQ35F150NLLLT 0.035" (0.89 MM) 150 CM (59") STRAIGHT TIP
IQ35F150NLLT 0.035" (0.89 MM) 150 CM (59") STRAIGHT TIP
IQ35F150NLT 0.035" (0.89 MM) 150 CM (59") STRAIGHT TIP
IQ35F150S 0.035" (0.89 MM) 150 CM (59") STRAIGHT TIP
IQ35F180B 0.035" (0.89 MM) 180 CM (71") STRAIGHT TIP
IQ35F180BC 0.035" (0.89 MM) 180 CM (71") STRAIGHT TIP
IQ35F180BST 0.035" (0.89 MM) 180 CM (71") STRAIGHT TIP
IQ35F180J15 0.035" (0.89 MM) 180 CM (71") 15 MM J-TIP
IQ35F180J1O5 0.035" (0.89 MM) 180 CM (71") 1.5 MM J-TIP
IQ35F180J1O5RS 0.035" (0.89 MM) 180 CM (71") 1.5 MM J-TIP
IQ35F180J3 0.035" (0.89 MM) 180 CM (71") 3 MM J-TIP
IQ35F180J3F 0.035" (0.89 MM) 180 CM (71") 3 MM J-TIP
IQ35F180J3S 0.035" (0.89 MM) 180 CM (71") 3 MM J-TIP/ STRAIGHT
IQ35F180J6F 0.035" (0.89 MM) 180 CM (71") 6 MM J-TIP
IQ35F210J1O5 0.035" (0.89 MM) 210 CM (83") 1.5 MM J-TIP
IQ35F210J1O5F 0.035" (0.89 MM) 210 CM (83") 1.5 MM J-TIP
IQ35F210J3 0.035" (0.89 MM) 210 CM (83") 3 MM J-TIP
IQ35F260B 0.035" (0.89 MM) 260 CM (102") STRAIGHT TIP
IQ35F260J1O5 0.035" (0.89 MM) 260 CM (102") 1.5 MM J-TIP

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DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

IQ35F260J1O5F 0.035" (0.89 MM) 260 CM (102") 1.5 MM J-TIP
IQ35F260J3 0.035" (0.89 MM) 260 CM (102") 3 MM J-TIP
IQ35F260S 0.035" (0.89 MM) 260 CM (102") STRAIGHT TIP
IQ35F80B 0.035" (0.89 MM) 80 CM (31.5") STRAIGHT TIP
IQ35F80J1O5RS 0.035" (0.89 MM) 80 CM (31.5") 1.5 MM J-TIP
IQ35F80J3 0.035" (0.89 MM) 80 CM (31.5") 3 MM J-TIP
IQ38F150B 0.038" (0.97 MM) 150 CM (59") STRAIGHT TIP
IQ38F150BC 0.038" (0.97 MM) 150 CM (59") STRAIGHT TIP
IQ38F150J15 0.038" (0.97 MM) 150 CM (59") 15 MM J-TIP
IQ38F150J1O5RS 0.038" (0.97 MM) 150 CM (59") 1.5 MM J-TIP
IQ38F150J3 0.038" (0.97 MM) 150 CM (59") 3 MM J-TIP
IQ38F150J3F 0.038" (0.97 MM) 150 CM (59") 3 MM J-TIP
IQ38F150J3S 0.038" (0.97 MM) 150 CM (59") 3 MM J-TIP/ STRAIGHT
IQ38F150J6 0.038" (0.97 MM) 150 CM (59") 6 MM J-TIP
IQ38F150S 0.038" (0.97 MM) 150 CM (59") STRAIGHT TIP
IQ38F180J3F 0.038" (0.97 MM) 180 CM (71") 3 MM J-TIP
IQ38F260J3 0.038" (0.97 MM) 260 CM (102") 3 MM J-TIP
IQ38F260S 0.038" (0.97 MM) 260 CM (102") STRAIGHT TIP
IQ38F50J3 0.038" (0.97 MM) 50 CM (20") 3 MM J-TIP
IQH35F150B 0.035" (0.89 MM) 150 CM (59") STRAIGHT TIP
IQH35F150J15 0.035" (0.89 MM) 150 CM (59") 15 MM J-TIP
IQH35F150J1O5 0.035" (0.89 MM) 150 CM (59") 1.5 MM J-TIP
IQH35F150J3 0.035" (0.89 MM) 150 CM (59") 3 MM J-TIP
IQH35F150NLT 0.035" (0.89 MM) 150 CM (59") STRAIGHT TIP
IQH35F150S 0.035" (0.89 MM) 150 CM (59") STRAIGHT TIP
IQH35F180B 0.035" (0.89 MM) 180 CM (71") STRAIGHT TIP
IQH35F180BST 0.035" (0.89 MM) 180 CM (71") STRAIGHT TIP
IQH35F180J3F 0.035" (0.89 MM) 180 CM (71") 3 MM J-TIP
IQH35F70J6 0.035" (0.89 MM) 70 CM (28") 6 MM J-TIP
IQH38F150B 0.038" (0.97 MM) 150 CM (59") STRAIGHT TIP
IQH38F150J3 0.038" (0.97 MM) 150 CM (59") 3 MM J-TIP
IQH38F70J6 0.038" (0.97 MM) 70 CM (28") 6 MM J-TIP
IQR35F150B 0.035" (0.89 MM) 150 CM (59") STRAIGHT TIP
IQR35F150BST 0.035" (0.89 MM) 150 CM (59") STRAIGHT TIP
IQR35F150J3S 0.035" (0.89 MM) 150 CM (59") 3 MM J-TIP/ STRAIGHT
IQR35F260J3 0.035" (0.89 MM) 260 CM (102") 3 MM J-TIP///

INQWIRE AMPLATZ GUIDE WIRES:;
IQA513 0.035" (0.89 MM) 75 CM (29") 1.0 CM STRAIGHT, SHORT TIP

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DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

IQA511 0.035" (0.89 MM) 180 CM (71") 1.0 CM STRAIGHT, SHORT TIP
IQA512 0.038" (0.97 MM) 180 CM (71") 1.0 CM STRAIGHT, SHORT TIP
IQA509 0.035" (0.89 MM) 260 CM (102") 1.0 CM STRAIGHT, SHORT TIP
IQA510 0.038" (0.97 MM) 260 CM (102") 1.0 CM STRAIGHT, SHORT TIP
IQA527 0.035" (0.89 MM) 145 CM (57") 3.5 CM STRAIGHT, SHORT TIP
IQA528 0.038" (0.97 MM) 145 CM (57") 3.5 CM STRAIGHT, SHORT TIP
IQA521 0.035" (0.89 MM) 75 CM (29") 4.0 CM STRAIGHT, SHORT TIP
IQA524 0.035" (0.89 MM) 145 CM (57") 4.0 CM STRAIGHT, SHORT TIP
IQA518 0.038" (0.97 MM) 145 CM (57") 4.0 CM STRAIGHT, SHORT TIP
IQA522 0.035" (0.89 MM) 180 CM (71") 4.0 CM STRAIGHT, SHORT TIP
IQA564 0.038" (0.97 MM) 75 CM (29") 6.0 CM STRAIGHT
IQA517 0.038" (0.97 MM) 145 CM (57") 6.0 CM STRAIGHT
IQA519 0.038" (0.97 MM) 180 CM (71") 6.0 CM STRAIGHT
IQA520 0.038" (0.97 MM) 260 CM (102") 6.0 CM STRAIGHT
IQA563 0.035" (0.89 MM) 75 CM (29") 7.0 CM STRAIGHT
IQA523 0.035" (0.89 MM) 145 CM (57") 7.0 CM STRAIGHT
IQA525 0.035" (0.89 MM) 180 CM (71") 7.0 CM STRAIGHT
IQA526 0.035" (0.89 MM) 260 CM (102") 7.0 CM STRAIGHT
IQA500 0.035" (0.89 MM) 145 CM (57") 7.0 CM 3MM J
IQA501 0.035" (0.89 MM) 180 CM (71") 7.0 CM 3MM J
IQA502 0.035" (0.89 MM) 260 CM (102") 7.0 CM 3MM J
IQA503 0.038" (0.97 MM) 145 CM (57") 7.0 CM 3MM J
IQA504 0.038" (0.97 MM) 180 CM (71") 7.0 CM 3MM J
IQA505 0.035" (0.89) 145 CM (57") 3.5 CM SHORT TAPER 3MM J
IQA506 0.035" (0.89) 180 CM (71") 3.5 CM SHORT TAPER 3MM J
IQA507 0.035" (0.89) 260 CM (102") 3.5 CM SHORT TAPER 3MM J

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LOTE Nº 8, 9, 10, 11, 14, 15, 18, 19, 24, 25, 26, 27, 28, 29 - ITem 1

DIRECCION NACIONAL DE VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

CERTIFICADO DE REGISTRO SANITARIO

Dispositivos Médicos, Materiales Cortopunzantes y Equipo de Protección Individual

La Dirección Nacional de Vigilancia Sanitaria, autoriza el Registro Sanitario del producto más abajo descripto, cumpliendo la misma con los requisitos y las legislaciones vigentes en la República del Paraguay según Código Sanitario Ley N° 836/80,Ley N° 6788/2021, Ley N° 4659/12, Resolución S.G. N° 669/16 y demás legislaciones vigentes.

Certificado N°: **DM-001911-02** Vencimiento: **16-08-2027**
Denominación Comercial: **ALAMBRE GUÍA HIDROFÍLICA**
Denominación Genérica/Código ECRI: **ALAMBRES GUÍA 11-925**
Clase: **CLASE IV**

Marca: **MERIT MEDICAL**
Material de Composición: **ALAMBRE DE NÚCLEO DE NITIDOL, CON COBERTURA DE POLIURETANO QUE CONTIENE TUNGSTENO Y UN RECUBRIMIENTO HIDROFÍLICO.MÉTODO DE ESTERILIZACIÓN: ÓXIDO DE ETILENO**
Accesorios: **NO POSEE**
Presentación: **ENVASE PRIMARIO: BOLSA FORMADA DE TYVEKENVASE SECUNDARIO: CAJAS DE CARTÓN UNIDAD DE VENTA: POR 1 UNIDAD, 5 UNIDADES Y 100 UNIDADES**
Plazo de Vida Útil: **VIDA ÚTIL: 3 AÑOS**
Condición de Venta: **VENTA EXCLUSIVA A PROFESIONALES E INSTITUCIONES SANITARIAS**

Titular: **JACK FACK S.R.L**
Director Técnico: **SILVA GONZÁLEZ NORMA CONCEPCIÓN**
Elaborador Producto Final: **PARKMORE BUSINESS PARK WEST, GALWAY, GALWAY, IRLANDA** por **MERIT MEDICAL IRELAND, LTD.** Fabricado para **MERIT MEDICAL SYSTEMS, INC. 1600 WEST SOUTH JORDAN, UATH ESTADOS UNIDOS MERIT PARKWAY**

Asunción 06 de Julio de 2024.

JORGE ILIOU SILVERO
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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

Certificado N°: **DM-001911-02** Vencimiento: **16-08-2027**
Denominación Comercial: **ALAMBRE GUÍA HIDROFÍLICA**
Denominación Genérica/Código ECRI: **ALAMBRES GUÍA 11-925**

ANEXO

Modelos
MERIT LAUREAT, ESTANDAR ANGULADA, ESTANDAR RECTA, RIGIDA ANGULADA, RIGIDA RECTA:

MERIT MEDICAL / ALAMBRE GUÍA

0,035" ESTÁNDAR ANGULADA
LWSTDA3580
LWSTDA35150
LWSTDA35180
LWSTDA35220
LWSTDA35260EX
0,035" ESTÁNDAR RECTA
LWSTDS3580
LWSTDS35150
LWSTDS35180
LWSTDS35220
LWSTDS35260EX
0,035" RIGIDA ANGULADA
LWSTFA3580
LWSTFA35150
LWSTFA35180
LWSTFA35220
LWSTFA35260EX
0,035" RIGIDA RECTA
LWSTFS3580
LWSTFS35150
LWSTFS35180
LWSTFS35220
LWSTFS35260EX
0,038" ESTÁNDAR ANGULADA
LWSTDA3880
LWSTDA38120
LWSTDA38150
LWSTDA38180

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DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

LWSTDA38260EX
0,038" ESTÁNDAR RECTA
LWSTDS38150
LWSTDS38180
LWSTDS38260EX
0,038" RIGIDA ANGULADA
LWSTFA3880
LWSTFA38150
LWSTFA38180
0,038" RIGIDA RECTA
LWSTFS38150
LWSTFS38180
0,025" ESTÁNDAR ANGULADA
LWSTDA25150
LWSTDA25180
LWSTDA25260EX
0,025" ESTÁNDAR RECTA
LWSTDS25150
LWSTDS25180
LWSTDS25260EX
0,018" ESTÁNDAR ANGULADA
LWSTDA1880
LWSTDA18150
LWSTDA18180
LWSTDA18260EX

0,018" ESTÁNDAR RECTA
LWSTDS18150
LWSTDS18180
LWSTDS18260EX

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Lote Nº 33, 35, 36 Item 4

DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

CERTIFICADO DE REGISTRO SANITARIO

Dispositivos Médicos, Materiales Cortopunzantes y Equipo de Protección Individual

La Dirección Nacional de Vigilancia Sanitaria, autoriza el Registro Sanitario del producto más abajo descripto, cumpliendo la misma con los requisitos y las legislaciones vigentes en la República del Paraguay según Código Sanitario Ley N° 836/80, Ley N° 6788/2021 y demás normativas vigentes.

Certificado N°: **DM-003365-02** Vencimiento: **04-01-2034**
Denominación Comercial: **ALAMBRE GUÍA CON REVESTIMIENTO HIDRÓFILO BOSTON SCIENTIFIC**
Denominación Genérica/Código ECRI: **ALAMBRES GUIA 11-925**
Clase: **CLASE IV**

Marca: **BOSTON SCIENTIFIC**
Material de Composición: **CON RECUBRIMIENTO HIDRÓFILO ICE SON GUÍAS DIRIGIBLES, DISPONIBLES CON UN DIÁMETRO NOMINAL DE 0,014 IN (0,37 MM) Y EN TRAMOS NOMINALES DE 182 Ó 300 CM. TODOS LOS MODELOS ESTÁN DISPONIBLES CON UNA PUNTA RECTA MOLDEABLE O CON UNA PUNTA EN "J" PREFORMADA.**
Accesorios: **NO APLICA**
Presentación: **ENVASE PRIMARIO: BOLSA DE POLIETILENO/TYVEK ENVASE SECUNDARIO: CAJA DE CARTÓN PRESENTACIÓN: 1 UNIDAD / 5 UNIDADES**
Plazo de Vida Útil: **25 MESES**
Condición de Venta: **VENTA EXCLUSIVA A PROFESIONALES E INSTITUCIONES SANITARIAS**

Titular: **JACK FACK S.R.L**
Director Técnico: **SILVA GONZÁLEZ NORMA CONCEPCIÓN**
Elaborador Producto Final: **302 PARKWAY, GLOBAL PARK, LA AURORA, HEREDIA, COSTA RICA** por **BOSTON SCIENTIFIC CORPORATION**

Asunción 05 de Noviembre de 2025.

JORGE ILIOU SILVERO
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Fecha: 2025.11.05 16:32:29 -03'00'

JACK FACK SRL

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY | PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

Certificado N°: **DM-003365-02** Vencimiento: **04-01-2034**
Denominación Comercial: **ALAMBRE GUÍA CON REVESTIMIENTO HIDRÓFILO BOSTON SCIENTIFIC**
Denominación Genérica/Código ECRI: **ALAMBRES GUIA 11-925**

ANEXO

Modelos

CHOLCE™ GUIDEWIRE WITH ICE™ HYDROPHILIC COATING
H74912116011 0.014", 300CM, FLOPPY, STRAIGHT/3CM
H74912116012 0.014", 300CM, FLOPPY, STRAIGHT/3CM, 5 PK
H7491211601J1 0.014", 300CM, FLOPPY, J TIP/3CM
H7491211601J2 0.014", 300CM, FLOPPY, J TIP/3CM, 5 PK
H74912117011 0.014", 300CM, INTERMEDIATE, STRAIGHT/3CM
H74912117012 0.014", 300CM, INTERMEDIATE, STRAIGHT/3CM, 5 PK
H7491211701J1 0.014", 300CM, INTERMEDIATE, J TIP/3CM
H7491211701J2 0.014", 300CM, INTERMEDIATE, J TIP/3CM, 5 PK
H74912118011 0.014", 300CM, STANDARD, STRAIGHT/3CM
H74912118012 0.014", 300CM, STANDARD, STRAIGHT/3CM, 5 PK
H7491211801J1 0.014", 300CM, STANDARD, J TIP/3CM
H7491211801J2 0.014", 300CM, STANDARD, J TIP/3CM, 5 PK
H74912119011 0.014", 300CM, EXTRA SUPPORT, STRAIGHT/3CM
H74912119012 0.014", 300CM, EXTRA SUPPORT, STRAIGHT/3CM, 5 PK
H7491211901J1 0.014", 300CM, EXTRA SUPPORT, J TIP/3CM
H7491211901J2 0.014", 300CM, EXTRA SUPPORT, J TIP/3CM, 5 PK
H74912132011 0.014", 182CM, FLOPPY, STRAIGHT/3CM
H74912132012 0.014", 182CM, FLOPPY, STRAIGHT/3CM, 5 PK
H7491213201J1 0.014", 182CM, FLOPPY, J TIP/3CM
H7491213201J2 0.014", 182CM, FLOPPY, J TIP/3CM, 5 PK
H74912133011 0.014", 182CM, INTERMEDIATE, STRAIGHT/3CM
H74912133012 0.014", 182CM, INTERMEDIATE, STRAIGHT/3CM, 5 PK
H7491213301J1 0.014", 182CM, INTERMEDIATE, J TIP/3CM
H7491213301J2 0.014", 182CM, INTERMEDIATE, J TIP/3CM, 5 PK
H74912134011 0.014", 182CM, STD, STRAIGHT/3CM
H74912134012 0.014", 182CM, STD, STRAIGHT/3CM, 5 PK
H7491213401J1 0.014", 182CM, STD, J TIP/3CM
H7491213401J2 0.014", 182CM, STD, J TIP/3CM, 5 PK
H74912135011 0.014", 182CM, EXTRA SUP, STRAIGHT/3CM
H74912135012 0.014", 182CM, EXTRA SUP, STRAIGHT/3CM, 5 PK
H7491213501J1 0.014", 182CM, EXTRA SUP, J TIP/3CM
H7491213501J2 0.014", 182CM, EXTRA SUP, J TIP/3CM, 5 PK

JACK PACK S.R.L.

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

CHOLCE™ MAGNET GUIDEWIRE WITH ICE™ HYDROPHILIC COATING
H7491213201M2 0.014", 182CM, STRAIGHT, 5 PK
H7491213201MJ2 0.014", 182CM, J TIP, 5 PK
H7491213501M2 0.014", 182CM, STRAIGHT, 5 PK
H7491213501MJ2 0.014", 182CM, J TIP, 5 PK
H7491213301M2 0.014", 182CM, STRAIGHT, 5 PK
H7491213301MJ2 0.014", 182CM, J TIP, 5 PK
H7491213401M2 0.014", 182CM, STRAIGHT, 5 PK
H7491213401MJ2 0.014", 182CM, J TIP, 5 PK

CHOLCE™ PT GUIDEWIRE WITH ICE™ HYDROPHILIC COATING
H74912154011 0.014", 300CM, FLOPPY, STRAIGHT/35CM
H74912154012 0.014", 300CM, FLOPPY, STRAIGHT/35CM, 5 PK
H7491215401J1 0.014", 300CM, FLOPPY, J TIP/35CM
H7491215401J2 0.014", 300CM, FLOPPY, J TIP/35CM, 5 PK
H74912155011 0.014", 300CM, EXTRA SUP, STRAIGHT/35CM
H74912155012 0.014", 300CM, EXTRA SUP, STRAIGHT/35CM, 5 PK
H7491215501J1 0.014", 300CM, EXTRA SUP, J TIP/35CM
H7491215501J2 0.014", 300CM, EXTRA SUP, J TIP/35CM, 5 PK
H74912160011 0.014", 182CM, FLOPPY, STRAIGHT/35CM
H74912160012 0.014", 182CM, FLOPPY, STRAIGHT/35CM, 5 PK
H7491216001J1 0.014", 182CM, FLOPPY, J TIP/35CM
H7491216001J2 0.014", 182CM, FLOPPY, J TIP/35CM, 5 PK
H74912161011 0.014", 182CM, EXTRA SUP, STRAIGHT/35CM
H74912161012 0.014", 182CM, EXTRA SUP, STRAIGHT/35CM, 5 PK
H7491216101J1 0.014", 182CM, EXTRA SUP, J TIP/35CM
H7491216101J2 0.014", 182CM, EXTRA SUP, J TIP/35CM, 5 PK
CHOICE™ PT MAGNET GUIDEWIRE WITH ICE™ HYDROPHILIC COATING
H7491216001M2 0.014", 182CM, STRAIGHT, 5 P
H7491216001MJ2 0.014", 182CM, J TIP, 5 PK
H7491216101M2 0.014", 182CM, STRAIGHT, 5 PK
H7491216101MJ2 0.014", 182CM, J TIP, 5 PK

LUGE™ GUIDEWIRE WITH ICE™ HYDROPHILIC COATING
H74912100010 0.014", 300CM, FLOPPY, STRAIGHT/3CM
H74912100012 0.014", 300CM, FLOPPY, STRAIGHT/3CM, 5PK
H7491210001J0 0.014", 300CM, FLOPPY, J TIP/3CM
H7491210001J2 0.014", 300CM, FLOPPY, J TIP/3CM, 5PK
H74912130010 0.014", 182CM, FLOPPY, STRAIGHT/3CM
H74912130012 0.014", 182CM, FLOPPY, STRAIGHT/3CM, 5PK

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY | PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

H7491213001J0 0.014", 182CM, FLOPPY, J TIP/3CM
H7491213001J2 0.014", 182CM, FLOPPY, J TIP/3CM, 5PK

"LUGE™ MAGNET GUIDEWIRE WITH ICE™ HYDROPHILIC COATING"
H7491213001M2 0.014", 182CM, STRAIGHT, 5 PK
H7491213001MJ2 0.014", 182CM, J TIP, 5 PK

MAILMAN™ GUIDEWIRE WITH ICE™ HYDROPHILIC COATING
H74912120011 0.014", 300CM, SUPER SUPPORT, ST/3CM
H74912120012 0.014", 300CM, SUPER SUPPORT, ST/3CM, 5 PK
H7491212001J1 0.014", 300CM, SUPER SUPPORT, J TIP/3CM
H7491212001J2 0.014", 300CM, SUPER SUPPORT, J TIP/3CM, 5 PK
H74912136011 0.014", 182CM, SUPER SUPPORT, ST/3CM
H74912136012 0.014", 182CM, SUPER SUPPORT, ST/3CM, 5 PK
H7491213601J1 0.014", 182CM, SUPER SUPPORT, J TIP/3CM
H7491213601J2 0.014", 182CM, SUPER SUPPORT, J TIP/3CM, 5 PK

"MAILMAN™ MAGNET GUIDEWIRE WITH ICE™ HYDROPHILIC COATING"
H7491213601M2 0.014", 182CM, STRAIGHT, 5 PK
H74981213601MJ2 0.014", 182CM, J TIP, 5 PK

PT GRAPHIX™ GUIDEWIRE WITH ICE™ HYDROPHILIC COATING
H74914902011 0.014", 182CM, INT, STRAIGHT/2CM
H74914902012 0.014", 182CM, INT, STRAIGHT/2CM, 5 PK
H7491490201J1 0.014", 182CM, INT, J TIP/2CM
H7491490201J2 0.014", 182CM, INT, J TIP/2CM, 5 PK
H74914903011 0.014", 182CM, STD, STRAIGHT/2CM
H74914903012 0.014", 182CM, STD, STRAIGHT/2CM, 5 PK
H7491490301J1 0.014", 182CM, STD, J TIP/2CM
H7491490301J2 0.014", 182CM, STD, J TIP/2CM, 5 PK
H74914905011 0.014", 182CM, SUPER SUP, STRAIGHT/2CM
H74914905012 0.014", 182CM, SUPER SUP, STRAIGHT/2CM, 5 PK
H7491490501J1 0.014", 182CM, SUPER SUP, J TIP/2CM
H7491490501J2 0.014", 182CM, SUPER SUP, J TIP/2CM, 5 PK
H74914914011 0.014", 300CM, INT, STRAIGHT/2CM
H74914914012 0.014", 300CM, INT, STRAIGHT/2CM, 5 PK
H7491491401J1 0.014", 300CM, INT, J TIP/2CM

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

H7491491401J2 0.014", 300CM, INT, J TIP/2CM, 5 PK
PT GRAPHIX™ MAGNET GUIDEWIRE WITH ICE™ HYDROPHILIC COATING
H7491490201M2 0.014", 182CM, STRAIGHT, 5 PK
H7491490201MJ2 0.014", 182CM, J TIP, 5 PK
H7491490501M2 0.014", 182CM, STRAIGHT, 5 PK
H7491490501MJ2 0.014", 182CM, J TIP, 5 PK
H7491490301M2 0.014", 182CM, STRAIGHT, 5 PK
H7491490301MJ2 0.014", 182CM, J TIP, 5 PK

PT2™ GUIDEWIRE
H74938931010 0.014", LIGHT, 185CM, STRAIGHT
H74938931012 0.014", LIGHT, 185CM, STRAIGHT, 5 PK
H7493893101J0 0.014", LIGHT, 185CM, J TIP
H7493893101J2 0.014", LIGHT, 185CM, J TIP, 5 PK
H74938931020 0.014", LIGHT, 300CM, STRAIGHT
H74938931022 0.014", LIGHT, 300CM, STRAIGHT, 5 PK
H7493893102J0 0.014", LIGHT, 300CM, J TIP
H7493893102J2 0.014", LIGHT, 300CM, J TIP, 5 PK
H74938931030 0.014", MODERATE, 185CM, STRAIGHT
H74938931032 0.014", MODERATE, 185CM, STRAIGHT, 5 PK
H7493893103J0 0.014", MODERATE, 185CM, J TIP
H7493893103J2 0.014", MODERATE, 185CM, J TIP, 5 PK
H74938931040 0.014", MODERATE, 300CM, STRAIGHT
H74938931042 0.014", MODERATE, 300CM, STRAIGHT, 5 PK
H7493893104J0 0.014", MODERATE, 300CM, J TIP
H7493893104J2 0.014", MODERATE, 300CM, J TIP, 5 PK

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Lote No 38 al 60 Item 1
Lote 124 - Item 1

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

CERTIFICADO DE REGISTRO SANITARIO

Dispositivos Médicos, Materiales Cortopunzantes y Equipo de Protección Individual

La Dirección Nacional de Vigilancia Sanitaria, autoriza el Registro Sanitario del producto más abajo descripto, cumpliendo la misma con los requisitos y las legislaciones vigentes en la República del Paraguay según Código Sanitario Ley N° 836/80,Ley N° 6788/2021, Ley N° 4659/12, Resolución S.G. N° 669/16 y demás legislaciones vigentes.

Certificado N°: **DM-001259-02** Vencimiento: **16-08-2027**
Denominación Comercial: **CATETER ANGIGRAFICO PERFORMA - MERIT MEDICAL**
Denominación Genérica/Código ECRI: **CATÉTERES PARA ANGIOGRAFÍA 10-688**
Clase: **CLASE IV**

Marca: **MERIT MEDICAL**
Material de Composición: **304V ACERO INOXIDABLE, NYLON BESNO 11, PEBAX 7233 SP01, SULFATO DE BARIO.**
Accesorios: **NO POSEE**
Presentación: **CAJA X1 UNIDADCAJA X5 UNIDADESCAJA X10 UNIDADESENVASE PRIMARIO: BOLSA TYVEKENVASE SECUNDARIO: BANDEJA DE CARTÓN SULFATADO BLANQUEADO SÓLIDO (SBS) ENVASE TERCIARIO : CAJA DE CARTÓN SULFATADO BLANQUEADO SÓLIDO (SBS)**
Plazo de Vida Útil: **VIDA ÚTIL: 3 AÑOS**
Condición de Venta: **VENTA EXCLUSIVA A PROFESIONALES E INSTITUCIONES SANITARIAS**

Titular: **JACK FACK S.R.L**
Director Técnico: **SILVA GONZÁLEZ NORMA CONCEPCIÓN**
Elaborador Producto Final: **1600 WEST MERIT PARKWAY, SOUTH JORDAN, UATH, ESTADOS UNIDOS** por **MERIT MEDICAL SYSTEMS, INC.**
Elaborador Producto Final: **AVENIDA SOR JUANA INES DE LA CRUZ 19970 INTERIOR B. EDIFICIO 2, PARQUE INDUSTRIAL FRONTERA, TIJUANA, BAJA CALIFORNIA, MEXICO** por **MERIT MAQUILADORA MÉXICO, S. DE R.L. DE C.V.**

Asunción 21 de Noviembre de 2023.

JORGE ILIOU SILVERO
Firmado digitalmente por JORGE ILIOU SILVERO
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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY | PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

Certificado N°: **DM-001259-02** Vencimiento: **16-08-2027**
Denominación Comercial: **CATETER ANGIGRAFICO PERFORMA - MERIT MEDICAL**
Denominación Genérica/Código ECRI: **CATÉTERES PARA ANGIOGRAFÍA 10-688**

ANEXO

Modelos
MERIT MEDICAL / CATÉTER ANGIOGRAFICO PERFORMA

7777-D3 UHF CARDIAC PIGTAIL 155 DEGREE 6F 110 CM
7777-C3 UHF CARDIAC PIGTAIL 145 DEGREE 6F 110 CM
7777-B1 UHF CARDIAC PIGTAIL 6F 110 CM
7777-43 CARDIAC PIGTAIL 155 DEGREE 6F 110 CM
7777-33 CARDIAC PIGTAIL 145 DEGREE 6F 110 CM
7777-21 CARDIAC PIGTAIL 6F 110 CM
7776-D3 UHF CARDIAC PIGTAIL 155 DEGREE 5F 110 CM
7776-C3 UHF CARDIAC PIGTAIL 145 DEGREE 5F 110 CM
7776-B1 UHF CARDIAC PIGTAIL 5F 110 CM
7776-43 CARDIAC PIGTAIL 155 DEGREE 5F 110 CM
7776-33 CARDIAC PIGTAIL 145 DEGREE 5F 110 CM
7776-21 CARDIAC PIGTAIL 5F 110 CM
7776-11 CARDIAC PIGTAIL 5F 90 CM
7757-20 INFANT PEDIATRIC PIGTAIL 4F 80 CM
7757-10 INFANT PEDIATRIC PIGTAIL 4F 65 CM
7756-20 STANDARD PEDIATRIC PIGTAIL 4F 80 CM
7756-10 STANDARD PEDIATRIC PIGTAIL 4F 65 CM
7709-20 RT CORONARY BYPASS BUMPER TIP 4F 100 CM
7709-10 LT CORONARY BYPASS BUMPER TIP 4F 100 CM
7708-60 MULTIPURPOSE B2 BUMPER TIP 4F 100 CM
7708-50 MULTIPURPOSE B1 BUMPER TIP 4F 100 CM
7708-40 MULTIPURPOSE B2 BUMPER TIP 4F 80 CM
7708-30 MULTIPURPOSE A2 BUMPER TIP 4F 80 CM
7708-20 MULTIPURPOSE A2 BUMPER TIP 4F 100 CM
7708-10 MULTIPURPOSE A1 BUMPER TIP 4F 100 CM
7707-10 PROGRESSIVE RIGHT CORONARY BT 4F 100 CM
7706-10 INTERNAL MAMMARY BUMPER TIP 4F 100 CM
7705-20 SONES BUMPER TIP 4F 100 CM
7705-10 SONES BUMPER TIP 4F 80 CM
7704-70 CARDIAC PIG STR 4F 80 CM
7704-30 CARDIAC PIG 155 DEGREE 4F 110 CM
7704-20 CARDIAC PIG 145 DEGREE 4F 110 CM

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PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

7704-10 CARDIAC PIG STR 4F 110 CM
7703-B0 AMPLATZ LEFT 2 4F 100 CM
7703-40 AMPLATZ LEFT 4 BUMPER TIP 4F 100 CM
7703-30 AMPLATZ LEFT 3 BUMPER TIP 4F 100 CM
7703-20 AMPLATZ LEFT 2 BUMPER TIP 4F 100 CM
7703-10 AMPLATZ LEFT 1 BUMPER TIP 4F 100 CM
7702-40 AMPLATZ RIGHT MOD BUMPER TIP 4F 100 CM
7702-30 AMPLATZ RIGHT 3 BUMPER TIP 4F 100 CM
7702-20 AMPLATZ RIGHT 2 BUMPER TIP 4F 100 CM
7702-10 AMPLATZ RIGHT 1 BUMPER TIP 4F 100 CM
7701-D0 JUDKINS RIGHT 3.0 CM BUMPER TIP 4F 70 CM
7701-C0 JUDKINS RIGHT 2.5 CM BUMPER TIP 4F 70 CM
7701-B0 JUDKINS RIGHT 2.0 CM BUMPER TIP 4F 70 CM
7701-A0 JUDKINS RIGHT 1.5 CM BUMPER TIP 4F 70 CM
7701-50 JUDKINS RIGHT 4.5 CM BUMPER TIP 4F 100 CM
7701-40 JUDKINS RIGHT 6.0 CM BUMPER TIP 4F 100 CM
7701-30 JUDKINS RIGHT 5.0 CM BUMPER TIP 4F 100 CM
7701-20 JUDKINS RIGHT 4.0 CM BUMPER TIP 4F 100 CM
7701-10 JUDKINS RIGHT 3.5 CM BUMPER TIP 4F 100 CM
7700-D0 JUDKINS LEFT 3.0 CM BUMPER TIP 4F 70 CM
7700-C0 JUDKINS LEFT 2.5 CM BUMPER TIP 4F 70 CM
7700-B0 JUDKINS LEFT 2.0 CM BUMPER TIP 4F 70 CM
7700-A0 JUDKINS LEFT 1.5 CM BUMPER TIP 4F 70 CM
7700-40 JUDKINS LEFT 6.0 CM BUMPER TIP 4F 100 CM
7700-30 JUDKINS LEFT 5.0 CM BUMPER TIP 4F 100 CM
7700-20 JUDKINS LEFT 4.0 CM BUMPER TIP 4F 100 CM
7700-10 JUDKINS LEFT 3.5 CM BUMPER TIP 4F 100 CM
7602-33 UHF CARDIAC PIGTAIL 155 DEGREE 5F 110 CM
7602-23 UHF CARDIAC PIGTAIL 145 DEGREE 5F 110 CM
7602-11 UHF CARDIAC PIGTAIL 5F 110 CM
7601-43 JUDKINS LEFT 6.0 CM HF 5F 100 CM
7601-33 JUDKINS LEFT 5.0 CM HF 5F 100 CM
7601-21 JUDKINS LEFT 4.0 CM HF 5F 100 CM
7601-13 JUDKINS LEFT 3.5 CM HF 5F 100 CM
7600-11 PROGRESSIVE RIGHT CORONARY HF 5F 100 CM
7574-43 JUDKINS LEFT 6.0 CM HF 6F 100 CM
7574-33 JUDKINS LEFT 5.0 CM HF 6F 100 CM
7574-21 JUDKINS LEFT 4.0 CM HF 6F 100 CM
7574-13 JUDKINS LEFT 3.5 CM HF 6F 100 CM
7572-11 PROGRESSIVE RIGHT CORONARY HF 6F 100 CM
7569-63 UHF CARDIAC PIGTAIL 155 DEGREE 6F 125 CM

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

7569-53 UHF CARDIAC PIGTAIL 145 DEGREE 6F 125 CM
7569-43 UHF CARDIAC PIGTAIL 6F 125 CM
7569-33 UHF CARDIAC PIGTAIL 155 DEGREE 6F 110 CM
7569-23 UHF CARDIAC PIGTAIL 145 DEGREE 6F 110 CM
7569-11 UHF CARDIAC PIGTAIL 6F 110 CM
7534-43 LEFT CORONARY BYPASS 5F 100 CM
7534-23 RIGHT CORONARY BYPASS 5F 100 CM
7534-13 LEFT CORONARY BYPASS 5F 100 CM
7533-63 MULTIPURPOSE B2 5F 80 CM
7533-53 MULTIPURPOSE A2 5F 80 CM
7533-43 MULTIPURPOSE B2 5F 100 CM
7533-33 MULTIPURPOSE B1 5F 100 CM
7533-23 MULTIPURPOSE A2 5F 100 CM
7533-13 MULTIPURPOSE A1 5F 100 CM
7532-13 PROGRESSIVE RIGHT CORONARY 5F 100 CM
7531-13 INTERNAL MAMMARY 5F 100 CM
7530-23 SONES TYPE 5F 100 CM
7530-13 SONES TYPE 5F 80 CM
7529-63 CARDIAC PIGTAIL 155 DEGREE 5F 125 CM
7529-53 CARDIAC PIGTAIL 145 DEGREE 5F 125 CM
7529-43 CARDIAC PIGTAIL 5F 125 CM
7529-33 CARDIAC PIGTAIL 155 DEGREE 5F 110 CM
7529-23 CARDIAC PIGTAIL 145 DEGREE 5F 110 CM
7529-11 CARDIAC PIGTAIL 5F 110 CM
7528-33 AMPLATZ RIGHT 3 5F 100 CM
7528-13 AMPLATZ RIGHT 1 5F 100 CM
7527-43 AMPLATZ LEFT 4 5F 100 CM
7527-33 AMPLATZ LEFT 3 5F 100 CM
7527-23 AMPLATZ LEFT 2 5F 100 CM
7527-13 AMPLATZ LEFT 1 5F 100 CM
7526-11 AMPLATZ RIGHT MODIFIED 5F 100 CM
7523-P3 JUDKINS RIGHT 3.0 CM BUMPER TIP 5F 70 CM
7523-N3 JUDKINS RIGHT 2.5 CM BUMPER TIP 5F 70 CM
7523-M3 JUDKINS RIGHT 2.0 CM BUMPER TIP 5F 70 CM
7523-L3 JUDKINS RIGHT 1.5 CM BUMPER TIP 5F 70 CM
7523-H3 JUDKINS RIGHT 6.0 CM SHORT TIP 5F 100 CM
7523-G3 JUDKINS RIGHT 5.0 CM SHORT TIP 5F 100 CM
7523-F1 JUDKINS RIGHT 4.0 CM SHORT TIP 5F 100 CM
7523-E3 JUDKINS RIGHT 3.5 CM SHORT TIP 5F 100 CM
7523-93 JUDKINS RIGHT 4.5 CM 5F 100 CM
7523-83 JUDKINS RIGHT 6.0 CM 5F 125 CM

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

7523-73 JUDKINS RIGHT 5.0 CM 5F 125 CM
7523-63 JUDKINS RIGHT 4.0 CM 5F 125 CM
7523-53 JUDKINS RIGHT 3.5 CM 5F 125 CM
7523-43 JUDKINS RIGHT 6.0 CM 5F 100 CM
7523-33 JUDKINS RIGHT 5.0 CM 5F 100 CM
7523-21 JUDKINS RIGHT 4.0 CM 5F 100 CM
7523-13 JUDKINS RIGHT 3.5 CM 5F 100 CM
7521-P3 JUDKINS LEFT 3.0 CM BUMPER TIP 5F 70 CM
7521-N3 JUDKINS LEFT 2.5 CM BUMPER TIP 5F 70 CM
7521-M3 JUDKINS LEFT 2.0 CM BUMPER TIP 5F 70 CM
7521-L3 JUDKINS LEFT 1.5 CM BUMPER TIP 5F 70 CM
7521-F1 JUDKINS LEFT 4.5 CM 5F 100 CM
7521-83 JUDKINS LEFT 6.0 CM 5F 125 CM
7521-73 JUDKINS LEFT 5.0 CM 5F 125 CM
7521-63 JUDKINS LEFT 4.0 CM 5F 125 CM
7521-53 JUDKINS LEFT 3.5 CM 5F 125 CM
7521-43 JUDKINS LEFT 6.0 CM 5F 100 CM
7521-33 JUDKINS LEFT 5.0 CM 5F 100 CM
7521-21 JUDKINS LEFT 4.0 CM 5F 100 CM
7521-13 JUDKINS LEFT 3.5 CM 5F 100 CM
7520-23 SONES TYPE 6F 100 CM
7513-F3 MULTIPURPOSE B1 6F 125 CM
7513-E3 MULTIPURPOSE B1 6F 100 CM
7513-D3 MULTIPURPOSE B1 6F 80 CM
7513-C3 MULTIPURPOSE A1 6F 125 CM
7513-B3 MULTIPURPOSE A1 6F 100 CM
7513-A3 MULTIPURPOSE A1 6F 80 CM
7513-63 MULTIPURPOSE B2 6F 125 CM
7513-53 MULTIPURPOSE A2 6F 125 CM
7513-43 MULTIPURPOSE B2 6F 100 CM
7513-33 MULTIPURPOSE B2 6F 80 CM
7513-23 MULTIPURPOSE A2 6F 100 CM
7513-13 MULTIPURPOSE A2 6F 80 CM
7512-23 PROGRESSIVE RIGHT CORONARY 6F 125 CM
7512-13 PROGRESSIVE RIGHT CORONARY 6F 100 CM
7511-13 INTERNAL MAMMARY 6F 100 CM
7510-23 RIGHT CORONARY BYPASS 6F 100 CM
7510-13 LEFT CORONARY BYPASS 6F 100 CM
7509-63 CARDIAC PIGTAIL 155 DEGREE 6F 125 CM
7509-53 CARDIAC PIGTAIL 145 DEGREE 6F 125 CM
7509-43 CARDIAC PIGTAIL 6F 125 CM

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

7509-33 CARDIAC PIGTAIL 155 DEGREE 6F 110 CM
7509-23 CARDIAC PIGTAIL 145 DEGREE 6F 110 CM
7509-11 CARDIAC PIGTAIL 6F 110 CM
7508-33 AMPLATZ RIGHT 3 6F 100 CM
7508-23 AMPLATZ RIGHT 2 6F 100 CM
7508-13 AMPLATZ RIGHT 1 6F 100 CM
7507-43 AMPLATZ LEFT 4 6F 100 CM
7507-33 AMPLATZ LEFT 3 6F 100 CM
7507-23 AMPLATZ LEFT 2 6F 100 CM
7507-13 AMPLATZ LEFT 1 6F 100 CM
7506-11 AMPLATZ RIGHT MODIFIED 6F 100 CM
7503-D3 JUDKINS RIGHT 6.0 CM SHORT TIP 6F 100 CM
7503-C3 JUDKINS RIGHT 5.0 CM SHORT TIP 6F 100 CM
7503-B1 JUDKINS RIGHT 4.0 CM SHORT TIP 6F 100 CM
7503-A3 JUDKINS RIGHT 3.5 CM SHORT TIP 6F 100 CM
7503-93 JUDKINS RIGHT 4.5 CM 6F 100 CM
7503-83 JUDKINS RIGHT 6.0 CM 6F 125 CM
7503-73 JUDKINS RIGHT 5.0 CM 6F 125 CM
7503-63 JUDKINS RIGHT 4.0 CM 6F 125 CM
7503-53 JUDKINS RIGHT 3.5 CM 6F 125 CM
7503-43 JUDKINS RIGHT 6.0 CM 6F 100 CM
7503-33 JUDKINS RIGHT 5.0 CM 6F 100 CM
7503-21 JUDKINS RIGHT 4.0 CM 6F 100 CM
7503-13 JUDKINS RIGHT 3.5 CM 6F 100 CM
7502-43 MODIFIED JUDKINS RIGHT 6.0 CM 6F 100 CM
7502-33 MODIFIED JUDKINS RIGHT 5.0 CM 6F 100 CM
7502-23 MODIFIED JUDKINS RIGHT 4.0 CM 6F 100 CM
7502-13 MODIFIED JUDKINS RIGHT 3.5 CM 6F 100 CM
7501-H1 JUDKINS LEFT 4.5 CM 6F 100 CM
7501-D3 JUDKINS LEFT 6.0 CM SHORT TIP 6F 100 CM
7501-C3 JUDKINS LEFT 5.0 CM SHORT TIP 6F 100 CM
7501-B1 JUDKINS LEFT 4.0 CM SHORT TIP 6F 100 CM
7501-A3 JUDKINS LEFT 3.5 CM SHORT TIP 6F 100 CM
7501-83 JUDKINS LEFT 6.0 CM 6F 125 CM
7501-73 JUDKINS LEFT 5.0 CM 6F 125 CM
7501-63 JUDKINS LEFT 4.0 CM 6F 125 CM
7501-53 JUDKINS LEFT 3.5 CM 6F 125 CM
7501-43 JUDKINS LEFT 6.0 CM 6F 100 CM
7501-33 JUDKINS LEFT 5.0 CM 6F 100 CM
7501-21 JUDKINS LEFT 4.0 CM 6F 100 CM
7501-13 JUDKINS LEFT 3.5 CM 6F 100 CM

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY | PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

7241-10 RBR BUMPER TIP 4F 100 CM
6RPS125-NB MIV RAD PIG ST 6F 125 CM
6RPS125 MIV RAD PIG ST 6F 125 CM
6RPS110-NB MIV RAD PIG ST 6F 110 CM
6RPS110 MIV RAD PIG ST 6F 110 CM
6RPL125-NB MIV RAD PIG LT 6F 125 CM
6RPL125 MIV RAD PIG LT 6F 125 CM
6RPL110-NB MIV RAD PIG LT 6F 110 CM
6RPL110 MIV RAD PIG LT 6F 110 CM
6110382ULT3 ULTIMATE 3 6F 110 CM
6110381ULT4-T45 ULTIMATE 4-T45 6F 110 CM
6110381ULT4-T40 ULTIMATE 4-T40 6F 110 CM
6110381ULT2 ULTIMATE 2 6F 110 CM
6110381ULT1 ULTIMATE 1 6F 110 CM
610038ULT4-T45 ULTIMATE 4-T45 6F 100 CM
610038ULT4-T40 ULTIMATE 4-T40 6F 100 CM
610038ULT3 ULTIMATE 3 6F 100 CM
610038ULT2 ULTIMATE 2 6F 100 CM
610038ULT1 ULTIMATE 1 6F 100 CM
6100382ULT3 ULTIMATE 3 6F 100 CM
6100381ULT4-T45 ULTIMATE 4-T45 6F 100 CM
6100381ULT4-T40 ULTIMATE 4-T40 6F 100 CM
6100381ULT2 ULTIMATE 2 6F 100 CM
6100381ULT1 ULTIMATE 1 6F 100 CM
5RPS125-NB MIV RAD PIG ST 5F 125 CM
5RPS125 MIV RAD PIG ST 5F 125 CM
5RPS110-NB MIV RAD PIG ST 5F 110 CM
5RPS110 MIV RAD PIG ST 5F 110 CM
5RPL125-NB MIV RAD PIG LT 5F 125 CM
5RPL125 MIV RAD PIG LT 5F 125 CM
5RPL110-NB MIV RAD PIG LT 5F 110 CM
5RPL110 MIV RAD PIG LT 5F 110 CM
5IMP10038ULT1 ULTIMATE 1 5F 100 CM
5IMP100381ULT1 ULTIMATE 1 5F 100 CM
57538CS CORONARY SINUS 5F 75 CM
5110382ULT3 ULTIMATE 3 5F 110 CM
5110381ULT4-T45 ULTIMATE 4-T45 5F 110 CM
5110381ULT4-T40 ULTIMATE 4-T40 5F 110 CM
5110381ULT2 ULTIMATE 2 5F 110 CM
5110381ULT1 ULTIMATE 1 5F 110 CM
510038ULT4-T45 ULTIMATE 4-T45 5F 100 CM

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DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

510038ULT4-T40 ULTIMATE 4-T40 5F 100 CM
510038ULT3 ULTIMATE 5F 100 CM
510038ULT2 ULTIMATE 2 5F 100 CM
510038ULT1 ULTIMATE 1 5F 100 CM
5100382ULT3 ULTIMATE 5F 100 CM
5100381ULT4-T45 ULTIMATE 4-T45 5F 100 CM
5100381ULT4-T40 ULTIMATE 4-T40 5F 100 CM
5100381ULT2 ULTIMATE 2 5F 100 CM
5100381ULT1 ULTIMATE 1 5F 100 CM
4RPS125-NB MIV RAD PIG ST 4F 125 CM
4RPS125 MIV RAD PIG ST 4F 125 CM
4RPS110-NB MIV RAD PIG ST 4F 110 CM
4RPS110 MIV RAD PIG ST 4F 110 CM
4RPL125-NB MIV RAD PIG LT 4F 125 CM
4RPL125 MIV RAD PIG LT 4F 125 CM
4RPL110-NB MIV RAD PIG LT 4F 110 CM
4RPL110 MIV RAD PIG LT 4F 110 CM
410038ULT4-T45 ULTIMATE 4-T45 4F 100 CM
410038ULT4-T40 ULTIMATE 4-T40 4F 100 CM
410038ULT3 ULTIMATE 3 4F 100 CM
410038ULT2 ULTIMATE 2 4F 100 CM
410038ULT1 ULTIMATE 1 4F 100 CM
4100382ULT3 ULTIMATE 3 4F 100 CM
4100381ULT4-T45 ULTIMATE 4-T45 4F 100 CM
4100381ULT4-T40 ULTIMATE 4-T40 4F 100 CM
4100381ULT2 ULTIMATE 2 4F 100 CM
4100381ULT1 ULTIMATE 1 4F 100 CM

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LOTE 10 67, 69, 71, 74, 79, 81, 85, 87, 89, 91, 97, 99, 101 - ITEM 1

DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

CERTIFICADO DE REGISTRO SANITARIO

Dispositivos Médicos, Materiales Cortopunzantes y Equipo de Protección Individual

La Dirección Nacional de Vigilancia Sanitaria, autoriza el Registro Sanitario del producto más abajo descripto, cumpliendo la misma con los requisitos y las legislaciones vigentes en la República del Paraguay según Código Sanitario Ley N° 836/80, Ley N° 6788/2021 y demás normativas vigentes.

Certificado N°: **DM-003605-01** Vencimiento: **24-12-2035**
Denominación Comercial: **RUNWAY CATÉTER GUÍA**
Denominación Genérica/Código ECRI: **CATÉTERES, PARA ANGIOPLASTIA 17-183**
Clase: **CLASE III**

Marca: **BOSTON SCIENTIFIC**
Material de Composición: **EL NÚCLEO/ALIVIO DE TENSIÓN DEL CATÉTER RUNWAY GUIDE ES UN ARNITEL DE UNA SOLA PIEZA.® (POLIETERÉSTER).LA CAPA INTERNA DE POLITETRAFLUOROETILENO (PTFE) LA CAPA INTERMEDIA CONSTA DE UN PATRÓN TRENZADO DE 2X4 QUE UTILIZA TREINTA Y DOS ALAMBRES DE ACERO INOXIDABLE.LA CAPA EXTERIOR, FABRICADA A PARTIR DE UNA MEZCLA DE VESTODUR.®3000 Y ARNITEL.LA PUNTA DEL CATÉTER RUNWAY GUIDE ESTÁ FABRICADA CON HYTREL**
Accesorios: **NO APLICA.**
Presentación: **ENVASE PRIMARIO: BOLSA DE POLIETILENO TYVEK.ENVASE SECUNDARIO: CAJA DE CARTONUNIDAD DE PRESENTACION: UNIDAD**
Plazo de Vida Útil: **3 AÑOS**
Condición de Venta: **VENTA EXCLUSIVA A PROFESIONALES E INSTITUCIONES SANITARIAS**

Titular: **JACK FACK S.R.L**
Director Técnico: **SILVA GONZÁLEZ NORMA CONCEPCIÓN**
Elaborador Producto Final: **C.INDUSTRIAL LT.001 MZ.105 NO. 20905 INT.A. COL. CD. INDUSTRIAL, TIJUANA, BAJA CALIFORNIA 22444, MEXICO** por **AVAILMED S.A.DE C.V.** Fabricado para **BOSTON SCIENTIFIC CORPORATION; 300 BOSTON SCIENTIFIC WAY MARLBOROUGH MA 01752 USA**
Comercializado por **BOSTON SCIENTIFIC INTERNATIONAL B.V. (VESTASTRAAT 6, 6468 EX KERKRADE, PAÍSES BAJOS), (DISTRIBUIDOR INTERNACIONAL)**

Asunción 24 de Diciembre de 2025.

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DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

Certificado N°: **DM-003605-01** Vencimiento: **24-12-2035**
Denominación Comercial: **RUNWAY CATÉTER GUÍA**
Denominación Genérica/Código ECRI: **CATÉTERES, PARA ANGIOPLASTIA 17-183**

ANEXO

Modelos

H74938969190 6F RUNWAY AL1
H74938969680 6F RUNWAY AL1 SH (SIDE HOLES)
H74938969200 6F RUNWAY AL2
H74938969690 6F RUNWAY AL2 SH (SIDE HOLES)
H74938969210 6F RUNWAY AL3
H74938969220 6F RUNWAY AL.75
H74938969170 6F RUNWAY AR1
H74938969660 6F RUNWAY AR1 SH (SIDE HOLES)
H74938969180 6F RUNWAY AR2
H74938969670 6F RUNWAY AR2 SH (SIDE HOLES)
H749389694960 6F RUNWAY ART3
H749389694980 6F RUNWAY ART3.5
H749389694990 6F RUNWAY ART3.5 SH (SIDE HOLES)
H749389695000 6F RUNWAY ART4
H749389695010 6F RUNWAY ART4 SH (SIDE HOLES)
H749389695730 6F RUNWAY CLS3
H749389695740 6F RUNWAY CLS3.5
H749389695780 6F RUNWAY CLS3.5 SH (SIDE HOLES)
H749389695770 6F RUNWAY CLS3.75
H749389695750 6F RUNWAY CLS4
H749389695790 6F RUNWAY CLS4 SH (SIDE HOLES)
H74938969050 6F RUNWAY FL3
H74938969060 6F RUNWAY FL3.5
H74938969520 6F RUNWAY FL3.5 SH (SIDE HOLES)
H74938969070 6F RUNWAY FL4
H74938969530 6F RUNWAY FL4 SH (SIDE HOLES)
H74938969080 6F RUNWAY FL4.5
H74938969090 6F RUNWAY FL5
H74938969100 6F RUNWAY FL6
H749389694420 6F RUNWAY FR3
H74938969010 6F RUNWAY FR3.5
H74938969470 6F RUNWAY FR3.5 SH (SIDE HOLES)
H74938969020 6F RUNWAY FR4
H74938969480 6F RUNWAY FR4 SH (SIDE HOLES)

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DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

H749389695140 6F RUNWAY FR4.5
H74938969030 6F RUNWAY FR5
H74938969040 6F RUNWAY FR6
H74938969410 6F RUNWAY HS
H749389691410 6F RUNWAY HS SH (SIDE HOLES)
H749389691220 6F RUNWAY IM 85CM
H749389694460 6F RUNWAY IM 90CM
H749389691230 6F RUNWAY IM 110CM
H74938969260 6F RUNWAY IM
H749389691290 6F RUNWAY IM SH (SIDE HOLES)
H749389696380 6F RUNWAY IMC 90CM
H749389696610 6F RUNWAY JL3.5
H749389696670 6F RUNWAY JL3.5 SH (SIDE HOLES)
H749389696620 6F RUNWAY JL4
H749389696680 6F RUNWAY JL4 SH (SIDE HOLES)
H749389696640 6F RUNWAY JL5
H749389696850 6F RUNWAY JR3.5
H749389696910 6F RUNWAY JR3.5 SH (SIDE HOLES)
H749389696860 6F RUNWAY JR4
H749389696920 6F RUNWAY JR4 SH (SIDE HOLES)
H749389696880 6F RUNWAY JR5
H749389696890 6F RUNWAY JR6
H749389695830 6F RUNWAY KIMNY
H749389695910 6F RUNWAY KIMNY SH (SIDE HOLES)
H749389696480 6F RUNWAY KR3H
H749389696510 6F RUNWAY KR3H SH (SIDE HOLES)
H749389696540 6F RUNWAY KR3S
H749389696570 6F RUNWAY KR3S SH (SIDE HOLES)
H749389696550 6F RUNWAY KR4S
H74938969250 6F RUNWAY LCB
H749389691270 6F RUNWAY LCB SH (SIDE HOLES)
H749389697130 6F RUNWAY LEFTBU3
H749389697140 6F RUNWAY LEFTBU3.5
H749389697200 6F RUNWAY LEFTBU3.5 SH (SIDE HOL
H749389697150 6F RUNWAY LEFTBU3.75
H749389697160 6F RUNWAY LEFTBU4
H74938969380 6F RUNWAY MP1
H749389691380 6F RUNWAY MP1 SH (SIDE HOLES)
H74938969390 6F RUNWAY MP2
H749389692930 6F RUNWAY Q3.5
H749389692970 6F RUNWAY Q3.5 SH (SIDE HOLES)

JACK FACK

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DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

PARAGUÁI
TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA
MOAKÃHA

H749389692940 6F RUNWAY Q4
H749389692950 6F RUNWAY Q4.5
H749389694720 6F RUNWAY RADIAL
H749389694700 6F RUNWAY RADIAL ST
H74938969240 6F RUNWAY RCB
H74938969710 6F RUNWAY VL3
H74938969720 6F RUNWAY VL3.5
H74938969780 6F RUNWAY VL3.5 SH (SIDE HOLES)
H74938969730 6F RUNWAY VL4
H74938969790 6F RUNWAY VL4 SH (SIDE HOLES)
H74938969740 6F RUNWAY VL4.5
H74938969750 6F RUNWAY VL5
H749389696090 6F RUNWAY WRP

JACK PACK S.R.L.

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LOTE NO 403 - ITEM 1

Dirección Nacional de
VIGILANCIA SANITARIA

■ TETÃ REKUÁI
■ GOBIERNO NACIONAL

Paraguay de la gente

CERTIFICADO DE REGISTRO SANITARIO

Dispositivos Médicos, Materiales Cortopunzantes y Equipo de Protección Individual

La Dirección Nacional de Vigilancia Sanitaria dependiente del Ministerio de Salud Pública y Bienestar Social, autoriza el Registro Sanitario del producto más abajo descripto, cumpliendo la misma con los requisitos y las legislaciones vigentes en la República del Paraguay según Código Sanitario Ley 836/80, Ley 1119/97, Resoluciones SG N° 669/16 y demás legislaciones vigentes.

Certificado N°: **DM-000612-02** Vencimiento: **29-03-2028**
Denominación Comercial: **INFLADORES PARA ANGIOPLASTIA MERIT MEDICAL**
Denominación Genérica/Código ECRI: **INFLADORES, DE BALONES PARA ANGIOPLASTIA 17-541**
Clase: **CLASE II**

Marca: **MERIT MEDICAL**
Modelo: **BASIXCOMPAK: IN4130, /IN4230, IN4330,/ IN4352, /IN4430, /IN4530, IN4802, /IN4852, /K05-00807A,**
K05-00808, /K05-00812,
K05-00828A, /K05-00842
K05-00892, /K05-01840,/ K05-02286..

BASIXTOUCH: IN8100, /IN8112
IN8130, /IN8152, /IN8302, /IN8352, IN8353, /IN8403, /IN8802, /IN8852.

BLUE DIAMOND: IN7112,/ IN7130, IN7152, /IN7352, /IN7403, /IN7462
Material de Composición: **POLICARBONATO**
Accesorios: **NO APLICA**
Presentación: **LOS MODELOS BASIXCOMPAK,BASIXTOUCH, BLUE DIAMOND TIENE MÚLTIPLES PRESENTACIONES, OPCIONALES:CAJAX1UNIDADCAJAX5UNIDADES,CAJAX 10 UNIDADES**
Plazo de Vida Útil: **3 AÑOS**
Condición de Venta: **VENTA EXCLUSIVA A PROFESIONALES E INSTITUCIONES SANITARIAS**

Titular: **JACK FACK S.R.L**
Director Técnico: **SILVA GONZÁLEZ NORMA CONCEPCIÓN**
Elaborador Producto Final: **1600 WEST MERIT PARKWAY, SOUTH JORDAN., UTAH, ESTADOS UNIDOS** por **MERIT MADICAL SYSTEMS, INC.**
Elaborador Producto Final: **AVENIDA SOR JUANA INES DE LA CRUZ 19970 , INFERIOR B , EDIFICIO 2 , PARQUE INDUSTRIAL FRONTERA, TIJUANA, BAJA CALIFORNIA, MEXICO** por **MERIT MAQUILADORA MEXICO S. DE R.L DE C.V**

Asunción 29 de Marzo de 2023.

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Licitación 120 - 127 - Item 1

TESÁI HA TEKO PORAVE MOTENONDEHA
MINISTERIO DE SALUD PÚBLICA Y BIENESTAR SOCIAL

DNVS
Dirección Nacional de Vigilancia Sanitaria

TETÃ REKUÁI
GOBIERNO NACIONAL

Paraguay de la gente

054079

CERTIFICADO DE REGISTRO SANITARIO
DISPOSITIVOS MEDICOS, MATERIALES CORTOPUNZANTES Y EQUIPO DE PROTECCION INDIVIDUAL

La Dirección Nacional de Vigilancia Sanitaria dependiente del Ministerio de Salud Pública y Bienestar Social, autoriza el Registro Sanitario del producto más abajo descripto, cumpliendo la misma con los requisitos y las legislaciones vigentes en la República del Paraguay según Código Sanitario Ley 836/80, Ley 1119/97, Resolución S.G. N° 669/16 y demás legislaciones vigentes

CERTIFICADO N° **01185-01-DM** Vencimiento: **22/11/2024**

Denominación Comercial: **VÁLVULA HOMEOSTÁTICA MERIT MEDICAL**

Denominación Genérica/Código Ecri: **14-325 VÁLVULAS**

Clase: **II**

Marca: **MERIT MÉDICAL**

Modelo:

MAP101	MAP152	MAP222	MAP400
MAP102	MAP152SD	MAP300	MAP403
MAP103	MAP153	MAP301	MAP450
MAP104	MAP154	MAP302	MAP453
MAP111	MAP201	MAP350	MAP461
MAP112	MAP202	MAP351	MAP462
MAP113	MAP203	MAP352	MAP463
MAP114	MAP204	MAP353	MAP464
MAP151	MAP221	MAP351	MAP465
			MAP467

Presentación: **SE PRESENTAN EN CAJAS X 1 UNIDAD. CAJA X 10 UNIDADES. CAJA X 25 UNIDADES Y CAJA X 100 UNIDADES**

Material del Producto: **SILICONA, POLICARBONATO**

Plazo de vida útil: **28 MESES**

Condición de venta: **VENTA EXCLUSIVA A PROFESIONALES E INSTITUCIONES SANITARIAS**

Solicitado por: **JACK FACK S.R.L.**
Director Técnico: **Q.F GLADIS MACIEL BUSTAMANTE**
Fabricado en: **PARKMORE BUSINESS PARK WEST, GALWAY, IRLANDA**
Por: **MERIT MEDICAL IRELAND, LTD**

Asunción, 22 de noviembre de 2019

MINISTERIO DE SALUD PUBLICA Y BIENESTAR SOCIAL · DIRECCION NACIONAL DE VIGILANCIA SANITARIA · DIRECCION GENERAL

Fco. Lourdes Mut Rivaldi de Cattebeke
Directora General
Dirección Nacional de Vigilancia Sanitaria
DNVS - M.S.P. y B.S.

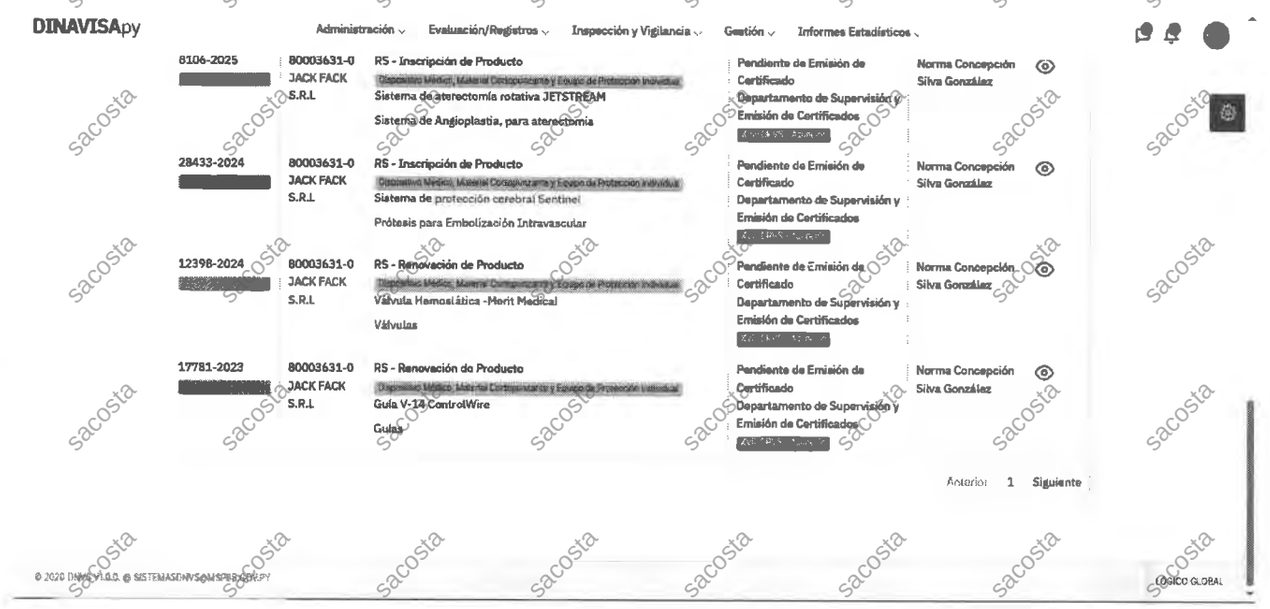
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DNVS

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Lote 128 - Item 1

Dirección Nacional de
VIGILANCIA SANITARIA

■ TETÃ REKUÁI
■ GOBIERNO NACIONAL

Paraguay de la gente

CERTIFICADO DE REGISTRO SANITARIO

Dispositivos Médicos, Materiales Cortopunzantes y Equipo de Protección Individual

La Dirección Nacional de Vigilancia Sanitaria dependiente del Ministerio de Salud Pública y Bienestar Social, autoriza el Registro Sanitario del producto más abajo descripto, cumpliendo la misma con los requisitos y las legislaciones vigentes en la República del Paraguay según Código Sanitario Ley 836/80, Ley 1119/97, Resoluciones SG N° 669/16 y demás legislaciones vigentes.

Certificado N°: **DM-000614-02** Vencimiento: **29-03-2028**
Denominación Comercial: **LLAVES DE PASO MANIFOLDS**
Denominación Genérica/Código ECRI: **LLAVES DE PASO 13-803**
Clase: **CLASE II**

Marca: **MERIT MEDICAL**
Material de Composición: **LAS LLAVES DE PASO CONSISTEN EN UN CUERPO DE PLÁSTICO TRANSPARENTE CON MANGOS DE COLOR QUE CONTROLAN EL FLUJO DE FLUIDOS A TRAVÉS DE MÚLTIPLES PUERTOS. COMPUESTO DE CUERPO DE POLICARBONATO, MANGO DE ACETAL Y FLUIDO DE SILICONA.**
Accesorios: **PODRÍAN INCLUIR:**
• ADAPTADOR GIRATORIO:
MODELO: MFA100 – MMA100
• INTERRUPTOR DE CONTROL DE FLUJO:
MODELOS: U1SHC
Presentación: **CAJA POR 1 UNIDAD CAJA POR 5 UNIDADES CAJA POR 100 UNIDADES**
Plazo de Vida Útil: **4 AÑOS**
Condición de Venta: **VENTA EXCLUSIVA A PROFESIONALES E INSTITUCIONES SANITARIAS**

Titular: **JACK FACK S.R.L**
Director Técnico: **SILVA GONZÁLEZ NORMA CONCEPCIÓN**
Elaborador Producto Final: **1600 WEST MERIT PARKWAY, SOUTH JORDAN, UTAH, ESTADOS UNIDOS** por **MERIT MEDICAL SYSTEMS, INC**

Asunción 29 de Marzo de 2023.

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Dirección Nacional de
VIGILANCIA SANITARIA

TETÃ REKUÁI
GOBIERNO NACIONAL

Paraguay de la gente

Certificado N°: **DM-000614-02** Vencimiento: **29-03-2028**
Denominación Comercial: **LLAVES DE PASO MANIFOLDS**
Denominación Genérica/Código ECRI: **LLAVES DE PASO 13-803**

ANEXO

Modelos

• TRAM MANIFOLD CON TRANSDUCTOR INTEGRADO:

MODELOS 200 PSI:
201LTPHN-R,
202LTPHWN-R,
202LTPHWF-R,
203LTPHWN-R,
203LTPHN-R,
203LTPHWF-R,
204LTPHWN-R,
204LTPHWF-R,
2V4LTPHWF-R,
2V4LTPHWF-RT

MODELOS 500 PSI:
501LTPHN-R,
502LTPHWN-R,
502LTPHWF-R,
503LTPHWN-R,
503LTPHN-R,
503LTPHWF-R,
503LTPHF-R,
504LTPHWN-R,
504LTPHWF-R.

• TRAM-P MANIFOLD CON TRANSDUCTOR INTEGRADO:

MODELOS 200 PSI:
201LTCHN-R,
202LTCWN-R,
202LTCHWF-R,
203LTCWN-R,
203LTCHN-R,
203LTCHWF-R,
203LTCHF-R,
204LTCHWN-R,

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204LTCHWF-R,
2V2LTCHWF-R,
2V2LTCHWF-RT

MODELOS 500 PSI:
501LTCHN-R,
501LTCHF-R,
502LTCHWN-R,
502LTCHWF-R,
503LTCHWN-R,
503LTCHN-R,
503LTCHWF-R,
503LTCHF-R,
504LTCHWN-R,
504LTCHWF-R.

• MERIT MANIFOLDS CON ORIENTACIÓN DE PUERTO DERECHO Y LUER ROTATIVO:
MODELOS 200 PSI:
202HN-R,
202LHWN-R,
202HF-R,
202LHWF-R,
203HN-R,
203LHWN-R,
203HF-R,
203LHWF-R,
204HN-R,
204LHWN-R,
204HF-R,
204LHWF-R,
204BN-R,
204BF-R,
204BF-RT,
203BN-R,
203BF-R,
203BF-RT,
203BN-RT,
202BN-R,
202BF-R.
MODELOS 500 PSI:

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Dirección Nacional de
VIGILANCIA SANITARIA

■ TETÃ REKUÁI
■ GOBIERNO NACIONAL

Paraguay de la gente

502HN-R,
502LHWN-R,
502HF-R,
502LHWF-R,
502HF-RT,
503HN-R,
503LHWN-R,
503HN-RT,
503HF-R,
503LHWF-R,
504HN-R,
504LHWN-R,
504HF-R,
504LHWF-R,
504BN-R,
504BF-R,
503BN-R,
503BF-R,
503BF-RT,
502BN-R,
502BF-R,
501BN-R,
501BF-R.

• MERIT MANIFOLD CON ORIENTACIÓN DE PUERTO IZQUIERDO Y LUER ROTATIVO:
MODELOS 200 PSI:
202HF-L,
203HF-L,
203BN-L,
203BF-L
MODELOS 500 PSI:
502HF-L,
503HFG-L

• MERIT MANIFOLDS CON TODOS LOS PUERTOS FEMENINOS:
MODELOS 200 PSI:
202HF-F,
203HF-F,
203BN-F,
203BF-FT,

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204BF-FT,
205BF-F,
205BF-FT.

MODELOS 500 PSI: 503BF-F

• MANIFOLDS CON TUBO DE ORIENTACIÓN DEL ORIFICIO DERECHO Y LUER ROTATIVO:
MODELOS 200 PSI:
202HN-RX,
202 HF-RX,
203HN-RX,
203HF-RX,
204HF-RX,
203BF-RX,
203BF-RXT.

MODELOS 500 PSI:
502LHWF-R,
503HN-RX,
503HF-RX,
504HF-RX,
503BF-RX,
503BF-RXT,
502BN-RX,
502BF-RX.

• DEVOS MANIFOLDS
MODELOS 200 PSI:
2V4LHWF-R,
2V4LHWF-RXT,
2V4LHWF-RT,
2V3HF-R,
2V3HF-RT,
2V2HF-R,
2V2HF-RT,
2V4LTPHWF-R,
2V4LTPHWF-RT,
2V4LTCHWF-R,
2V4LTCHWF-RT.

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Dirección Nacional de
VIGILANCIA SANITARIA

■ TETÃ REKUÁI
■ GOBIERNO NACIONAL

Paraguay de la gente

• LLAVES DE PASO DE LA SERIE MARQUIS

MODELOS 50 PSI:
L3SNC,
L4SNC

MODELOS 200 PSI:
S1SLC,
S1FLC,
S1SNC,
S3FC,
S3SLC,
S4SLC,
S3FLC,
S4FLC,
S3SNC,
S4SNC.

MODELOS 500 PSI:
M1SLC,
M1FLC,
M1SNC,
M3FLC,
M4FLC,
M3SNC,
M4SNC,
M3RRC,
M4RRC,
M3RLC.

MODELOS 1050 PSI:
H1FLC,
H1SNC,
H1RC,
H3FLC,
H3SNC,
H3RRC,
H4RRC,
H3RLC

MODELOS 200 PSI:
U3RRC

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HPRA
HPRA CERTIFIED

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HPRA
An tUdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

CE lote nº 1 - item 1 al 18

20th May 2025

CERTIFICATE OF FREE SALE FOR MEDICAL DEVICES

Certificate of Free Sale Number: CFS16094

The Health Products Regulatory Authority (HPRA) hereby certifies the following information for the devices in the attached schedule in accordance with Regulation (EU) 2017/745 on medical devices:

Manufacturer:	Boston Scientific Corporation 300 Boston Scientific Way, Marlborough, MA 01752 USA
Authorised representative:	Boston Scientific Limited Ballybrit Business Park, Galway, Ireland
Physical site of manufacture:	Boston Scientific Corporation Two Scimed Place, Maple Grove, MN 55311 USA

The authorised representative has declared that the devices are CE marked in accordance with the above legislation and may be marketed and sold in Ireland.

Exportation of these devices is not prohibited.

The granting of this certificate is based on the information available to the HPRA on the date of issue of the certificate. The HPRA does not authorise or approve any devices prior to placing on the market. As the regulatory status of the devices may change, it is important that this certificate is considered in combination with the manufacturer's declaration of conformity and the notified body certificates, where applicable.

Issued to: Boston Scientific Limited
Ballybrit Business Park
Galway
Ireland

Cheryl Convey
Medical Devices Department
Health Products Regulatory Authority

An overview of the regulatory framework in Europe can be found on the EU Commission website: https://ec.europa.eu/health/md_sector/overview_en.

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APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Country: Pays/País:	**IRELAND**
This public document Le présent acte public / El presente documento público	
2. has been signed by a été signé par ha sido firmado por	Cheryl Convey
3. acting in the capacity of agissant en qualité de quien actúa en calidad de	Health Products Regulatory Authority
4. bears the seal / stamp of est revêtu du sceau / timbre de y está revestido del sello / timbre de	Health Products Regulatory Authority
Certified Attesté / Certificado	
5. at à / en	Dublin
6. the le / el día	02/07/2025
7. by par / por	Department of Foreign Affairs & Trade
8. No sous no bajo el número	6246892025
9. Seal / stamp: Sceau / timbre Sello / timbre	**10. Signature:** Signature: Firma:

AN ROINN GNÓTHAÍ EACHTRACHA AGUS TRÁDÁLA
DEPARTMENT OF FOREIGN AFFAIRS AND TRADE

This Apostille certifies only the authenticity of the signature, the capacity of the person who has signed the public document and the identity of the seal or stamp which the public document bears. N/A denotes inapplicable information on the document. This Apostille does not certify the content of the underlying document. This Apostille is not valid for use anywhere within Ireland. To verify this Apostille, see https://authentications.dfa.ie

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QUIRNO CODAS THOMPSON LLANO
Traductor Público Matriculado
Reclus 283
Tel.: 600 865 – Fax 612 314
Asunción - Paraguay

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CERTIFICADO DE LIBRE VENTA PARA DISPOSITIVOS MÉDICOS

Número de Certificado de Libre Venta: CFS16096

La Autoridad Reguladora de Productos Sanitarios (HPRA) certifica por la presente la siguiente información para los dispositivos incluidos en el anexo adjunto, de conformidad con el Reglamento (UE) 2017/745 sobre dispositivos médicos:

Fabricante:

Boston Scientific Corporation

300 Boston Scientific Way, Marlborough, MA 01752, EE.UU.

Representante autorizado:

Boston Scientific Limited

Ballybrit Business Park, Galway, Irlanda

Sitio físico de fabricación: Boston Scientific Medical Device (Malaysia) SDN BHD

PMT 741, Persiaran Cassia Selatan 1, Taman Perindustrian Batu Kawan, 14110 Bandar Cassia, Pulau Pinang, Malasia.

El representante autorizado ha declarado que los dispositivos cuentan con marcado CE de conformidad con la legislación mencionada anteriormente y pueden comercializarse y venderse en Irlanda.

La exportación de estos dispositivos no está prohibida.

La emisión de este certificado se basa en la información disponible para la HPRA en la fecha de emisión del certificado. La HPRA no autoriza ni aprueba ningún dispositivo antes de su comercialización. Dado que el estado regulatorio de los dispositivos puede cambiar, es importante que este certificado sea considerado junto con la declaración de conformidad del fabricante y los certificados del organismo notificado, cuando corresponda.

Emitido a:
Boston Scientific Limited
Ballybrit Business Park
Galway
Irlanda

Cheryl Convey

Departamento de Dispositivos Médicos

Autoridad Reguladora de Productos Sanitarios

Puede encontrarse una descripción general del marco regulatorio en Europa en el sitio web de la Comisión Europea: https://ec.europa.eu/health/md_sector/overview_en

QUIRNO CODAS THOMPSON LL.
Traductor Público
Matrícula N° 670

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los 10 días del mes de marzo del 2026

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MEDICAL DEVICE SCHEDULE

Device Basic UDI-DI	Product code	Device name	Notified body certificate number	Notified body certificate expiry date
19150600000000000000254MZ	UPN	Emerge™ MONORAIL™ PTCA Dilatation Catheter	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308120	1.20mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312120	1.20mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315120	1.20mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320120	1.20mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308150	1.50mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312150	1.50mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315150	1.50mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320150	1.50mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308200	2.00mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312200	2.00mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315200	2.00mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320200	2.00mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330200	2.00mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308220	2.25mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312220	2.25mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315220	2.25mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320220	2.25mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330220	2.25mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308250	2.50mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312250	2.50mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315250	2.50mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320250	2.50mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330250	2.50mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308270	2.75mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312270	2.75mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028

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19150600000000000000254MZ	H7493919315270	2.75mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320270	2.75mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330270	2.75mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308300	3.00mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312300	3.00mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315300	3.00mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320300	3.00mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330300	3.00mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308320	3.25mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312320	3.25mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315320	3.25mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320320	3.25mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330320	3.25mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308350	3.50mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312350	3.50mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315350	3.50mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320350	3.50mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330350	3.50mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308370	3.75mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312370	3.75mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315370	3.75mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320370	3.75mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330370	3.75mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308400	4.00mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312400	4.00mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315400	4.00mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320400	4.00mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330400	4.00mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	UPN	Emerge™ Push MONORAIL™ PTCA Dilatation Catheter	3830129CE01 3831192TD01	25/10/2027 16/05/2028

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19150600000000000000254MZ	H7493919408120	(Push) 1.20mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919412120	(Push) 1.20mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919415120	(Push) 1.20mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919420120	(Push) 1.20mm x 20 mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919408150	(Push) 1.50 mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919412150	(Push) 1.50mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919415150	(Push) 1.50mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919420150	(Push) 1.50mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	UPN	Emerge™ OVER-THE-WIRE PTCA Dilatation Catheter	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919508120	1.20mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919512120	1.20mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919515120	1.20mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919520120	1.20mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919508150	1.50mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919512150	1.50mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919515150	1.50mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919520150	1.50mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919508200	2.00mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919512200	2.00mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919515200	2.00mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919520200	2.00mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919530200	2.00mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919508220	2.25mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919512220	2.25mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919515220	2.25mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919520220	2.25mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919530220	2.25mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919508250	2.50mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919512250	2.50mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028

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19150600000000000000254MZ	H7493919515250	2.50mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919520250	2.50mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919530250	2.50mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919508270	2.75mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919512270	2.75mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919515270	2.75mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919520270	2.75mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919530270	2.75mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919508300	3.00mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919512300	3.00mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919515300	3.00mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919520300	3.00mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919530300	3.00mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919508320	3.25mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919512320	3.25mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919515320	3.25mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919520320	3.25mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919530320	3.25mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919508350	3.50mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919512350	3.50mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919515350	3.50mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919520350	3.50mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919530350	3.50mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919508370	3.75mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919512370	3.75mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919515370	3.75mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919520370	3.75mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919530370	3.75mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919508400	4.00mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028

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19150600000000000000254MZ	H7493919512400	4.00mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919515400	4.00mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919520400	4.00mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919530400	4.00mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	UPN	Emerge™ Push OVER-THE-WIRE PTCA Dilatation Catheter.	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919608120	(Push) 1.20mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919612120	(Push) 1.20mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919615120	(Push) 1.20mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919620120	(Push) 1.20mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919608150	(Push) 1.50mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919612150	(Push) 1.50mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919615150	(Push) 1.50mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919620150	(Push) 1.50mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
01915060000000000000255N3	UPN	NC Emerge™ MONORAIL™ PTCA Dilatation Catheter.	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606200	2.00mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606220	2.25mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606250	2.50mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606270	2.75mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606300	3.00mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606320	3.25mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606350	3.50mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606370	3.75mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606400	4.00mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606450	4.50mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606500	5.00mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608200	2.00mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608220	2.25mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608250	2.50mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028

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01915060000000000000255N3	H7493927608270	2.75mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608300	3.00mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608320	3.25mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608350	3.50mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608370	3.75mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608400	4.00mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608450	4.50mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608500	5.00mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608550	5.50mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608600	6.00mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927612200	2.00mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927612220	2.25mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927612250	2.50mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927612270	2.75mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927612300	3.00mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927612320	3.25mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927612350	3.50mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927612370	3.75mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927612400	4.00mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927612450	4.50mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927612500	5.00mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927612550	5.50mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927612600	6.00mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927615200	2.00mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927615220	2.25mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927615250	2.50mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927615270	2.75mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927615300	3.00mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927615320	3.25mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028

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01915060000000000000255N3	H7493927615350	3.50mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927615370	3.75mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927615400	4.00mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927615450	4.50mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927615500	5.00mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927615550	5.50mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927615600	6.00mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620200	2.00mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620220	2.25mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620250	2.50mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620270	2.75mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620300	3.00mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620320	3.25mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620350	3.50mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620370	3.75mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620400	4.00mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620450	4.50mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620500	5.00mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620550	5.50mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620600	6.00mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630200	2.00mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630220	2.25mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630250	2.50mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630270	2.75mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630300	3.00mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630320	3.25mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630350	3.50mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630370	3.75mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630400	4.00mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028

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HPRA
HPRA CERTIFIED

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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CE Note N°1 - Item 7.a) i) 8)

20th May 2025

CERTIFICATE OF FREE SALE FOR MEDICAL DEVICES

Certificate of Free Sale Number: CFS16096

The Health Products Regulatory Authority (HPRA) hereby certifies the following information for the devices in the attached schedule in accordance with [redacted]:

Manufacturer:	Boston Scientific Corporation 300 Boston Scientific Way, Marlborough, MA 01752 USA
Authorised representative:	Boston Scientific Limited Ballybrit Business Park, Galway, Ireland
Physical site of manufacture:	Boston Scientific Medical Device (Malaysia) SDN BHD PMT 741, Persiaran Cassia Selatan 1, Taman Perindustrian Batu Kawan, 14110 Bandar Cassia, Pulau Pinang, Malaysia

The authorised representative has declared that the devices are CE marked in accordance with the above legislation and may be marketed and sold in Ireland.

Exportation of these devices is not prohibited.

The granting of this certificate is based on the information available to the HPRA on the date of issue of the certificate. The HPRA does not authorise or approve any devices prior to placing on the market. As the regulatory status of the devices may change, it is important that this certificate is considered in combination with the manufacturer's declaration of conformity and the notified body certificates, where applicable.

Issued to: Boston Scientific Limited
Ballybrit Business Park
Galway
Ireland

Cheryl Convey
Medical Devices Department
Health Products Regulatory Authority

An overview of the regulatory framework in Europe can be found on the EU Commission website: https://ec.europa.eu/health/md_sector/overview_en.

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APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Country: Pays/País:	IRELAND
This public document Le présent acte public / El presente documento público	
2. has been signed by a été signé par ha sido firmado por	Cheryl Convey
3. acting in the capacity of agissant en qualité de quien actúa en calidad de	Health Products Regulatory Authority
4. bears the seal / stamp of est revêtu du sceau / timbre de y está revestido del sello / timbre de	Health Products Regulatory Authority

Certified
Attesté / Certificado

5. at à / en	Dublin	6. the le / el día	02/07/2025
7. by par / por	Department of Foreign Affairs & Trade		
8. No sous no bajo el número	4192112025		
9. Seal/stamp: Sceau/timbre: Sello/timbre:	10. Signature: Signature: Firma:		

This Apostille certifies only the authenticity of the signature, the capacity of the person who has signed the public document and the identity of the seal or stamp which the public document bears. N/A denotes inapplicable information on the document. This Apostille does not certify the content of the underlying document. This Apostille is not valid for use anywhere within Ireland. To verify this Apostille, see https://authentications.dfa.ie

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QUIRNO CODAS THOMPSON LLANO
Traductor Público Matriculado
Reclus 283
Tel.: 600 865 – Fax 612 314
Asunción - Paraguay

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CERTIFICADO DE LIBRE VENTA PARA DISPOSITIVOS MÉDICOS

Número de Certificado de Libre Venta: CFS16094

20 de mayo de 2025

La Autoridad Reguladora de Productos Sanitarios (HPRA) certifica la siguiente información para los dispositivos incluidos en el cronograma adjunto, de conformidad con el Reglamento (UE) 2017/745 sobre dispositivos médicos.

Fabricante:

Boston Scientific Corporation

300 Boston Scientific Way, Marlborough, MA 01752, EE.UU.

Representante autorizado:

Boston Scientific Limited

Ballybrit Business Park, Galway, Irlanda

Sitio físico de fabricación:

Boston Scientific Corporation

Two Scimed Place, Maple Grove, MN 55311, EE.UU.

El representante autorizado ha declarado que los dispositivos poseen marcado CE de conformidad con la legislación mencionada anteriormente y pueden comercializarse y venderse en Irlanda.

La exportación de estos dispositivos no está prohibida.

La emisión de este certificado se basa en la información disponible para la HPRA en la fecha de emisión del certificado. La HPRA no autoriza ni aprueba ningún dispositivo antes de su comercialización. Dado que el estado regulatorio de los dispositivos puede cambiar, es importante que este certificado sea considerado junto con la declaración de conformidad del fabricante y los certificados del organismo notificado, cuando corresponda.

Emitido a:

Boston Scientific Limited
Ballybrit Business Park
Galway
Irlanda

Cheryl Convey

Departamento de Dispositivos Médicos

Autoridad Reguladora de Productos Sanitarios

Puede encontrarse una descripción general del marco regulatorio en Europa en el sitio web de la Comisión Europea: https://ec.europa.eu/health/md_sector/overview_en.

QUIRNO CODAS THOMPSON LL.
Traductor Público
Matrícula Nº 670

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los 10 días del mes de marzo del 2026

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MEDICAL DEVICE SCHEDULE

Device Basic UDI-DI	Product code	Device name	Notified body certificate number	Notified body certificate expiry date
19150600000000000000254MZ	UPN	Emerge™ MONORAIL™ PTCA Dilatation Catheter	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308120	1.20mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312120	1.20mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315120	1.20mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320120	1.20mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308150	1.50mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312150	1.50mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315150	1.50mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320150	1.50mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308200	2.00mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312200	2.00mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315200	2.00mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320200	2.00mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330200	2.00mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308220	2.25mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312220	2.25mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315220	2.25mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320220	2.25mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330220	2.25mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308250	2.50mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312250	2.50mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315250	2.50mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320250	2.50mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330250	2.50mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308270	2.75mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028

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19150600000000000000254MZ	H7493919312270	2.75mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315270	2.75mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320270	2.75mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330270	2.75mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308300	3.00mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312300	3.00mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315300	3.00mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320300	3.00mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330300	3.00mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308320	3.25mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312320	3.25mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315320	3.25mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320320	3.25mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330320	3.25mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308350	3.50mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312350	3.50mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315350	3.50mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320350	3.50mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330350	3.50mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308370	3.75mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312370	3.75mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315370	3.75mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320370	3.75mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330370	3.75mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919308400	4.00mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919312400	4.00mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919315400	4.00mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919320400	4.00mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919330400	4.00mm x 30mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028

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19150600000000000000254MZ	UPN	Emerge™ Push MONORAIL™ PTCA Dilatation Catheter	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919408120	(Push) 1.20mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919412120	(Push) 1.20mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919415120	(Push) 1.20mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919420120	(Push) 1.20mm x 20 mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919408150	(Push) 1.50 mm x 8mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919412150	(Push) 1.50mm x 12mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919415150	(Push) 1.50mm x 15mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
19150600000000000000254MZ	H7493919420150	(Push) 1.50mm x 20mm	3830129CE01 3831192TD01	25/10/2027 16/05/2028
01915060000000000000255N3	UPN	NC Emerge™ MONORAIL™ PTCA Dilatation Catheter	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606200	2.00mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606220	2.25mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606250	2.50mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606270	2.75mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606300	3.00mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606320	3.25mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606350	3.50mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606370	3.75mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606400	4.00mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606450	4.50mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927606500	5.00mm x 6mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608200	2.00mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608220	2.25mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608250	2.50mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608270	2.75mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608300	3.00mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608320	3.25mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608350	3.50mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927608370	3.75mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028

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0191506000000000000255N3	H7493927608400	4.00mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927608450	4.50mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927608500	5.00mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927608550	5.50mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927608600	6.00mm x 8mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927612200	2.00mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927612220	2.25mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927612250	2.50mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927612270	2.75mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927612300	3.00mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927612320	3.25mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927612350	3.50mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927612370	3.75mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927612400	4.00mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927612450	4.50mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
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0191506000000000000255N3	H7493927612600	6.00mm x 12mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927615200	2.00mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927615220	2.25mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927615250	2.50mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927615270	2.75mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927615300	3.00mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927615320	3.25mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927615350	3.50mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927615370	3.75mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927615400	4.00mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927615450	4.50mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
0191506000000000000255N3	H7493927615500	5.00mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028

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01915060000000000000255N3	H7493927615550	5.50mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927615600	6.00mm x 15mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620200	2.00mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620220	2.25mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620250	2.50mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620270	2.75mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620300	3.00mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620320	3.25mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620350	3.50mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620370	3.75mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620400	4.00mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620450	4.50mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620500	5.00mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620550	5.50mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927620600	6.00mm x 20mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630200	2.00mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630220	2.25mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630250	2.50mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630270	2.75mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630300	3.00mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630320	3.25mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630350	3.50mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630370	3.75mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028
01915060000000000000255N3	H7493927630400	4.00mm x 30mm	3830129CE01 3830129TD02	25/10/2027 25/08/2028

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APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by Cesar A. Perez, Ph.D.

3. acting in the capacity of Director, Office of Regulatory Programs

4. bears the seal/stamp of U. S. Department of Health and Human Services

Certified

5. at Washington, D.C.

6. the twentieth of June, 2025

7. by *Assistant Authentication Officer, United States Department of State*

8. No. 25054406-1

9. Seal/Stamp:

10. Signature:

Ari H Chernoff

* FDA

- Lote 3 - Item 9 a 16
- Lote 6 y 7 - Item 2
- Lote 12 - 13 - 16 - 17 - 20 - 21 - 37
- Lote: 8 - 9 - 10 - 11 - 14 - 15 - 18 - 19 - 24 - 25 - 26 - 27 - 28 - 29
- Lote 101
- Lote 109
- Lote 110
- Lote 112/125
- Lote 125 / 126 / 127

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U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 8311-5-2025-1

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(17 Pages)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from May 19, 2025 to May 18, 2027.

To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.

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U.S. FOOD & DRUG ADMINISTRATION
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Silver Spring, MD 20993
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Certificate No. 8311-5-2025-1

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator
Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT
USA 84095

Name of Manufacturer
Legal Manufacturer
Manufacturing Site
MERIT MEDICAL SYSTEMS, INC.
1600 WEST MERIT PKWY.
South Jordan, UT
USA 84095

Manufacturing Site
MERIT MEDICAL IRELAND, LTD
Parkmore Business Park West
Galway, Galway
IRELAND 0000

Manufacturing Site
Akita Sumitomo Bakelite Co., Ltd.
27-4, Aza Nakajimashita, Souzen-machi
Tsuchizakiminato
Akita, Akita
JAPAN 011-8510

Manufacturing Site
PIOLAX MEDICAL DEVICES, INC.
2265-3 Kamiyabe-cho Totsuka-ku
Yokohama, Kanagawa
JAPAN 2450053

Manufacturing Site
HEALTH LINE INTERNATIONAL CORPORATION
260 North Ace Yeager Court
Unit D
Salt Lake City, UT
USA 84116

Manufacturing Site
BIOSPHERE MEDICAL, S.A.
Parc des Nations - Paris Nord 2, 383 rue de la Belle Etoile
95700 ROISSY-EN-FRANCE, FRANCE
Roissy, Val-d'Oise
FRANCE 95700

Address Also Known As
BIOSPHERE MEDICAL, S.A.
Parc des Nations, Paris Nord 2,
383 Rue de la Belle Etoile
Roissy-en-France, Paris
FRANCE 95700

Manufacturing Site
Merit Maquiladora Mexico, S. DE R.L. DE C.V.
Avenida Sor Juana Ines de la Cruz
19970 Interior B, Edificio 2, Parque Industrial Frontera
Tijuana, Baja California
MEXICO 22630

Manufacturing Site
Paragon Medical - Mansfield
111 Forbes Blvd Suite 101
Mansfield, MA
USA 02048

Manufacturing Site
KA Medical
1265 Grey Fox Road
Suite 550
Arden Hills, MN
USA 55112

Name of Manufacturer/Distributor
Legal Manufacturer/Distributor
MERIT MEDICAL SYSTEMS, INC.
1600 WEST MERIT PKWY.
South Jordan, UT
USA 84095

----END OF MANUFACTURER/DISTRIBUTOR LIST----

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Certificate No. 8311-5-2025-1

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 17

Name of Manufacturer
Legal Manufacturer
Manufacturing Site

MERIT MEDICAL SYSTEMS, INC.
1600 WEST MERIT PKWY.
South Jordan, UT
USA 84095

Name of Product(s)

Coronary Control Syringe
CCS100 CCS321 CCS800 CCSB711
CCS101 CCS460 CCS801 CCSB900
CCS200 CCS461 CCSB700 CCSB901
CCS201 CCS600 CCSB701 CCSB910
CCS320 CCS601 CCSB710 CCSB911
Coronary Control Syringe Inject10™
CCX010 CCXB010 CCX011 CCXB011
Coronary Control Syringe Inject8™
CCS880 CCS881 CCSB880 CCSB881 CCSW880 CCSW881
Coronary Control Syringe Smart Tip™
ST320 ST600 ST800 STP600
ST321 ST601 ST801 STP601
Medallion® Syringe
MSS011 MSS061-LG MSS121-Y MSSW11
MSS011-DG MSS061-PR MSS131 MSSW11-DG
MSS011-LB MSS061-R MSS131-DG MSSW11-LB
MSS011-LG MSS061-Y MSS131-LB MSSW11-LG
MSS011-PR MSS111 MSS131-LG MSSW11-PR
MSS011-R MSS111-DG MSS131-PR MSSW11-R
MSS011-Y MSS111-LB MSS131-R MSSW11-Y
MSS031 MSS111-LG MSS131-Y MSSW21
MSS031-DG MSS111-PR MSS160 MSSW21-DG
MSS031-LB MSS111-R MSS160-R MSSW21-LB
MSS031-LG MSS111-Y MSS160T MSSW21-LG
MSS031-PR MSS121 MSSF011 MSSW21-PR
MSS031-R MSS121-DG MSSF031 MSSW21-R
MSS031-Y MSS121-LB MSSF061 MSSW21-Y
MSS061 MSS121-LG MSSF111
MSS061-DG MSS121-PR MSSF121
MSS061-LB MSS121-R MSSF160
MEDALLION IZOFF™ SYRINGE
MIZ10
Medallion® COP Syringe
COP111PC-B COP121PC-B
VacLok® Syringe
VAC110 VAC120 VAC130 VAC160
VAC111 ENDO-VAC20-SC ENDO-VAC30-SC
ENDO-VAC20 ENDO-VAC30 ENDO-VAC60
Squirt® Fluid Dispensing System
FDS100
RXP® FLUSHING SYRINGE
RXPOR
IntelliSystem® Inflation Devices
IN1125 IN1225 IN1425 IN1525
Monarch® Inflation Device
IN2130 IN2230 IN2330 IN2430 IN2530
BLUE DIAMOND™ INFLATION DEVICE
IN7112 IN7130 IN7152 IN7352

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Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 17

IN7403 IN7952 IN7802 IN7852
BLUE FIRE™ Inflation Device
IN10140 IN10152 IN10802 IN10852
BLUE FIRE™ Remote Monitor
IN10PAD
BLUE FIRE™ Starter Kit
IN10START IN10START2
basixSKY™ Inflation Device
SKY1130 SKY1152 SKY1302 SKY1802
Inflation Kit
K05-L1-L5B K05-L3-L4C
SAFEGUARD FOCUS™ Compression Device
SGF1V SGF1A
SAFEGUARD FOCUS COOL™ Compression Device
SGF1AC SGF1VC
SAFEGUARD® Pressure Assisted Device
82050 SG127AC SG12AC SG2440MED
82000 SG127MED SG2440AC SG24AC
SAFEGUARD™ Syringe
SG40AC SG40MD SG7AC SG7MD
SAFEGUARD RADIAL™ Compression Device
SGR26 SGR267AC SGR267MED SGR26AC
Air-band™ Radial Compression Device
0684-00-0572
Rad Board® Reusable Arm Board
RB050 RB100
Rad Board Xtra™ Arm Board Accessory
RBX
RadRest® Arm Cushion
RR811
RadTrac™ Arm Board Support Base
RT913
PAL ™ PEN AND LABELS Labeling System
PAL100 PAL300 PAL425 PAL700 PAL200 PAL325 PAL450
PAL225 PAL350 PAL500 PAL250 PAL400 PAL600
Rotating Adapter
MMA100 MMA200 MFA100 MFA200
Valve Adapter
VA-40
Marquis® Stopcock
H1FLC H4RRC M3RRC-R S3FC
H1RC H4SNC M3SLC S3FLC
H1SLC L3SNC M3SNC S3SLC
H1SNC L4SNC M4FLC S3SNC
H3FLC M1FLC M4RRC S4FLC
H3RLC M1SLC M4SNC S4SLC
H3RRC M1SNC MN4RRC S4SNC
H3SLC M3FLC S1FLC U3RRC
H3SNC M3RLC S1SLC H4FLC M3RRC S1SNC
Flow Control Switch
U1SHC U1SHC-W U1SHC-R U1SHC-Y U1SHC-G
Merit® Manifold
201BF-R 202BF-FT 202BF-L 202BF-R
202BF-RT 202BN-F 202BN-R 202BN-RT
202HF-F 202HF-L 202HF-R 202HF-RX
202HN-R 202HN-RX 202LHWF-R 202LHWN-R
203BF-FT 203BF-L 203BF-R 203BF-RT
203BF-RX 203BF-RXT 203BN-F 203BN-L

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U.S. FOOD & DRUG ADMINISTRATION
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Silver Spring, MD 20993
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Certificate No. 8311-5-2025-1

Certificate to Foreign Government - Name of Product(s) Attachment Page 3 of 17

203BN-R 203BN-RT 203BN-RX 203HF-F
203HF-L 203HF-R 203HF-RX 203HN-L
203HN-R 203HN-RX 203LHF-R 203LHN-R
203LHWF-R 203LHWN-R 204BF-FT 204BF-R
204BF-RT 204BN-R 204HF-FT 204HF-L
204HF-R 204HF-RT 204HF-RX 204HN-R
204LHWF-R 204LHWN-R 204LHWF-L 205BF-F
205BF-FT 205BF-FTC 2V2HF-R 2V2HF-RT
2V3HF-R 2V3HF-RT 2V3HN-R 2V4LHWF-R
2V4LHWF-RT 2V4LHWF-RXT
501BF-R 501BN-R 502BF-L 502BF-R
502BF-RX 502BN-R 502BN-RX 502HF-L
502HF-R 502HF-RT 502HN-R 502LHWF-R
502LHWN-R 503BF-F 503BF-R 503BF-RT
503BF-RX 503BF-RXT 503BN-R 503HF-L
503HF-R 503HF-RT 503HF-RX 503HN-R
503HN-RT 503HN-RX 503LHF-R 503LHN-R
503LHWF-R 503LHWN-R 504BF-R 504BF-RT
504BN-R 504HF-R 504HF-RX 504HN-R
504HN-RT 504LHWF-R 504LHWN-R
Merit® TRAM®
201LTPHF-R 201LTPHN-R 202LTPHWF-R 202LTPHWN-R
203LTPHF-R 203LTPHN-R 203LTPHWF-R 203LTPHWN-R
204LTPHWF-R 204LTPHWN-R 2V4LTPHWF-RT 2V4LTPHWF-R
501LTPHN-R 502LTPHWN-R 503LTPHF-R 503LTPHWN-R
501LTPHF-R 502LTPHWF-R 503LTPHN-R 503LTPHWF-R
504LTPHWN-R 504LTPHWF-R
Merit® TRAM®P
201LTCHN-R 202LTCHWF-R 203LTCHN-R 204LTCHWF-R
201LTCHF-R 203LTCHWN-R 203LTCHF-R 204LTCHWN-R
202LTCHWN-R 203LTCHWF-R 2V4LTCHWF-RT 2V4LTCHWF-R
501LTCHN-R 502LTCHWF-R 503LTCHN-R 504LTCHWF-R
501LTCHF-R 503LTCHWN-R 503LTCHF-R
504LTCHWN-R 503LTCHWF-R 504LTCHWN-R
Meritrans® Pressure Transducer
MER100 MER148 MER200 MER212
Fountain® Infusion Catheter
IS4-45-10 IS4-90-50 IS5-45-10 IS5-90-50
IS4-45-20 IS4-135-5 IS5-45-20 IS5-135-5
IS4-90-5 IS4-135-10 IS5-90-5 IS5-135-10
IS4-90-10 IS4-135-20 IS5-90-10 IS5-135-20
IS4-90-20 IS4-135-30 IS5-90-20 IS5-135-30
IS4-90-30 IS4-135-40 IS5-90-30 IS5-135-40
IS4-90-40 IS4-135-50 IS5-90-40 IS5-135-50
FIS4-135-10 FIS4-45-20 FIS5-45-10 FIS5-90-50
FIS4-135-20 FIS4-90-10 FIS5-90-10 FIS5-135-10
FIS4-135-30 FIS4-90-20 FIS5-90-20 FIS5-135-20
FIS4-135-40 FIS4-90-30 FIS5-90-30 FIS5-135-30
FIS4-135-5 FIS4-90-40 FIS5-90-40 FIS5-135-40
FIS4-135-50 FIS4-90-5 FIS5-45-20 FIS5-135-5
FIS4-45-10 FIS4-90-50 FIS5-90-5 FIS5-135-50
Fountain ® Infusion System with Squirt
FIS4-135-10SQ FIS4-90-20SQ FIS5-135-20SQ FIS5-90-10SQ
FIS4-135-20SQ FIS4-90-30SQ FIS5-135-30SQ FIS5-90-20SQ
FIS4-135-30SQ FIS4-90-40SQ FIS5-135-40SQ FIS5-90-30SQ
FIS4-135-40SQ FIS4-90-50SQ FIS5-45-20SQ FIS5-90-40SQ
FIS4-45-10SQ FIS5-45-10SQ FIS5-135-50SQ FIS5-90-50SQ
FIS4-135-50SQ FIS5-135-10SQ FIS5-135-5SQ FIS5-90-5SQ

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FIS4-135-5SQ FIS4-45-20SQ FIS4-90-10SQ FIS4-90-5SQ
FW4-45 FW4-90 FW4-135 FW5-45
FW5-90 FW5-135
Fountain® Infusion Catheter Valve Tip
IS4-135-10-V IS4-135-20-V IS4-135-30-V
IS4-135-40-V IS4-135-5-V IS4-135-50-V
IS4-45-10-V IS4-45-20-V IS4-90-10-V
IS4-90-20-V IS4-90-30-V IS4-90-40-V
IS4-90-5-V IS4-90-50-V IS5-135-10-V
IS5-135-20-V IS5-135-30-V IS5-135-40-V
IS5-135-5-V IS5-135-50-V IS5-45-10-V
IS5-45-20-V IS5-90-10-V IS5-90-20-V
IS5-90-30-V IS5-90-40-V IS5-90-5-V IS5-90-50-V
FIS4-135-10-V FIS4-45-20-V FIS5-135-10-V FIS5-45-20-V
FIS4-135-20-V FIS4-90-10-V FIS5-135-20-V FIS5-90-10-V
FIS4-135-30-V FIS4-90-20-V FIS5-135-30-V FIS5-90-20-V
FIS4-135-40-V FIS4-90-30-V FIS5-135-40-V FIS5-90-30-V
FIS4-135-50-V FIS4-90-40-V FIS5-135-50-V FIS5-90-40-V
FIS4-135-5-V FIS4-90-50-V FIS5-135-5-V FIS5-90-50-V
FIS4-45-10-V FIS4-90-5-V FIS5-45-10-V FIS5-90-5-V
FIS4-135-10SQ-V FIS4-45-20SQ-V
FIS4-135-20SQ-V FIS4-90-10SQ-V
FIS4-135-30SQ-V FIS4-90-20SQ-V
FIS4-135-40SQ-V FIS4-90-30SQ-V
FIS4-135-50SQ-V FIS4-90-40SQ-V
FIS4-135-5SQ-V FIS4-90-50SQ-V
FIS4-45-10SQ-V FIS4-90-5SQ-V
FIS5-135-10SQ-V FIS5-90-10SQ-V FIS5-45-10SQ-V
FIS5-135-20SQ-V FIS5-90-20SQ-V FIS5-45-20SQ-V
FIS5-135-30SQ-V FIS5-90-30SQ-V
FIS5-135-40SQ-V FIS5-90-40SQ-V
FIS5-135-50SQ-V FIS5-90-50SQ-V
FIS5-135-5SQ-V FIS5-90-5SQ-V
stique® Infusion Catheter
MIC5-135-10-035 MIC5-135-5-035 MIC5-45-10-035 MIC5-45-5-035
MIC5-90-10-035 MIC5-90-5-035
MAJESTIK®SERIES ANGIOGRAPHIC NEEDLES
AN18T52C AN18T52MC AN18T53CO AN18T53MCO
AN18T71WR-25 AN18T72MC AN18T72S-25 AN18T72SC
AN18T72SH AN18T73SHO AN18T73SO AN19U52MC
AN19U72S-25 AN19U73SO SH792065
Merit Advance® Needle
AD18N91W AD18T51W AD18T71W AD18T71W-E
AD18T71WT AD19U41W AD19U51W AD19U71W
AD19U71W-E AD20T41W AD20T41W-E AD20T71W
AD21T21W AD21T21WT AD21T41W AD21T41W-E
AD21T41WT AD21T41WT-E AD21T71W AD21T71W-E
AD21T71WT AD21T71WT-E AD21T91W AD21T91W-E
AD21T91WT AD21T91WT-E AD22T61W AD20T71W-E
AD18T51WS AD18T71WS AD19U71WS
AD18T71WC AD19U41WC AD19U71WC AD21T41WC
AD21T91R AD21T91RE AD18N91W-E AD22T41WT
Merit Advance® ANGIOGRAPHIC SAFETY NEEDLE
SL18T71W SL18T71WS SL21T71W SL21T71WS
MiniStop® Covered Waste Basin
MMS100
MiniStop®+ Covered Waste Basin
MMSP100

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MiniStop® Filter
MMSF200
Prelude® SHEATH INTRODUCER
PSI-4F-11-035 PSI-7F-11-038 PSI-4F-23-035 PSI-7F-23-038
PSI-5F-11-035 PSI-8F-11-038 PSI-5F-23-035 PSI-8F-23-038
PSI-6F-11-035 PSI-4F-11 PSI-6F-23-035 PSI-4F-23
PSI-7F-11-035 PSI-5F-11 PSI-7F-23-035 PSI-5F-23
PSI-8F-11-035 PSI-6F-11 PSI-8F-23-035 PSI-6F-23
PSI-5F-11-038 PSI-7F-11 PSI-5F-23-038 PSI-7F-23
PSI-6F-11-038 PSI-8F-11 PSI-6F-23-038 PSI-8F-23
Prelude® PRO SHEATH INTRODUCER
PRO-4F-11-035 PRO-8F-11-035 PRO-8F-11-038 PRO-7F-11
PRO-5F-11-035 PRO-5F-11-038 PRO-4F-11 PRO-8F-11
PRO-6F-11-035 PRO-6F-11-038 PRO-5F-11
PRO-7F-11-035 PRO-7F-11-038 PRO-6F-11
Prelude® SHEATH INTRODUCER
PSI-4F-11-035ACT PSI-7F-11-038ACT PSI-5F-11ACT PSI-8F-11ACT
PSI-5F-11-038ACT PSI-8F-11-038ACT PSI-6F-11ACT
PSI-6F-11-038ACT PSI-4F-11ACT PSI-7F-11ACT
Prelude® SHORT SHEATH INTRODUCER
PSS-5F-4-018MT PSS-5F-4-035MT PSS-5F-4-038MT PSS-5F-4MT
PSS-6F-4-018MT PSS-6F-4-035MT PSS-6F-4-038MT PSS-6F-4MT
PSS-7F-4-018MT PSS-7F-4-035MT PSS-7F-4-038MT PSS-7F-4MT
PSS-8F-4-018MT PSS-8F-4-035MT PSS-8F-4-038MT PSS-8F-4MT
Prelude® +NEEDLE SHEATH INTRODUCER
PSI-4F-11-018 PSI-4F-11-018NT4 PSI-4F-11-025 PSI-4F-23-018NT4
PSI-4F-23-018NT7 PSI-4F-7-018 PSI-4F-7-018NT4 PSI-4F-7-025
PSI-5F-11-018 PSI-5F-11-018NT4 PSI-5F-11-025 PSI-5F-23-018NT4
PSI-5F-23-018NT7 PSI-5F-7-018 PSI-5F-7-018NT4 PSI-5F-7-025
PSI-6F-11-018 PSI-6F-11-018NT4 PSI-6F-11-025 PSI-6F-23-018NT4
PSI-6F-23-018NT7 PSI-6F-7-018 PSI-6F-7-018NT4 PSI-6F-7-025
PSI-7F-11-018 PSI-7F-23-018NT4 PSI-7F-7-018
PSI-5F-11-035-18G PSI-6F-11-035-18G PSI-7F-11-035-18G PSI-8F-11-035-18G
PSI-5F-11-038-18G PSI-6F-11-038-18G PSI-7F-11-038-18G PSI-8F-11-038-18G
Prelude® PRO +NEEDLE SHEATH INTRODUCER
PRO-4F-11-018NT7 PRO-5F-11-018NT7 PRO-6F-11-018NT7 PRO-7F-11-018NT7
PRO-5F-11-038-18G PRO-6F-11-038-18G
PreludeSYNC™ Radial Compression Device
SRB24AC SRB24MED SRB29AC SRB29MED
PreludeSYNC™ Syringe
SRB20AC
PreludeSYNC DISTAL™ Radial Compression Device
SDRB-REG-RT SDRB-REG-LT
PreludeSYNC DISTAL™ Radial Compression Device Syringe
SDRB10AC
PreludeSYNC EZ™ Radial Compression Device
EZ-SML EZ-REG
PreludeSYNC EVO™ Radial Compression Device Syringe
SRB20EVOAC
Prelude IDEAL™ HYDROPHILIC Sheath Introducer
PID4F7018NTPD PID7F11018SS PID5F23021SC PID5F23021PW
PID5F7018NTPD PID4F11021SC PID6F23021SC PID6F23021PW
PID6F7018NTPD PID5F11021SC PID7F23021SC PID7F23021PW
PID4F11018SC PID6F11021SC PID5F23021SSC PID4F11025PW
PID5F11018SC PID7F11021SC PID6F23021SSC PID5F11025PW
PID6F11018SC PID5F11021SSC PID4F11021PW PID6F11025PW
PID7F11018SC PID6F11021SSC PID5F11021PW PID7F11025PW
PID4F11018NTPD PID4F16021SC PID6F11021PW PID4F16025PW

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PID5F11018NTPD PID5F16021SC PID7F11021PW PID5F16025PW
PID6F11018NTPD PID6F16021SC PID4F16021PW PID6F16025PW
PID7F11018NTPD PID7F16021SC PID5F16021PW PID7F16025PW
PID4F11018SS PID5F16021SSC PID6F16021PW PID4F11021SSC
PID5F11018SS PID6F16021SSC PID7F16021PW PID4F16021SSC
PID6F11018SS PID4F23021SC PID4F23021PW PID4F23021SSC
PID5F11021SSC20G PID7F11021SSC PID7F16021SSC PID7F23021SSC
PID6F11021SSC20G
PreludeEASE™ HYDROPHILIC Sheath Introducer
PHR4F11018NTPD PHR4F7018SC PHR5F7018SC PHR6F11025PW
PHR4F11018SC PHR5F11018NTPD PHR6F11018NTPD PHR6F11035SC
PHR4F11021PW PHR5F11018SC PHR6F11018SC PHR6F23021SC
PHR4F11021SC PHR5F11021PW PHR6F11021PW PHR6F7018SC
PHR4F11025PW PHR5F11021SC PHR6F23018NT PHR7F11018SC
PHR4F16018NT PHR5F11018SS PHR6F23021PW PHR7F11021SC
PHR4F16021SC PHR5F7018NTPD PHR6F16018NT PHR7F11035SC
PHR4F16025PW PHR5F11025PW PHR6F16021SC PHR7F16018NT
PHR4F11018SS PHR5F16018NT PHR6F16025PW PHR7F16021SC
PHR4F11021SCSN PHR5F16021SC PHR5F11021SCSN PHR7F23018NT
PHR4F7018NTPD PHR5F16025PW PHR6F11021SCSN PHR7F23021SC
PHR4F23018NT PHR5F23018NT PHR6F7018NTPD PHR4F11018SSSN
PHR4F23021PW PHR5F23021PW PHR6F11018SS PHR5F11018SSSN
PHR4F23021SC PHR5F23021SC PHR6F11021SC PHR6F11018SSSN
PHR5F11021SSC PHR6F11021SSC PHR5F23021SSC PHR6F23021SSC
Prelude® PRO SHEATH INTRODUCER Marker Tip
PRO-4F-11-035MT PRO-5F-11-035MT PRO-6F-11-035MT PRO-7F-11-035MT
PRO-8F-11-035MT PRO-5F-11-038MT PRO-6F-11-038MT PRO-7F-11-038MT
PRO-8F-11-038MT PRO-4F-11MT PRO-5F-11MT PRO-6F-11MT
PRO-7F-11MT PRO-8F-11MT
Prelude® SHEATH INTRODUCER Marker Tip
PSI-4F-23-035MT PSI-4F-23MT PSI-5F-23-035MT PSI-5F-23-038MT
PSI-5F-23MT PSI-6F-23-035MT PSI-6F-23-038MT PSI-6F-23MT
PSI-7F-23-035MT PSI-7F-23-038MT PSI-7F-23MT PSI-8F-23-035MT
PSI-8F-23-038MT PSI-8F-23MT
Prelude Wave™ Hydrophilic Sheath Introducer
WAV4F11018NTPD WAV4F11018NTPD-F WAV4F11018SC-F WAV4F11018SSC-F WAV4F11021PW
WAV4F11021PW-F WAV4F11021SSC WAV4F11021SSC-F WAV4F23021PW-F WAV4F23021SC-F
WAV5F11018NTPD WAV5F11018NTPD-F WAV5F11018SC-F WAV5F11018SS-F WAV5F11021PW
WAV5F11021PW-F WAV5F11021SC-F WAV5F11021SSC WAV5F11021SSC-F WAV5F11025PW
WAV5F11025PW-F WAV5F23021PW WAV5F23021PW-F WAV5F23021SC-F WAV5F23021SSC
WAV5F23021SSC-F WAV6F11018NTPD WAV6F11018NTPD-F WAV6F11018SC-F WAV6F11018SS-F
WAV6F11021PW WAV6F11021PW-F WAV6F11021SC-F WAV6F11021SSC WAV6F11021SSC-F
WAV6F11025PW WAV6F11025PW-F WAV6F23018PW-F WAV6F23021PW WAV6F23021PW-F
WAV6F23021SC-F WAV6F23021SSC WAV6F23021SSC-F WAV7F11018NTPD WAV7F11018NTPD-F
WAV7F11018SC-F WAV7F11018SSC-F WAV7F11021PW WAV7F11021PW-F WAV7F11021SC-F
WAV7F11021SSC WAV7F11021SSC-F WAV7F23021PW WAV7F23021PW-F WAV7F23021SC-F
WAV7F23021SSC WAV7F23021SSC-F WAV5F11021NTPD WAV5F11021NTPD-F WAV5F11025SSC-F
WAV6F11021NTPD WAV6F11021NTPD-F WAV6F11025SSC WAV6F11025SSC-F WAV7F11025SSC-F
WAV6F11025SS-F
Prelude® SHEATH INTRODUCER Dilator
PD4F035 PD7F038 PSD6F035-8cm
PD5F038 PD8F038 PSD7F035-8cm
PD6F038 PSD5F035-8cm PSD8F035-9cm
Prelude® SHEATH INTRODUCER Obturator
OBT-4F-11 OBT-6F-11 OBT-4F-23 OBT-6F-23
OBT-5F-11 OBT-7F-11 OBT-5F-23 OBT-7F-23
Prelude Choice™ Hemostasis Valve Adapter
PCHVA08

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Prelude Choice™ Universal Hemostasis Valve Adapter
UHVA08
ProGuide™ Chronic Dialysis Catheter
61124 61128 61132 61136
61140 62124 62128 62132
62136 62140 63124 63128
63132 63136 63140 64124
64128 64132 64136 64140
DC01452419 DC01452419-NE5 DC01452823 DC01452823-NE5
DC01453227 DC01453227-NE5 DC01453631 DC01454035
DC01455550 DC21452419 DC21452419-NE5 DC21452823
DC21452823-NE5 DC21453227 DC21453227-NE5 DC21453631
DC21454035 DC21455550
Prelude® Roadster Guide Sheath
PG4F45S PG4F90S PG5F45MP PG5F45R
PG5F45S PG5F90MP PG5F90S PG6F45C
PG6F45HS PG6F45MP PG6F45R PG6F45S
PG6F65MP PG6F65S PG6F65SX PG6F90MP
PG6F90MPX PG6F90SX PG7F45MP PG7F45MPX
PG7F45RX PG7F45S PG7F45SX PG7F65SX
PG7F90SX PG8F45MPX PG8F45S PG8F45SX
PG8F65SX PG8F90SX PG5F45S018 PG7F30S
PG5F90S018 PG6F45S018 PG6F90SX018
Impella Low Profile Companion Sheath
X9PG700001
Hemostasis Valve Adapter
HVA-100 HVA-60
10 Fore™ Hemostasis Valve
MAPTEN4 MAPTEN42 MAPTEN452
CentrosFLO® Long-Term Hemodialysis Catheter Kit
CENFP15K CENFP17K CENFP19K CENFP23K CENFP27K CENFP31K
CENFT15K CENFT17K CENFT19K CENFT23K CENFT27K CENFT31K
CentrosFLO® Long-Term Hemodialysis Catheter
CENFT15C CENFT17C CENFT19C CENFT23C CENFT27C CENFT31C
Centros® Long-Term Hemodialysis Catheter Kit
CENP15K CENP17K CENP19K CENP23K CENP27K CENP31K
CENT15K CENT17K CENT19K CENT23K CENT27K CENT31K
Centros® Long-Term Hemodialysis Catheter Kit
CENT15C CENT17C CENT19C CENT23C CENT27C CENT31C
Valved Peelable Sheath Introducer
DCVP1600 DCVP1500
A•S•K MERIT Access® Safety Kit
ASK200
SLIP-NOT® Suture Retention Device
SRD100 SRD200
BOWTIE™ Guide Wire Insertion Device
BT01
SeaDragon™ Torque Device
TD500
SeaDragon 2™ Torque Device
TD500/A
Merit Angioplasty Pack™
MAP952 MAP900 MAP600 MAP550
MAP500 MAP501 MAP600B
ASAP® ASPIRATION CATHETER KIT
ASAP100
ASAPLP™ LOW PROFILE ASPIRATION CATHETER KIT
ASAPLP

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OstialPRO® Stent Positioning System
3011
InQwire® Guide Wires PTFE Coated W/Ringmaster™
IQR35F150B IQR35F150J3 IQR35F150J3F
IQR35F150BST IQR35F260J3 IQR35F150J3S
RingMASTER™ GUIDE WIRE BASIN
RM01
DIAMOND TOUCH™ Inflation Device
IN9135 IN9152 IN9302 IN9352
IN9403 IN9802 IN9852
DiamondTouch™ Syringe
IN9KVCF IN9VCF
basixTau™ Inflation Device
IN4T130 IN4T530 IN4T952 IN4TXR52
IN4T802 IN4T852
Brighton® Bipolar Coagulation Probe
BP-7F-SP-350 BP-10F-SP-350 BP-7F-DP-350 BP-10F-DP-350
ENDOTEK BIG 60® INFLATION DEVICE
ENDO-AN6012
Endotek Digital Inflation Device
ENDO-DI2030
TIO™ THREE IN ONE ORAL AIRWAY· BITE BLOCK· O2 PORT
TIO60-90 TIO60-100 TIO60-110
Flex-Neck® Classic Peritoneal Dialysis Catheter
CF-5250 CF-5260 CF-5270 CF-5243
CF-5161 CF-5244 CF-5249 CF-5242
CF-5247 CF-4230 CF-4235
Flex-Neck® ARC™ Peritoneal Dialysis Catheter
CF-5450 CF-5460 CF-5470 CF-5443
CF-5442 CF-4430
Flex-Neck® ExxTended™ Adult Peritoneal Dialysis Catheter
CF-5560 CF-5570
Peritoneal Dialysis Catheter Accessories
CC-1301 CC-1360 CC-2300 CE-1400
CS-242 CS-352 CS-362 FT-1100
IA-102 TE-1000 VP-210 VP-211
VP-411 VP-511 VP-511M ST-700MG
ST-700 ST-700EU FS-300 VS-1800
VS-1810 SS-100 SS-200 SS-300
CSS-242 CSS-352 CSS-362 FR-300
Merit Maestro® MICROCATHETER
28MC2111045 28MC21110SN 28MC21110ST 28MC2113045
28MC21130SN 28MC21130ST 28MC2115045 28MC21150SN
28MC21150ST 28MC2411045 28MC24110SN 28MC24110ST
28MC2413045 28MC24130SN 28MC24130ST 28MC2415045
28MC24150SN 28MC24150ST 28MC2811045 28MC28110SN
28MC28110ST 28MC2813045 28MC28130SN 28MC28130ST
28MC2815045 28MC28150SN 28MC28150ST 29MC2911045
29MC29110SN 29MC29110ST 29MC2913045 29MC29130SN
29MC29130ST 29MC2915045 29MC29150SN 29MC29150ST
28MC2116545 28MC2816545 28MC2117545 28MC2817545
28MC21165SN 28MC28165SN 28MC21175SN 28MC28175SN
28MC21165ST 28MC28165ST 28MC21175ST 28MC28175ST
28MC2416545 29MC2916545 28MC2417545 29MC2917545
28MC24165SN 29MC29165SN 28MC24175SN 29MC29175SN
28MC24165ST 29MC29165ST 28MC24175ST 29MC29175ST
Merit Maestro® MICROCATHETER + TrueForm™ RESHAPABLE GUIDE WIRE™
28MC24110ST-I 28MC24130SN-I 28MC21110ST-I 28MC2113045-I

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28MC2411045-I 28MC24150ST-I 28MC2111045-I 28MC21150SN-I
28MC24110SN-I 28MC2415045-I 28MC21110SN-I 28MC21150ST-I
28MC24130ST-I 28MC24150SN-I 28MC21130ST-I 28MC2115045-I
28MC2413045-I 28MC21130SN-I
28MC2411045-W 28MC24130SN-W 28MC24110ST-W 28MC2415045-W
28MC24110SN-W 28MC24130ST-W 28MC2413045-W 28MC24150SN-W
28MC24150ST-W
ELATION® BALLOON DILATOR Fixed Wire Esophageal Balloon Dilation Catheter
E6 E10 E15 E8 E12 E18
ELATION® BALLOON DILATOR Wireguided Esophageal/Biliary Balloon Dilation Catheter
EB18
ELATION® BALLOON DILATOR Wireguided Esophageal/Colonic/Biliary Balloon Dilation Catheter
ECB18
ELATION® BALLOON DILATOR Wireguided Esophageal/Pyloric/Biliary Balloon Dilation Catheter
[redacted]B10 EPB12 EPB15 EPB6
EPB8
ELATION® BALLOON DILATOR Wireguided Esophageal/Pyloric/Colonic/Biliary Balloon Dilation Catheter
EPCB6 EPCB8 EPCB10 EPCB12
EPCB15
ELATION® BALLOON DILATOR Pulmonary Balloon Dilation Catheter
P10L20 P12L30 P18L55 P8L20
P10L30 P12L55 P6L20 P8L30
P12L20 P15L55 P6L30 P4L15
ELATION 5™ FIVE-STAGE BALLOON DILATOR Fixed Wire Esophageal Balloon Dilation Catheter
EX6 EX8 EX10 EX12 EX15 EX18
ELATION 5™ FIVE-STAGE BALLOON DILATOR Wireguided Esophageal/Pyloric Balloon Dilation Catheter
EPX10 EPX12 EPX15 EPX18 EPX6 EPX8
ELATION 5™ FIVE-STAGE BALLOON DILATOR Wireguided Esophageal/Pyloric/Colonic Balloon Dilation Catheter
EPCX10 EPCX12 EPCX15 EPCX18 EPCX6 EPCX8
SPINR™ High-Performance Guidewire Controller
5X-GW 3X-GW
Merit Drainage Depot™
[redacted]24
Contrast Management System
CAS100 CAS200
HeRO® GRAFT Venous Outflow Component
HEROVOC HERO1001 HERO1001VOC
HeRO® GRAFT Arterial Graft Component
HEROGRAFT HERO1002
HeRO® GRAFT Accessory Component Kit
HEROACK HERO1003
SUPER HeRO® Venous Outflow and Adapter Component Kit
SUPERHERO HERO1000
HeRO® ALLY Revision Kit
HEROALLY HERO1006
SCOUT Bx™ Reflector and Delivery System
SSR13B-01
EsophyX®Z+
R2007
SerosaFuse® Implantable Fasteners
R2175 R2375
EsophyX®Z+ with SerosaFuse® Implantable Fasteners
R2275
SAFETY PARACENTESIS PROCEDURE TRAY
SPPT-100 SPPT-5F-10L SPPT-5F-10S SPPT-5F-12PL
SPPT-5F-12PS SPPT-5F-17PL SPPT-5F-17PS SPPT-5F-7L
SPPT-5F-7S SPPT-6F-10L SPPT-6F-10S SPPT-6F-12PL

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SPPT-6F-12PS SPPT-6F-17PL SPPT-6F-17PS SPPT-6F-7L
SPPT-6F-7S SPPT-8F-10L SPPT-8F-10S SPPT-8F-12PL
SPPT-8F-12PS SPPT-8F-17PL SPPT-8F-17PS SPPT-8F-7L
SPPT-8F-7S
THORACENTESIS AND PARACENTESIS SET
TAPS-100 TAPS-5F-10LT TAPS-5F-10T TAPS-5F-12PLT
TAPS-5F-12PT TAPS-5F-17PLT TAPS-5F-17PT TAPS-5F-7LT
TAPS-5F-7T TAPS-6F-10LT TAPS-6F-10T TAPS-6F-12PLT
TAPS-6F-12PT TAPS-6F-17PLT TAPS-6F-17PT TAPS-6F-7LT
TAPS-6F-7T TAPS-8F-10LT TAPS-8F-10T TAPS-8F-12PLT
TAPS-8F-12PT TAPS-8F-17PLT TAPS-8F-17PT TAPS-8F-7LT
TAPS-8F-7T
Merit PAK™ PEDAL ACCESS KIT Hydrophilic
PAKPHR47NPD4 PAKPHR47NPD7
Merit Pursue™ Microcatheter
28HC1711045 28HC17130SN 28HC17150ST 29HC2013045
28HC17110SN 28HC17130ST 29HC2011045 29HC20130SN
28HC17110ST 28HC1715045 29HC20110SN 29HC20130ST
28HC1713045 28HC17150SN 29HC20110ST 29HC2015045
29HC20150SN 29HC20150ST
Merit Pursue™ Microcatheter Preloaded With: TrueForm™ RESHAPABLE GUIDE WIRE™
28HC1711045-I 28HC17130ST-I 29HC20110SN-I 29HC2015045-I
28HC17110SN-I 28HC1715045-I 29HC20110ST-I 29HC20150SN-I
28HC17110ST-I 28HC17150SN-I 29HC2013045-I 29HC20150ST-I
28HC1713045-I 28HC17150ST-I 29HC20130SN-I
28HC17130SN-I 29HC2011045-I 29HC20130ST-I
Ventrax™ Delivery System
VTR851 VTR852 VTR853
CT Transfer Set
TS520L
CT Transfer Set with Disinfectant Caps
TS120DC
FastBreak™ Breakaway Connector
FBG3U5 FBG10
ClariVein Infusion Catheter
45-018-E2S 65-018-E4S 85-018-E140S
ClariPak™ ClariVein® Procedure Pack
K22C-00001
Arcadia™ Steerable Balloon Catheter
ARC10SB ARC15SB ARC20SB ARC25SB ARC30SB
Arcadia™ Straight Balloon Catheter
ARC10ST ARC15ST ARC20ST ARC25ST ARC30ST
Arcadia™ Steerable Balloon Catheter Kit
ARC10SB-LK ARC15SB-LK ARC20SB-LK ARC25SB-LK ARC30SB-LK
ARC10SB-LK-2 ARC15SB-LK-2 ARC20SB-LK-2 ARC25SB-LK-2 ARC30SB-LK-2
Arcadia™ Straight Balloon Catheter Kit
ARC10ST-LK ARC15ST-LK ARC20ST-LK ARC25ST-LK ARC30ST-LK
ARC10ST-LK-2 ARC15ST-LK-2 ARC20ST-LK-2
basixALPHA™ Inflation Device
IN3130 IN3152 IN3302 IN3802
GRANDSTAND® ShortStop® Sharps Holder
SS30
Worley™ Vein Selector
57538CS-WOR 57538CSV-WOR 57538CSHK-WOR
Worley™ Advanced Contrast Administration Kit
K12-WORLEY1 K12-WORLEY2
Merit H20™ Hydrophilic Guide Wire
H2OSTDA18150 H2OSTDA18180 H2OSTDA18260EX

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H2OSTDA1880 H2OSTDA25150 H2OSTDA25180
H2OSTDA25260EX H2OSTDA35150 H2OSTDA35150LT
H2OSTDA35180 H2OSTDA35180P H2OSTDA35260EX
H2OSTDA3580 H2OSTDA38150 H2OSTDS25180
H2OSTDS35150 H2OSTFA35150 H2OSTFA35180
H2OSTFA35260EX H2OSTFA3580 H2OSTFS35180
H2OSTFS35260EX H2OSTFS38180
Evacuated Drainage Bottle
EVAC1000
TEMNO Elite™ Coaxial Introducer
CX1410 CX1415 CX1610 CX1615
CX1810 CX1815 CX1820 CX2010
CX2015 CX2020
TEMNO Elite™ Standalone Biopsy Needle
TE1406 TE1410 TE1415 TE1606
TE1610 TE1615 TE1806 TE1810
TE1815 TE1820 TE2006 TE2010
TE2015 TE2020
TEMNO Elite™ Coaxial Bundle
TEC1410 TEC1415 TEC1610 TEC1615
TEC1810 TEC1815 TEC1820 TEC2010
TEC2015 TEC2020
TEMNO Elite™ Valved Coaxial Bundle
TEVC1410 TEVC1415 TEVC1610 TEVC1615
TEVC1810 TEVC1815 TEVC1820 TEVC2010
TEVC2015 TEVC2020
TEMNO Elite™ Valved Coaxial Introducer
VC1410 VC1415 VC1610 VC1615
VC1810 VC1815 VC1820 VC2010
VC2015 VC2020
Custom Manifold Kit
K09T-10440D
Medallion® COP Syringe and Kits
K01-07826 K01-07944 K01-08064P K02-01587 K06-00316
Procedure Kit - Dilator - Non Vascular
K12-08322 K12-08323 K12-08324 K12-08325
Waste Management Kit
K10-04750 K10-00230B K10-04843 K10-05180 K10-04750
Drainage connecting tube
K10-04129 K10-04130 K10-04131 K10-04132 K08-02027 K10-03450
Manifold Kit Angiographic Tray
K09T-08952
Digital Inflation Device
K05-03069 K05-03069A
Convenience Kits
KXX-YYYYY
'K' - indicates that it is a Kit
'XX' - designates the Kit type
'YYYYY' - is a sequential number uniquely identifying the Kit
'KXXT' - indicates that it is a Procedure Pack
'-' is the character - (dash)
K01 = Single Medallion (syringe)
K02 = Multiple Medallion (syringe)
K04 = Tubing
K05 = Inflation Device
K06 = Single Control Syringe
K07 = Control Syringe combined with other syringes
K08 = Fluid Management

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K09 = Manifolds
K10 = Waste Management
K11 = Pressure Monitoring
K12 = Procedure Kit
K13 = Pens and Labels
K14 = Dialysis Kit
K15 = Sheath Introducer Kit
K16 = Microcatheter Kit
K17 = Interventional Kit
K18 = Sheath Introducer Kit
K19 = See Combination Packs
K20 = Custom Endoscopic Kit
'-' is the character - (dash)

Name of Manufacturer
Manufacturing Site
Akita Sumitomo Bakelite Co., Ltd.
27-4, Aza Nakajimashita, Souzen-machi
Tsuchizakiminato
Akita, Akita
JAPAN 011-8510

Name of Product(s)
SwiftNINJA® Steerable Microcatheter
MIV-20500 26SN24150ST 26SN24125ST
SwiftNINJA® Steerable Coronary Microcatheter
SNCM125 26SNCM24125ST 26SNCM24150ST

Name of Manufacturer
Manufacturing Site
PIOLAX MEDICAL DEVICES, INC.
2265-3 Kamiyabe-cho Totsuka-ku
Yokohama, Kanagawa
[redacted]AN 2450053

Name of Product(s)
TrueForm™ RESHAPABLE GUIDE WIRE™
TF14145S TF14165S TF14180S TF14180A

Name of Manufacturer
Manufacturing Site
Paragon Medical - Mansfield
111 Forbes Blvd Suite 101
Mansfield, MA
USA 02048

Name of Product(s)
Surfacer® Inside-Out® Access Catheter System
600200

Name of Manufacturer
Manufacturing Site
HEALTH LINE INTERNATIONAL CORPORATION
260 North Ace Yeager Court
Unit D
Salt Lake City, UT
USA 84116

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Name of Product(s)
DualCap® Solo™ Disinfecting Caps Needle-free Valves
001-300 001-400 450-LB 460-DB
DualCap® IV Pole Strips® Disinfecting Caps Needle-free Valves
500-LB 550-LB 600-DB 660-DB

Name of Manufacturer
Manufacturing Site
BIOSPHERE MEDICAL, S.A.
Parc des Nations - Paris Nord 2, 383 rue de la Belle Etoile
95700 ROISSY-EN-FRANCE, FRANCE
Roissy, Val-d'Oise
FRANCE 95700

Address Also Known As
BIOSPHERE MEDICAL, S.A.
Parc des Nations, Paris Nord 2,
383 Rue de la Belle Etoile
Roissy-en-France, Paris
FRANCE 95700

Name of Product(s)
Bearing™ nsPVA Embolization Particles
V100EP V200EP V300EP V400EP V600EP V800EP V1100EP
Bearing nsPVA Express™ Embolization Particles
S100EP S200EP S300EP S400EP S600EP S800EP S1100EP

Name of Manufacturer
Manufacturing Site
KA Medical
1265 Grey Fox Road
Suite 550
[redacted]en Hills, MN
USA 55112

Name of Product(s)
SIEGE™ Vascular Plug
SVP2.5-0.021 SVP4-0.021 SVP6-0.027

Name of Manufacturer
Manufacturing Site
MERIT MEDICAL IRELAND, LTD
Parkmore Business Park West
Galway, Galway
IRELAND 0000

Name of Product(s)
basixCOMPAK™ Inflation Device ✱
IN4130 IN4330 IN4352 IN4530
Endotek Analog Inflation Device
ENDO-AN2030
Merit Angioplasty Pack™ ✱
MAP101 MAP102 MAP104 MAP111
MAP112 MAP113 MAP150 MAP151
MAP152 MAP152SD MAP153 MAP154
MAP220 MAP221 MAP222 MAP300
MAP301 MAP302 MAP350 MAP351

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MAP352 MAP353 MAP354 MAP400
MAP403 MAP450 MAP453
FLO40XR™ Hemostasis Valve
FLO40XR
FLO30™
FLO30
Prelude® Guide Wire
SW35DE50SST SW35DE80SST SW38DE50SST SW38DE80SST
EN Snare® Endovascular Snare System
EN1003004 EN2007030 EN2006015 EN2007045
EN1003008 EN2006010 EN2006020
ONE Snare® Endovascular Snare System
ONE500 ONE2000 ONE3500 ONE1500
ONE1000 ONE2500 ONE4000 ONE3000
ONE1001 ONE2501 ONE6000 ONE1501
ONE Snare® Microsnare System
ONE200 ONE400 ONE700
ONE201 ONE401 ONE701
InQwire® Guide Wires PTFE Coated
6500-11 6682-L3 IQ35F150J1O5S IQ35F260J1O5
6500-31 6682-M1 IQ35F150J3 IQ35F260J1O5F
6609-13 6682-N3 IQ35F150J3F IQ35F260J1O5RS
6609-31 6682-R1 IQ35F150J3K IQ35F260J3
6609-33 6684-41 IQ35F150J3S IQ35F260J3S
6676-A1 6689-11 IQ35F150J3SHD IQ35F260S
6676-B3 6689-A1 IQ35F150J3SK IQ35F80B
6676-C1 6690-41 IQ35F150J6 IQ35F80J1O5RS
6676-D3 6690-61 IQ35F150NLLLT IQ35F80J3
6676-G1 6693-41 IQ35F150NLLT IQ38F150B
6676-H1 6693-61 IQ35F150NLT IQ38F150BC
6677-B1 6693-71 IQ35F150S IQ38F150J15
6678-71 6693-A1 IQ35F180B IQ38F150J1O5RS
6678-81 6694-21 IQ35F180BC IQ38F150J3
6678-B3 6695-31 IQ35F180BK IQ38F150J3F
6680-11 6697-11 IQ35F180BST IQ38F150J3S
6680-23 6697-21 IQ35F180J15 IQ38F150J6
6680-23J3 8818-73 IQ35F180J1O5 IQ38F150J6K
6680-31 8818-B1 IQ35F180J1O5RS IQ38F150S
6680-43 8818-G1 IQ35F180J3 IQ38F180J3F
6680-51 8818-F1 IQ35F180J3F IQ38F180J6F
6680-61 8819-K1 IQ35F180J3K IQ38F260J3
6680-71 8819-L1 IQ35F180J3S IQ38F260J3F
6682-21 IQ35F100J15 IQ35F180J6F IQ38F260S
6682-41 IQ35F150B IQ35F210J1O5 IQ38F50J3
6682-61 IQ35F150BC IQ35F210J1O5F IQ38F80J3
6682-81 IQ35F150BST IQ35F210J3 IQ35F100J3SHD
6682-B3 IQ35F150J15 IQ35F220J3 IQ35F260J3K
6682-E1 IQ35F150J1O5 IQ35F260B IQ35F210J3K
6682-K1 IQ35F150J1O5RS IQ35F260BST IQ35F80J3SHD 6680-93
Prelude® Plastic Jacketed Guide Wire
SW21A45PW SW21A80PW SW25A45PW SW25A80PW
InQwire® Guide Wires PTFE Coated
IQH35F150B IQH38F150J3 IQH35F150J3 IQH35F150J1O5
IQH35F150S IQH35F150J15 IQH35F150NLT IQH35F70J6
IQH35F180B IQH38F150B IQH35F180J3F IQH38F70J6
MERIT LAUREATE™ HYDROPHILIC GUIDE WIRE
LWSTDA3580 LWSTDS35150 LWSTFA3580 LWSTDA35260EX
LWSTDA35150 LWSTDS35180 LWSTFA35150 LWSTDS35260EX

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LWSTDA35180 LWSTDS35220 LWSTFA35180 LWSTFA35260EX
LWSTDA35220 LWSTDA38180 LWSTFA35220 LWSTFS35260EX
LWSTFS35180 LWSTDS38150 LWSTFA3880 LWSTFS35150
LWSTFS35220 LWSTDS38180 LWSTFA38150 LWSTFS38150
LWSTDA3880 LWSTDS25150 LWSTFA38180 LWSTFS38180
LWSTDA38120 LWSTDS25180 LWSTDA25260EX LWSTDA38260EX
LWSTDA38150 LWSTDA18180 LWSTDS25260EX LWSTDS38260EX
LWSTDA25150 LWSTFS3580 LWSTDS18150 LWSTDS18260EX
LWSTDA25180 LWSTDS3580 LWSTDS18180 LWSTDA18260EX
LWSTDA1880 LWSTDA18150 LWSTDS35110
InQwire® AMPLATZ
IQA500 IQA510 IQA519 IQA525
IQA501 IQA511 IQA520 IQA526
IQA502 IQA512 IQA521 IQA527
IQA503 IQA513 IQA522 IQA528
IQA504 IQA517 IQA523 IQA563
IQA509 IQA518 IQA524 IQA564
IQA505 IQA506 IQA507
Merit Angioplasty Pack™ PhD™ Hemostasis Valve
MAP800 MAP801 MAP802 MAP803
MAP804 MAP850 MAP851 MAP852
MAP853 MAP854
GO2WIRE™ Floppy Straight Steerable Guide Wire
G2WFS35145 G2WFS35145NE G2WFS35175 G2WFS35175NE
G2WFS35210 G2WFS35260 G2WFS35300
GO2WIRE™ Intermediate Mod J Steerable Guide Wire
G2WIJ35145 G2WIJ35145NE G2WIJ35175 G2WIJ35175NE
G2WIJ35210 G2WIJ35260 G2WIJ35300
GO2WIRE™ Standard Straight Steerable Guide Wire
G2WSS35145 G2WSS35145NE G2WSS35175 G2WSS35175NE
G2WSS35210 G2WSS35260 G2WSS35300
GO2WIRE™ Extension System Steerable Guide Wire
G2WES35001
LASHWire™ Hydrophilic Guide Wire *
MSWSTDA1880 MSWSTDA18150 MSWSTDA18180 MSWSTDA18260EX
MSWSTDS18150 MSWSTDS18180 MSWSTDS18260EX MSWSTDA25150
MSWSTDA25180 MSWSTDA25260EX MSWSTDS25150 MSWSTDS25180
MSWSTDS25260EX MSWSTDA3580 MSWSTDA35150 MSWSTDA35180
MSWSTDA35220 MSWSTDA35260EX MSWSTDS3580 MSWSTDS35150
MSWSTDS35180 MSWSTDS35220 MSWSTDS35260EX MSWSTDA3880
MSWSTDA38120 MSWSTDA38150 MSWSTDA38180 MSWSTDA38260EX
MSWSTDS38150 MSWSTDS38180 MSWSTDS38260EX MSWSTFA3580
MSWSTFA35150 MSWSTFA35180 MSWSTFA35220 MSWSTFA35260EX
MSWSTFS3580 MSWSTFS35150 MSWSTFS35180 MSWSTFS35220
MSWSTFS35260EX MSWSTFA3880 MSWSTFA38150 MSWSTFA38180
MSWSTFS38150 MSWSTFS38180
MIGHTYwire™ GuideWire
MW35904S MW351454S MW351457S MW351804S
MW351807S MW352304S MW352307S MW352604S
MW352607S MW353004S MW353007S MW35907S
MW352304J MW352604J MW353004J MW352604DC
MW353004DC MW352604EDC MW353004EDC
Osseoflex® SN Steerable Needle
OF-0020 OF-0231
Osseoflex® Access Kit Vertebral Introduction System
OS-0001
Osseoflex® SB Steerable Balloon
OF-0222 OF-0224

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Osseoflex® SB Straight Balloon
OT-0222 OT-0224
Osseoflex® CD-H Hydraulic Cement Delivery System
OF-0348
Osseoflex® Straight Hand Drill
OF-0217
Osseoflex® BFD Bone Filler Device
OF-0298
Westbrook™ Bone Biopsy System
KBD1110 KBD1115
Kensington™ Guide Wire Bone Biopsy System
KBC1110 KBC1115
Preston™ Hard Bone Introducer
KTP1110 KTP1115
[redacted]ford™ Guide Wire Hard Bone Biopsy System
KBP1110 KBP1115
Preston™ Bone Biopsy Needle
CD1110 CD1115
Preston™ Hard Bone Access Needle with Drill
ANP1165 ANP1185 ANP1110 ANP1115
Preston™ Long Drill
ML1110 ML1115
Madison™ Perforating Bone Biopsy System with Drill
KDPD1110 KDPD1115 KDPD1165 KDPD1185 KDPD139
Madison™ Mini Bone Biopsy System
KDP136
Preston™ Transpedicular Introducer
TV1110 TV813
Preston™ Bone Filler
CR1320 CR1020
Preston™ Transpedicular Drill
MV1110
Huntington Guided Perforating Bone Biopsy System with Drill
[redacted]165 OM1110 OM1115

Name of Manufacturer
Manufacturing Site
Merit Maquiladora Mexico, S. DE R.L. DE C.V.
Avenida Sor Juana Ines de la Cruz
19970 Interior B, Edificio 2, Parque Industrial Frontera
Tijuana, Baja California
MEXICO 22630

Name of Product(s)
Prelude® Roadster Guide Sheath
PG4F45S PG4F90S PG5F45MP PG5F45R
PG5F45S PG5F90MP PG5F90S PG6F45C
PG6F45HS PG6F45MP PG6F45R PG6F45S
PG6F65MP PG6F65S PG6F65SX PG6F90MP
PG6F90MPX PG6F90SX PG7F45MP PG7F45MPX
PG7F45RX PG7F45S PG7F45SX PG7F65SX
PG7F90SX PG8F45MPX PG8F45S PG8F45SX
PG8F65SX PG8F90SX PG5F45S018
PG5F90S018 PG6F45S018 PG6F90SX018
BioFlo DuraMax® Hemodialysis Catheter
H965103028011 H965103028161 H965103038011 H965103038161 H965103029011
H965103028021 H965103028171 H965103038021 H965103038171 H965103029021
H965103028031 H965103028181 H965103038031 H965103038181 H965103029031

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H965103028041 H965103028191 H965103038041 H965103038191 H965103029041
H965103028051 H965103028201 H965103038051 H965103038201 H965103029051
H965103028061 H965103028211 H965103038061 H965103038211 H965103029061
H965103028070 H965103028220 H965103038070 H965103038220 H965103029071
H965103028080 H965103028230 H965103038080 H965103038230 H965103029081
H965103028090 H965103028240 H965103038090 H965103038240 H965103029091
DuraMax® Hemodialysis Catheter
H787103028015 H787103028165 H787103029015
H787103028025 H787103028175 H787103029025
H787103028035 H787103028185 H787103029035
H787103028045 H787103028195 H787103029045
H787103028055 H787103028205 H787103029055
H787103028065 H787103028215 H787103029065
H787103028031 H787103028181 H787103029075
H787103028041 H787103028191 H787103029085
H787103028051 H787103028201 H787103029095
H787103028061 H787103028225 H787103029041
H787103028075 H787103028235
H787103028085 H787103028245
H787103028095
DuraFlow™ 2 Hemodialysis Catheter
H787103012145 H787103012185 H787103017015
H787103012125 H787103012195 H787103017025
H787103012015 H787103012205 H787103017035
H787103012025 H787103012215 H787103017045
H787103012035 H787103012225 H787103017055
H787103012045 H787103012235 H787103017155
H787103012011 H787103012245 H787103017145
H787103012021
H787103012031
H787103012041
H787103012055
H787103012155
H787103012115
EvenMore® Chronic Dialysis Catheter
H787103035115 H787103036015
H787103035125 H787103036025
H787103035015 H787103036035
H787103035025 H787103036065
H787103035035
H787103035045
H787103035055
H787103035065
H787103035075
H787103035085
H787103035095
H787103035105
Dialysis Accessory Perchick Button
H787138002015
Biosentry® Tract Sealant System
H787768022019S1
Micro ACE™ Advanced Micro Access System
ACE400SSS ACE401PTE ACE401PTS ACE421PTE
ACE500SSS ACE501PTE ACE501PTS ACE521PTE
----------END OF PRODUCT LIST----------

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Reclus 238
Tel.: 021 612 314
Asunción - Paraguay

APOSTILLA

(Convención de La Haya del 5 de octubre de 1961)

1. País: Estados Unidos de América

Este documento público

2. ha sido firmado por el Dr. Cesar A. Pérez
3. actúa como Director de la Oficina de Programas Regulatorios
4. lleva el sello/timbre del Departamento de Salud y Servicios Humanos de los EE. UU.

Certificado

5. en Washington, D.C.
6. el 20 de junio de 2025
7. por el Suboficial de Autenticación del Departamento de Estado de los Estados Unidos
8. N.° 25054406-1
9. Sello/Estampilla
10. Firma:

Ari H Chernoff

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Traductor Público
Matrícula Nº 670

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los 31 días del mes de julio del 2025

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Tel.: 021 612 314
Asunción - Paraguay

Certificado n.° 8311-5-2025-1

CERTIFICADO PARA GOBIERNO EXTRANJERO

Para permitir la importación de productos estadounidenses a países extranjeros, la Administración de Alimentos y Medicamentos de los Estados Unidos (FDA) certifica la siguiente información sobre los productos que se exportarán y que se enumeran a continuación:

Nombre del/de los producto(s)	**Nombre del fabricante/distribuidor, dirección**
Ver lista adjunta	Ver lista adjunta
(17 páginas)	(Una página)

El/los producto(s) descrito(s) anteriormente (y el/los centro(s) de fabricación/distribución que lo(s) producen/distribuyen) está(n) sujeto(s) a la jurisdicción de la FDA en virtud de la Ley Federal de Alimentos, Medicamentos y Cosméticos.

Se certifica que el/los producto(s) mencionado(s) puede(n) comercializarse y exportarse legalmente desde los Estados Unidos de América actualmente. La(s) planta(s) de fabricación donde se produce(n) el/los producto(s) está(n) sujeta(s) a inspecciones periódicas.

Atentamente

CDR Cesar A. Perez, PhD, Director
DRP2: División de Apoyo al Establecimiento,
Oficina de Programas Regulatorios
Oficina de Evaluación y Calidad de Productos,
Centro de Dispositivos y Salud Radiológica,
Administración de Alimentos y Medicamentos de EE. UU., DHHS

Este certificado es válido desde el 19 de mayo de 2025 hasta el 18 de mayo de 2027

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Certificado n.° 8311-5-2025-1
Certificado para un gobierno extranjero - Nombre del fabricante/distribuidor (anexo, página 1 de 1)

Nombre del propietario/operador

Merit Medical Systems, Inc.

1600 West Merit Parkway
South Jordan, UT
EE. UU. 84095

Nombre del fabricante

Fabricante legal
Centro de fabricación
MERIT MEDICAL SYSTEMS, INC.
1600 WEST MERIT PKWY.
South Jordan, UT
EE. UU. 84095

Centro de fabricación
MERIT MEDICAL IRELAND, LTD
Parkmore Business Park West
Galway, Galway

IRLANDA 0000

Centro de fabricación
Akita Sumitomo Bakelite Co., Ltd.
27-4, Aza Nakajimashita, Souzen-machi
Tsuchizakiminato
Akita, Akita

JAPÓN 011-8510

Centro de fabricación
PIOLAX MEDICAL DEVICES, INC.
2265-3 Kamiyabe-cho Totsuka-ku
Yokohama, Kanagawa
JAPÓN 2450053

Centro de fabricación
HEALTH LINE INTERNATIONAL CORPORATION
260 North Ace Yeager Court
Unidad D
Salt Lake City, UT
EE. UU. 84116

Centro de fabricación
BIOSPHERE MEDICAL, S.A.
Parc des Nations - Paris Nord 2, 383 rue de la Belle Etoile 95700 ROISSY-EN-FRANCE, FRANCIA
Roissy, Valle del Oise
FRANCIA 95700

Dirección también conocida como
BIOSPHERE MEDICAL, S.A. Parc des Nations, Paris Nord 2, 383 Rue de la Belle Etoile Roissy-en-France, Paris FRANCIA 95700

Planta de fabricación
Merit Maquiladora México, S. DE R.L. DE C.V. Avenida Sor Juana Inés de la Cruz 19970 Interior B, Edificio 2, Parque Industrial Frontera, Tijuana, Baja California
MÉXICO 22630

Planta de fabricación
Paragon Medical - Mansfield
111 Forbes Blvd. Suite 101, Mansfield, MA
EE. UU. 02048

Planta de fabricación
OR Medical
1265 Gray Fox Road
Suite 550
Arden Hills, MN
EE. UU. 55112

Nombre del fabricante/distribuidor
Fabricante/distribuidor legal
MERIT MEDICAL SYSTEMS, INC. 1600 WEST MERIT PKWY.
South Jordan, UT, EE. UU. 84095

--FIN DE LA LISTA DE FABRICANTES/DISTRIBUIDORES--

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Matrícula Nº 670

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Certificado n.° 8311-5-2025-1
Certificado para un gobierno extranjero - Nombre del producto (Adjunto, página 1 de 17) Nombre del fabricante
Fabricante legal
Sitio de fabricación
MERIT MEDICAL SYSTEMS, INC.
1600 WEST MERIT PKWY.
South Jordan, UT
EE. UU. 84095

Nombre del producto(s)
Jeringa de control coronario
CCS100 CCS321 CCS800 CCSB711
CCS101 CCS460 CCS801 CCSB900
CCS200 CCS461 CCSB700 CCSB901
CCS201 CCS600 CCSB701 CCSB910
CCS320 CCS601 CCSB710 CCSB911
Jeringa de control coronario Inject10™
CCX010 CCXB010 CCX011 CCXB011
Jeringa de control coronario Inject8™
CCS880 CCS881 CCSB880 CCSB881 CCSW880 CCSW881
Jeringa de control coronario Smart Tip™
ST320 ST600 ST800 STP600
ST321 ST601 ST801 STP60
Jeringa Medallion®
MSS011 MSS061-LG MSS121-Y MSSW11
MSS011-DG MSS061-PR MSS131 MSSW11-DG MSS011-LB MSS061-R MSS131-DG MSSW11-LB MSS011-LG
MSS061-Y MSS131-LB MSSW11-LG MSS011-PR MSS111 MSS131-LG MSSW11-PR MSS011-R MSS111-DG
MSS131-PR MSSW11-R MSS011-Y MSS111-LB MSS131-R MSSW11-Y MSS031 MSS111-LG MSS131-Y
MSSW21 - MSS031-DG MSS111-PR MSS160 MSSW21-DG MSS031-LB MSS111-R MSS160-R MSSW21-LB
MSS031-LG MSS111-Y MSS160T MSSW21-LG MSS031-PR MSS121 MSSF011 MSSW21-PR MSS031-R
MSS121-DG MSSF031 MSSW21-R MSS031-Y MSS121-LB MSSF061 MSSW21-Y
MSS061 MSS121-LG MSSF111 - MSS061-DG MSS121-PR MSSF121 -MSS061-LB MSS121-R MSSF160
JERINGA MEDALLION IZOFF™
MIZ10
Jeringa Medallion® COP
COP111PC-B COP121PC-B
Jeringa VacLok®
VAC110 VAC120 VAC130 VAC160
VAC111 ENDO-VAC20-SC ENDO-VAC30-SC
ENDO-VAC20 ENDO-VAC30 ENDO-VAC60
Sistema de dispensación de fluidos Squirt®
FDS100
JERINGA DE LAVADO RXP®
RXPOR
Dispositivos de inflado IntelliSystem®
IN1125 IN1225 IN1425 IN1525
Dispositivo de inflado Monarch®
IN2130 IN2230 IN2330 IN2430 IN2530
DISPOSITIVO DE INFLADO BLUE DIAMOND™
IN7112 IN7130 IN7152 IN7352

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Certificado para un gobierno extranjero - Nombre del producto (anexo) Página 2 de 17

IN7403 IN7952 IN7802 IN7852
Dispositivo de inflado BLUE FIRE™
IN10140 IN10152 IN10802 IN10852
Monitor remoto BLUE FIRE™
IN10PAD
Kit de inicio BLUE FIRE™
IN10START IN10START2
Dispositivo de inflado basixSKY™
SKY1130 SKY1152 SKY1302 SKY1802
Kit de inflado
K05-L1-L5B K05-L3-L4C
Dispositivo de compresión SAFEGUARD FOCUS™
SGF1V SGF1A
Dispositivo de compresión SAFEGUARD FOCUS COOL™
SGF1AC SGF1VC
Dispositivo de presión asistida SAFEGUARD®
82050 SG127AC SG12AC SG2440MED
82000 SG127MED SG2440AC SG24AC
Jeringa SAFEGUARD™
SG40AC SG40MD SG7AC SG7MD
Dispositivo de compresión SAFEGUARD RADIAL™
SGR26 SGR267AC SGR267MED SGR26AC
Compresión radial Air-band™ Dispositivo
0684-00-0572
Tablero de brazo reutilizable Rad Board®
RB050 RB100
Accesorio para tablero de brazo Rad Board Xtra™
RBX
Cojín de brazo RadRest®
RR811
Base de soporte para tablero de brazo RadTrac™
RT913
Sistema de etiquetado PAL™ PEN AND LABELS
PAL100 PAL300 PAL425 PAL700 PAL200 PAL325 PAL450 PAL225 PAL350 PAL500 PAL250 PAL400 PAL600
Adaptador giratorio
MMA100 MMA200 MFA100 MFA200
Adaptador de válvula
VA-40
Llave de paso Marquis®
H1FLC H4RRC M3RRC-R S3FC
H1RC H4SNC M3SLC S3FLC
H1SLC L3SNC M3SNC S3SLC
H1SNC L4SNC M4FLC S3SNC
H3FLC M1FLC M4RRC S4FLC
H3RLC M1SLC M4SNC S4SLC
H3RRC M1SNC MN4RRC S4SNC
H3SLC M3FLC S1FLC U3RRC
H3SNC M3RLC S1SLC H4FLC M3RRC S1SNC Interruptor de control de flujo
U1SHC U1SHC-W U1SHC-R U1SHC-Y U1SHC-G
Colector Merit®
201BF-R 202BF-FT 202BF-L 202BF-R
202BF-RT 202BN-F 202BN-R 202BN-RT
202HF-F 202HF-L 202HF-R 202HF-RX
202HN-R 202HN-RX 202LHWF-R 202LHWN-R 203BF-FT 203BF-L 203BF-R 203BF-RT
203BF-RX 203BF-RXT 203BN-F 203BN-L

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Certificado n.° 8311-5-2025-1
Certificado para un gobierno extranjero - Nombre del producto (anexo) Página 3 de 17

203BN-R 203BN-RT 203BN-RX 203HF-F
203HF-L 203HF-R 203HF-RX 203HN-L
203HN-R 203HN-RX 203LHF-R 203LHN-R
203LHWF-R 203LHWN-R 204BF-FT 204BF-R
204BF-RT 204BN-R 204HF-FT 204HF-L
204HF-R 204HF-RT 204HF-RX 204HN-R
204LHWF-R 204LHWN-R 204LHWF-L 205BF-F
205BF-FT 205BF-FTC 2V2HF-R 2V2HF-RT
2V3HF-R 2V3HF-RT 2V3HN-R 2V4LHWF-R
2V4LHWF-RT 2V4LHWF-RXT
501BF-R 501BN-R 502BF-L 502BF-R
502BF-RX 502BN-R 502BN-RX 502HF-L
502HF-R 502HF-RT 502HN-R 502LHWF-R
502LHWN-R 503BF-F 503BF-R 503BF-RT
503BF-RX 503BF-RXT 503BN-R 503HF-L
503HF-R 503HF-RT 503HF-RX 503HN-R
503HN-RT 503HN-RX 503LHF-R 503LHN-R
503LHWF-R 503LHWN-R 504BF-R 504BF-RT
504BN-R 504HF-R 504HF-RX 504HN-R
504HN-RT 504LHWF-R 504LHWN-R

Merit® TRAM®

201LTPHF-R 201LTPHN-R 202LTPHWF-R 202LTPHWN-R
203LTPHF-R 203LTPHN-R 203LTPHWF-R 203LTPHWN-R
204LTPHWF-R 204LTPHWN-R 2V4LTPHWF-RT 2V4LTPHWF-R
501LTPHN-R 502LTPHWN-R 503LTPHF-R 503LTPHWN-R
501LTPHF-R 502LTPHWF-R 503LTPHN-R 503LTPHWF-R
504LTPHWN-R 504LTPHWF-R

Merit® TRAM®P

201LTCHN-R 202LTCHWF-R 203LTCHN-R 204LTCHWF-R
201LTCHF-R 203LTCHWN-R 203LTCHF-R 204LTCHWN-R
202LTCHWN-R 203LTCHWF-R 2V4LTCHWF-RT 2V4LTCHWF-R
501LTCHN-R 502LTCHWF-R 503LTCHN-R 504LTCHWF-R
501LTCHF-R 503LTCHWN-R 503LTCHF-R
502LTCHWN-R 503LTCHWF-R 504LTCHWN-R

Transductor de presión Meritrans®
MER100 MER148 MER200 MER212

Catéter de infusión Fountain®

IS4-45-10 IS4-90-50 IS5-45-10 IS5-90-50
IS4-45-20 IS4-135-5 IS5-45-20 IS5-135-5
IS4-90-5 IS4-135-10 IS5-90-5 IS5-135-10
IS4-90-10 IS4-135-20 IS5-90-10 IS5-135-20
IS4-90-20 IS4-135-30 IS5-90-20 IS5-135-30
IS4-90-30 IS4-135-40 IS5-90-30 IS5-135-40
IS4-90-40 IS4-135-50 IS5-90-40 IS5-135-50
FIS4-135-10 FIS4-45-20 FIS5-45-10 FIS5-90-50
FIS4-135-20 FIS4-90-10 FIS5-90-10 FIS5-135-10
FIS4-135-30 FIS4-90-20 FIS5-90-20 FIS5-135-20
FIS4-135-40 FIS4-90-30 FIS5-90-30 FIS5-135-30
FIS4-135-5 FIS4-90-40 FIS5-90-40 FIS5-135-40
FIS4-135-50 FIS4-90-5 FIS5-45-20 FIS5-135-5
FIS4-45-10 FIS4-90-50 FIS5-90-5 FIS5-135-50

Sistema de infusión Fountain® con chorro

FIS4-135-10SQ FIS4-90-20SQ FIS5-135-20SQ FIS5-90-10SQ
FIS4-135-20SQ FIS4-90-30SQ FIS5-135-30SQ FIS5-90-20SQ
FIS4-135-30SQ FIS4-90-40SQ FIS5-135-40SQ FIS5-90-30SQ
FIS4-135-40SQ FIS4-90-50SQ FIS5-45-20SQ FIS5-90-40SQ
FIS4-45-10SQ FIS5-45-10SQ FIS5-135-50SQ FIS5-90-50SQ
FIS4-135-50SQ FIS5-135-10SQ FIS5-135-5SQ FIS5-90-5SQ

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Certificado para un gobierno extranjero - Nombre del producto (anexo) Página 4 de 17

FIS4-135-5SQ FIS4-45-20SQ FIS4-90-10SQ FIS4-90-5SQ FW4-45 FW4-90 FW4-135 FW5-45 FW5-90 FW5-135

Punta de válvula de catéter de infusión Fountain®

IS4-135-10-V IS4-135-20-V IS4-135-30-V
IS4-135-40-V IS4-135-5-V IS4-135-50-V
IS4-45-10-V IS4-45-20-V IS4-90-10-V
IS4-90-20-V IS4-90-30-V IS4-90-40-V
IS4-90-5-V IS4-90-50-V IS5-135-10-V
IS5-135-20-V IS5-135-30-V IS5-135-40-V
IS5-135-5-V IS5-135-50-V IS5-45-10-V
IS5-45-20-V IS5-90-10-V IS5-90-20-V
IS5-90-30-V IS5-90-40-V IS5-90-5-V IS5-90-50-V
FIS4-135-10-V FIS4-45-20-V FIS5-135-10-V FIS5-45-20-V
FIS4-135-20-V FIS4-90-10-V FIS5-135-20-V FIS5-90-10-V
FIS4-135-30-V FIS4-90-20-V FIS5-135-30-V FIS5-90-20-V
FIS4-135-40-V FIS4-90-30-V FIS5-135-40-V FIS5-90-30-V
FIS4-135-50-V FIS4-90-40-V FIS5-135-50-V FIS5-90-40-V
FIS4-135-5-V FIS4-90-50-V FIS5-135-5-V FIS5-90-50-V
FIS4-45-10-V FIS4-90-5-V FIS5-45-10-V FIS5-90-5-V
FIS4-135-10SQ-V FIS4-45-20SQ-V
FIS4-135-20SQ-V FIS4-90-10SQ-V
FIS4-135-30SQ-V FIS4-90-20SQ-V
FIS4-135-40SQ-V FIS4-90-30SQ-V
FIS4-135-50SQ-V FIS4-90-40SQ-V
FIS4-135-5SQ-V FIS4-90-50SQ-V
FIS4-45-10SQ-V FIS4-90-5SQ-V
FIS5-135-10SQ-V FIS5-90-10SQ-V FIS5-45-10SQ-V
FIS5-135-20SQ-V FIS5-90-20SQ-V FIS5-45-20SQ-V
FIS5-135-30SQ-V FIS5-90-30SQ-V
FIS5-135-40SQ-V FIS5-90-40SQ-V
FIS5-135-50SQ-V FIS5-90-50SQ-V
FIS5-135-5SQ-V FIS5-90-5SQ-V

Catéter de infusión Mistique®

MIC5-135-10-035 MIC5-135-5-035 MIC5-45-10-035 MIC5-45-5-035
MIC5-90-10-035 MIC5-90-5-035

AGUJAS ANGIOGRÁFICAS SERIE MAJESTIK®

AN18T52C AN18T52MC AN18T53CO AN18T53MCO
AN18T71WR-25 AN18T72MC AN18T72S-25 AN18T72SC
AN18T72SH AN18T73SHO AN18T73SO AN19U52MC
AN19U72S-25 AN19U73SO SH792066

Aguja Merit Advance®

AD18N91W AD18T51W AD18T71W AD18T71W-E
AD18T71WT AD19U41W AD19U51W AD19U71W
AD19U71W-E AD20T41W AD20T41W-E AD20T71W
AD21T21W AD21T21WT AD21T41W AD21T41W-E
AD21T41WT AD21T41WT-E AD21T71W AD21T71W-E
AD21T71WT AD21T71WT-E AD21T91W AD21T91W-E
AD21T91WT AD21T91WT-E AD22T61W AD20T71W-E
AD18T51WS AD18T71WS AD19U71WS
AD18T71WC AD19U41WC AD19U71WC AD21T41WC
AD21T91R AD21T91RE AD18N91W-E AD22T41WT

Aguja de seguridad angiográfica Merit Advance®

SL18T71W SL18T71WS SL21T71W SL21T71WS

Desagüe cubierto MiniStop®

MMS100

Desagüe cubierto MiniStop®

MMSP100

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Certificado para un gobierno extranjero - Nombre del producto (anexo) Página 5 de 17

Filtro MiniStop®
MMSF200
Introductor de vaina Prelude®

Prelude® INTRODUCTOR DE VAINA

PSI-4F-11-035 PSI-7F-11-038 PSI-4F-23-035 PSI-7F-23-038
PSI-5F-11-035 PSI-8F-11-038 PSI-5F-23-035 PSI-8F-23-038
PSI-8F-11-035 PSI-4F-11 PSI-6F-23-035 PSI-4F-23
PSI-7F-11-035 PSI-5F-11 PSI-7F-23-035 PSI-5F-23
PSI-8F-11-035 PSI-6F-11 PSI-8F-23-035 PSI-6F-23
PSI-5F-11-038 PSI-7F-11 PSI-5F-23-038 PSI-7F-23
PSI-6F-11-038 PSI-8F-11 PSI-6F-23-038 PSI-8F-23

Prelude® PRO INTRODUCTOR DE VAINA

PRO-4F-11-035 PRO-8F-11-035 PRO-8F-11-038 PRO-7F-11
PRO-5F-11-035 PRO-5F-11-038 PRO-4F-11 PRO-8F-11
PRO-6F-11-035 PRO-6F-11-038 PRO-5F-11
PRO-7F-11-035 PRO-7F-11-038 PRO-6F-11

Prelude® INTRODUCTOR DE VAINA

PSI-4F-11-035ACT PSI-7F-11-038ACT PSI-5F-11ACT PSI-8F-11ACT
PSI-5F-11-038ACT PSI-8F-11-038ACT PSI-6F-11ACT
PSI-6F-11-038ACT PSI-4F-11ACT PSI-7F-11ACT

Prelude® INTRODUCTOR DE VAINA CORTA

PSS-5F-4-018MT PSS-5F-4-035MT PSS-5F-4-038MT PSS-5F-4MT
PSS-6F-4-018MT PSS-6F-4-035MT PSS-6F-4-038MT PSS-6F-4MT
PSS-7F-4-018MT PSS-7F-4-035MT PSS-7F-I-038MT PSS-7F-4MT
PSS-8F-4-018MT PSS-8F-4-035MT PSS-8F-4-038MT PSS-8F-4MT

Prelude®+INTRODUCTOR DE VAINA DE AGUJA

PSI-4F-11-018 PSI-4F-11-018NT4 PSI-4F-11-025 PSI-4F-23-018NT4
PSI-4F-23-018NT7 PSI-4F-7-018 PSI-4F-7-018NT4 PSI-4F-7-025
PSI-5F-11-018 PSI-5F-11-018NT4 PSI-5F-11-025 PSI-5F-23-018NT4
PSI-5F-23-018NT7 PSI-5F-7-018 PSI-5F-7-018NT4 PSI-5F-7-025
PSI-6F-11-018 PSI-6F-11-018NT4 PSI-6F-11-025 PSI-6F-23-018NT4
PSI-6F-23-018NT7 PSI-6F-7-018 PSI-6F-7-018NT4 PSI-6F-7-025
PSI-7F-11-018 PSI-7F-23-018NT4 PSI-7F-7-018
PSI-5F-11-035-18G PSI-6F-11-035-18G PSI-7F-11-035-18G PSI-8F-11-035-18G
PSI-5F-11-038-18G PSI-6F-11-038-18G PSI-7F-11-038-18G PSI-8F-11-038-18G

Prelude® PRO + INTRODUCTOR DE VAINA DE AGUJA

PRO-4F-11-018NT7 PRO-5F-11-018NT7 PRO-6F-11-018NT7 PRO-7F-11-018NT7
PRO-5F-11-038-18G PRO-6F-11-038-18G

Dispositivo de compresión radial PreludeSYNC™
SRB24AC SRB24MED SRB29AC SRB29MED

Jeringa PreludeSYNC™
SRB20AC

Dispositivo de compresión radial PreludeSYNC DISTAL™
SDRB-REG-RT SDRB-REG-LT

Jeringa para dispositivo de compresión radial PreludeSYNC DISTAL™
SDRB10AC

Dispositivo de compresión radial PreludeSYNC EZ™
EZ-SML EZ-REG

Jeringa para dispositivo de compresión radial PreludeSYNC EVO™
SRB20EVOAC

Introductor de vaina hidrofílico Prelude IDEAL™

PID4F7018NTPD PID7F11018SS PID5F23021SC PID5F23021PW
PID5F7018NTPD PID4F11021SC PID6F23021SC PID6F23021PW
PID6F7018NTPD PID5F11021SC PID7F23021SC PID7F23021PW
PID4F11018SC PID6F11021SC PID5F23021SSC PID4F11025PW
PID5F11018SC PID7F11021SC PID6F23021SSC PID5F11025PW
PID6F11018SC PID5F11021SSC PID4F11021PW PID6F11025PW
PID7F11018SC PID6F11021SSC PID5F11021PW PID7F11025PW
PID4F11018NTPD PID4F16021SC PID6F11021PW PID4F16025PW

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Traductor Público
Matrícula Nº 670

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Traductor Público Matriculado
Reclus 238
Tel.: 021 612 314
Asunción - Paraguay

Certificado n.° 8311-5-2025-1

Certificado para un gobierno extranjero - Nombre del producto (anexo) Página 6 de 17

PID5F11018NTPD PID5F16021SC PID7F11021PW PID5F16025PW
PID6F11018NTPD PID6F16021SC PID4F16021PW PID6F16025PW
PID7F11018NTPD PID7F16021SC PID5F16021PW PID7F16025PW
PID4F11018SS PID5F16021SSC PID6F16021PW PID4F11021SSC
PID5F11018SS PID6F16021SSC PID7F16021PW PID4F16021SSC
PID6F11018SS PID4F23021SC PID4F23021PW PID4F23021SSC
PID5F11021SSC20G PID7F11021SSC PID7F16021SSC PID7F23021SSC
PID6F11021SSC20G

Introductor de vaina PreludeEASE ™ HIDROFILICA

PHR4F11018NTPD PHR4F7018SC PHR5F7018SC PHR6F11025PW
PHR4F11018SC PHR5F11018NTPD PHR6F11018NTPD PHR6F11035SC
PHR4F11021PW PHR5F11018SC PHR6F11018SC PHR6F23021SC
PHR4F11021SC PHR5F11021PW PHR6F11021PW PHR6F7018SC
PHR4F11025PW PHR5F11021SC PHR6F23018NT PHR7F11018SC
PHR4F16018NT PHR5F11018SS PHR6F23021PW PHR7F11021SC
PHR4F16021SC PHR5F7018NTPD PHR6F16018NT PHR7F11035SC
PHR4F16025PW PHR5F11025PW PHR6F16021SC PHR7F16018NT
PHR4F11018SS PHR5F16018NT PHR6F16025PW PHR7F16021SC
PHR4F11021SCSN PHR5F16021SC PHR5F11021SCSN PHR7F23018NT
PHR4F7018NTPD PHR5F16025PW PHR6F11021SCSN PHR7F23021SC
PHR4F23018NT PHR5F23018NT PHR6F7018NTPD PHR4F11018SSSN
PHR4F23021PW PHR5F23021PW PHR6F11018SS PHR5F11018SSSN
PHR4F23021SC PHR5F23021SC PHR6F11021SC PHR6F11018SSSN
PHR5F11021SSC PHR6F11021SSC PHR5F23021SSC PHR6F23021SSC

Punta marcadora del introductor de funda Prelude® PRO

PRO-4F-11-035MT PRO-5F-11-035MT PRO-6F-11-035MT PRO-7F-11-035MT
PRO-8F-11-035MT PRO-5F-11-038MT PRO-6F-11-038MT PRO-7F-11-038MT
PRO-8F-11-038MT PRO-4F-11MT PRO-5F-11MT PRO-6F-11MT
PRO-7F-11MT PRO-8F-11MT

Prelude® INTRODUCTOR DE FUNDA Punta marcadora

PSI-4F-23-035MT PSI-4F-23MT PSI-5F-23-035MT PSI-5F-23-038MT
PSI-5F-23MT PSI-6F-23-035MT PSI-6F-23-038MT PSI-6F-23MT
PSI-7F-23-035MT PSI-7F-23-038MT PSI-7F-23MT PSI-8F-23-035MT
PSI-8F-23-038MT PSI-8F-23MT

Introductor de vaina hidrofílica Prelude Wave™

WAV4F11018NTPD WAV4F11018NTPD-F WAV4F11018SC-F WAV4F11018SSC-F WAV4F11021PW
WAV4F11021PW-F WAV4F11021SSC WAV4F11021SSC-F WAV4F23021PW-F WAV4F23021SC-F
WAV5F11018NTPD WAV5F11018NTPD-F WAV5F11018SC-F WAV5F11018SS-F WAV5F11021PW
WAV5F11021PW-F WAV5F11021SC-F WAV5F11021SSC WAV5F11021SSC-F WAV5F11025PW
WAV5F11025PW-F WAV5F23021PW WAV5F23021PW-F WAV5F23021SC-F WAV5F23021SSC
WAV5F23021SSC-F WAV6F11018NTPD WAV6F11018NTPD-F WAV6F11018SC-F WAV6F11018SS-F
WAV6F11021PW WAV6F11021PW-F WAV6F11021SC-F WAV6F11021SSC WAV6F11021SSC-F
WAV6F11025PW WAV6F11025PW-F WAV6F23018PW-F WAV6F23021PW WAV6F23021PW-F
WAV6F23021SC-F WAV6F23021SSC WAV6F23021SSC-F WAV7F11018NTPD WAV7F11018NTPD-F
WAV7F11018SC-F WAV7F11018SSC-F WAV7F11021PW WAV7F11021PW-F WAV7F11021SC-F
WAV7F11021SSC WAV7F11021SSC-F WAV7F23021PW WAV7F23021PW-F WAV7F23021SC-F
WAV7F23021SSC WAV7F23021SSC-F WAV5F11021NTPD WAV5F11021NTPD-F WAV5F11025SSC-F
WAV6F11021NTPD WAV6F11021NTPD-F WAV6F11025SSC WAV6F11025SSC-F WAV7F11025SSC-F
WAV6F11025SS-F

Prelude® INTRODUCTOR DE VAINA Dilatador

PD4F035 PD7F038 PSD6F035-8cm
PD5F038 PD8F038 PSD7F035-8cm
PD6F038 PSD5F035-8cm PSD8F035-9cm

Prelude® INTRODUCTOR DE VAINA Obturador

OBT-4F-11 OBT-6F-11 OBT-4F-23 OBT-6F-23 OBT-5F-11 OBT-7F-11 OBT-5F-23 OBT-7F-23

Adaptador de válvula hemostática Prelude Choice™

PCHVA08

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N. 870

2026-07-22 10:05:56.224342-03

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QUIRNO CODAS THOMPSON LLANO
Traductor Público Matriculado
Reclus 238
Tel.: 021 612 314
Asunción - Paraguay

Certificado n.° 8311-5-2025-1
Certificado para un gobierno extranjero - Nombre del producto (anexo) Página 7 de 17

Adaptador universal para válvula de hemostasia Prelude Choice™
UHVA08
Catéter para diálisis crónica ProGuide™
61124 61128 61132 61136
61140 62124 62128 62132
62136 62140 63124 63128
63132 63136 63140 64124
64128 64132 64136 64140
DC01452419 DC01452419-NE5 DC01452823 DC01452823-NE5
DC01453227 DC01453227-NE5 DC01453631 DC01454035
DC01455550 DC21452419 DC21452419-NE5 DC21452823
DC21452823-NE5 DC21453227 DC21453227-NE5 DC21453631
DC21454035 DC21455550
Funda de guía Prelude® Roadster
PG4F45S PG4F90S PG5F45MP PG5F45R
PG5F45S PG5F90MP PG5F90S PG6F45C
PG6F45HS PG6F45MP PG6F45R PG6F45S
PG6F65MP PG6F65S PG6F65SX PG6F90MP
PG6F90MPX PG6F90SX PG7F45MP PG7F45MPX
PG7F45RX PG7F45S PG7F45SX PG7F65SX
PG7F90SX PG8F45MPX PG8F45S PG8F45SX
PG8F65SX PG8F90SX PG5F45S018 PG7F30S
PG5F90S018 PG6F45S018 PG6F90SX018
Vaina acompañante de perfil bajo Impella
X9PG700001
Adaptador de válvula hemostática
HVA-100 HVA-60
Válvula hemostática 10 Fore™
MAPTEN4 MAPTEN42 MAPTEN452
Kit de catéter para hemodiálisis de larga duración CentrosFLO®
CENFP15K CENFP17K CENFP19K CENFP23K CENFP27K CENFP31K
CENFT15K CENFT17K CENFT19K CENFT23K CENFT27K CENFT31K
CentrosFLO® Catéter de hemodiálisis de larga duración
CENFT15C CENFT17C CENFT19C CENFT23C CENFT27C CENFT31C
Centros® Kit de catéter de hemodiálisis de larga duración
CENP15K CENP17K CENP19K CENP23K CENP27K CENP31K
CENT15K CENT17K CENT19K CENT23K CENT27K CENT31K
Centros® Kit de catéter de hemodiálisis de larga duración
CENT15C CENT17C CENT19C CENT23C CENT27C CENT31C
Vaina pelable con válvula introductor
DCVP1600 DCVP1500
Kit de seguridad A-S-K MERIT Access®
ASK200
Dispositivo de retención de sutura SLIP-NOT®
SRD100SRD200
Dispositivo de inserción de guía BOWTIE™
BT01
Dispositivo de torsión SeaDragon™
TD500
Dispositivo de torsión SeaDragon 2™
TD500/A
Paquete de angioplastia Merit™
MAP952 MAP900 MAP600 MAP550
MAP500 MAP501 MAP600B
KIT DE CATÉTER DE ASPIRACIÓN ASAP®
ASAP 100
KIT DE CATÉTER DE ASPIRACIÓN DE PERFIL BAJO ASAPLP™ ASAPLP

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Certificado n.° 8311-5-2025-1
Certificado para un gobierno extranjero - Nombre del producto (anexo) Página 8 de 17

Sistema de posicionamiento de stents OstialPRO®
3011
Guías InQwire® recubiertas de PTFE con Ringmaster™
IQR35F150B IQR35F150J3 IQR35F150J3F
IQR35F150BST IQR35F260J3 IQR35F150J3S
Recipiente para guía RingMASTER™
RM01
Dispositivo de inflado DIAMOND TOUCH™
IN9135 IN9152 IN9302 IN9352
IN9403 IN9802 IN9852
Jeringa DiamondTouch™
IN9KVCF IN9VCF
Dispositivo de inflado basixTau™
IN4T130 IN4T530 IN4T952 IN4TXR52
IN4T802 IN4T852
Sonda de coagulación bipolar Brighton®
BP-7F-SP-350 BP-10F-SP-350 BP-7F-DP-350 BP-10F-DP-350
DISPOSITIVO DE INFLADO ENDOTEK BIG 60®
ENDO-AN6012
Dispositivo de inflado digital Endotek
ENDO-DI2030
TIO™ VÍA AÉREA ORAL TRES EN UNO - BLOQUE DE MORDIDA - PUERTO DE 02 PUERTOS
TI060-90 TI060-100 TIO60-110
Catéter de diálisis peritoneal Flex-Neck® Classic
CF-5250 CF-5260 CF-5270 CF-5243
CF-5161 CF-5244 CF-5249 CF-5242
CF-5247 CF-4230 CF-4235
Catéter de diálisis peritoneal Flex-Neck® ARC™
CF-5450 CF-5460 CF-5470 CF-5443
CF-5442 CF-4430
Catéter de diálisis peritoneal para adultos Flex-Neck® ExxTended™
CF-5560 CF-5570
Accesorios para catéter de diálisis peritoneal
CC-1301 CC-1360 CC-2300 CE-1400
CS-242 CS-352 CS-362 FT-1100
IA-102 TE-1000 VP-210 VP-211
VP-411 VP-511 VP-511M ST-700MG
ST-700 ST-700EU FS-300 VS-1800
VS-1810 SS-100 SS-200 SS-300
CSS-242 CSS-352 CSS-362 FR-300
MICROCATETER Merit Maestro®
28MC2111045 28MC21110SN 28MC21110ST 28MC2113045
28MC21130SN 28MC21130ST 28MC2115045 28MC21150SN
28MC21150ST 28MC2411045 28MC24110SN 28MC24110ST
28MC2413045 28MC24130SN 28MC24130ST 28MC2415045
28MC24150SN 28MC24150ST 28MC2811045 28MC28110SN
28MC28110ST 28MC2813045 28MC28130SN 28MC28130ST
28MC2815045 28MC28150SN 28MC28150ST 29MC2911045
29MC29110SN 29MC29110ST 29MC2913045 29MC29130SN
29MC29130ST 29MC2915045 29MC29150SN 29MC29150ST
28MC2116545 28MC2816545 28MC2117545 28MC2817545
28MC21165SN 28MC28165SN 28MC21175SN 28MC28175SN
28MC21165ST 28MC28165ST 28MC21175ST 28MC28175ST
28MC2416545 29MC2916545 28MC2417545 29MC2917545
28MC24165SN 29MC29165SN 28MC24175SN 29MC29175SN
28MC24165ST 29MC29165ST 28MC24175ST 29MC29175ST
Microcatéter Merit Maestro® + Alambre guía reconfigurable TrueForm™
28MC24110ST-I 28MC24130SN-I 28MC21110ST-I 28MC2113045-1

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28MC2411045-1 28MC24150ST-I 28MC2111045-1 28MC21150SN-I
28MC24110SN-I 28MC2415045-I 28MC21110SN-I 28MC21150ST-I
28MC24130ST-I 28MC24150SN-I 28MC21130ST-I 28MC2115045-1
28MC2413045-1 28MC21130SN-I
28MC2411045-W 28MC24130SN-W 28MC24110ST-W 28MC2415045-W
28MC24110SN-W 28MC24130ST-W 28MC2413045-W 28MC24150SN-W
28MC24150ST-W
ELATION® BALLOON DILATADOR Catéter de dilatación esofágica con balón de alambre fijo
E6 E10 E15 E8 E12 E18
ELATION® BALLOON DILATADOR Catéter de dilatación esofágica/biliar con balón guiado por alambre
EB18
ELATION® BALLOON DILATADOR Catéter de dilatación esofágica/colónica/biliar con balón guiado por alambre
ECB18
ELATION® BALLOON DILATADOR Catéter de dilatación esofágica/pilórica/biliar con balón guiado por alambre
EPB10 EPB12 EPB15 EPB6 EPB8
ELATION® BALLOON DILATADOR Catéter de dilatación esofágica/pilórica/colónica/biliar con balón guiado por alambre EPCB6 EPCB8 EPCB10 EPCB12 EPCB15
ELATION® BALLOON DILATADOR Catéter de dilatación pulmonar con balón
P10L20 P12L30 P18L55 P8L20
P10L30 P12L55 P6L20 P8L30
P12L20 P15L55 P6L30 P4L15
ELATION 5™ DILATADOR DE BALÓN DE CINCO ETAPAS Catéter de dilatación esofágica con balón de alambre fijo
EX6 EX8 EX10 EX12 EX15 EX18
ELATION 5™ DILATADOR DE BALÓN DE CINCO ETAPAS Catéter de dilatación esofágica/pilórica con balón guiado por alambre EPX10 EPX12 EPX15 EPX18 EPX6 EPX8
ELATION 5™ DILATADOR DE BALÓN DE CINCO ETAPAS Catéter de dilatación esofágica/pilórica/colónica con balón guiado por alambre
EPCX10 EPCX12 EPCX15 EPCX18 EPCX6 EPCX8
SPINR™ Guía de alto rendimiento Controlador
5X-GW 3X-GW
Merit Drainage Depot™
FZ624
Sistema de gestión de contraste
CAS 100 CAS200
Componente de salida venosa HeRO® GRAFT
HEROVOC HERO1001 HERO1001VOC
Componente de injerto arterial HeRO® GRAFT
HEROGRAFT HERO1002
Kit de accesorios HeRO® GRAFT
HEROACK HERO1003
Kit de salida venosa y adaptador Super HeRO® SUPERHERO
HERO1000
Kit de revisión HeRO® ALLY
HEROALLY HERO1006
Sistema de reflector y administración SCOUT Bx™
SSR13B-01
EsophyX®Z+
R2007
Sujetadores implantables SerosaFuse®
R2175 R2375
EsophyX®Z+ con implante SerosaFuse® sujetadores
R2275
BANDEJA PARA PROCEDIMIENTOS DE PARACENTESIS DE SEGURIDAD
SPPT-100 SPPT-5F-10L SPPT-5F-10S SPPT-5F-12PL SPPT-5F-12PS SPPT-5F-17PL SPPT-5F-17PS SPPT-5F-7L
SPPT-5F-7S SPPT-6F-10L SPPT-6F-10S SPPT-6F-12PL

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SPPT-6F-12PS SPPT-6F-17PL SPPT-6F-17PS SPPT-6F-7L SPPT-6F-7S SPPT-8F-10L SPPT-8F-10S SPPT-8F-12PL SPPT-8F-12PS SPPT-8F-17PL SPPT-8F-17PS SPPT-8F-7L SPPT-8F-7S

SET DE TORACENTESIS Y PARACENTESIS

TAPS-100 TAPS-5F-10LT TAPS-5F-10T TAPS-5F-12PLT TAPS-5F-12PT TAPS-5F-17PLT TAPS-5F-17PT TAPS-5F-7LT TAPS-5F-7T TAPS-6F-10LT TAPS-6F-10T TAPS-6F-12PLT TAPS-6F-12PT Grifos-6F-17PLT Grifos-6F-17PT Grifos-6F-7LT Grifos-6F-7T Grifos-8F-10LT Grifos-8F-10T Grifos-8F-12PLT Grifos-8F-12PT Grifos-8F-17PLT Grifos-8F-17PT Grifos-8F-7LT Grifos-8F-7T

Kit de acceso a pedal Merit PAK™ hidrofílico

PAKPHR47NPD4 PAKPHR47NPD7

Microcatéter Merit Pursue™

28HC1711045 28HC17130SN 28HC17150ST 29HC2013045
28HC17110SN 28HC17130ST 29HC2011045 29HC20130SN
28HC17110ST 28HC1715045 29HC20110SN 29HC20130ST
28HC1713045 28HC17150SN 29HC20110ST 29HC2015045
29HC20150SN 29HC20150ST

Microcatéter Merit Pursue™ precargado con: Alambre guía remodelable TrueForm™

28HC1711045-I 28HC17130ST-I 29HC20110SN-I 29HC2015045-I
28HC17110SN-I 28HC1715045-I 29HC20110ST-I 29HC20150SN-I
28HC17110ST-I 28HC17150SN-I 29HC2013045-I 29HC20150ST-I
28HC1713045-I 28HC17150ST-I 29HC20130SN-I
28HC17130SN-I 29HC2011045-I 29HC20130ST-I

Sistema de administración Ventrax™

VTR851 VTR852 VTR853

Set de transferencia CT

TS520L

Set de transferencia CT con tapones desinfectantes

TS120DC

Conector desprendible FastBreak™

FB3U5 FBG10

Catéter de infusión ClariVein

45-018-E2S 65-018-E4S 85-018-E140S

ClariPak™ Paquete de procedimiento ClariVein®

K22C-00001

Catéter de balón dirigible Arcadia™

ARC10SB ARC15SB ARC20SB ARC25SB ARC30SB

Catéter de balón recto Arcadia™

ARC1 OST ARC15ST ARC20ST ARC25ST ARC30ST

Catéter de balón dirigible Arcadia™ Kit

ARC10SB-LK ARC15SB-LK ARC20SB-LK ARC25SB-LK ARC30SB-LK
ARC10SB-LK-2 ARC15SB-LK-2 ARC20SB-LK-2 ARC25SB-LK-2 ARC30SB-LK-2

Kit de catéter con balón recto Arcadia™

ARC10ST-LK ARC15ST-LK ARC20ST-LK ARC25ST-LK ARC30ST-LK ARC10ST-LK-2 ARC15ST-LK-2 ARC20ST-LK-2

Dispositivo de inflado basixALPHA™

IN3130 IN3152 IN3302 IN3802

Soporte para objetos punzantes GRANDSTAND® Shortstop®

SS30

Selector de venas Worley™

57538CS-WOR 57538CSV-WOR 57538CSHK-WOR Kit de administración de contraste avanzado Worley™
K12-WORLEY1 K12-WORLEY2

Guía hidrofílica Merit H20™

H2OSTDA18150 H2OSTDA18180 H2OSTDA18260EX

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los 31 días del mes de julio del 2025

QUIRNO CODAS THOMPSON LL
Traductor Público
Matrícula N° 670

2026-07-22 10:05:56.224342-03

QUIRNO CODAS THOMPSON LLANO
Traductor Público Matriculado
Reclus 238
Tel.: 021 612 314
Asunción - Paraguay

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Certificado para un gobierno extranjero - Nombre del producto (anexo) Página 11 de 17

H2OSTDA1880 H2OSTDA25150 H2OSTDA25180
H2OSTDA25260EX H2OSTDA35150 H2OSTDA35150LT
H2OSTDA35180 H2OSTDA35180P H2OSTDA35260EX
H2OSTDA3580 H2OSTDA38150 H2OSTDS25180
H2OSTDS35150 H2OSTFA35150 H2OSTFA35180
H2OSTFA35260EX H2OSTFA3580 H2OSTFS35180
H2OSTFS35260EX H2OSTFS38180
Botella de drenaje al vacío
EVAC1000
Introductor coaxial TEMNO Elite™
CX1410 CX1415 CX1610 CX1615
CX1810 CX1815 CX1820 CX2010
CX2015 CX2020
Aguja de biopsia independiente TEMNO Elite™
TE1406 TE1410 TE1415 TE1606
TE1610 TE1615 TE1806 TE1810
TE1815 TE1820 TE2006 TE2010
TE2015 TE2020
Haz coaxial valvulado TEMNO Elite™
TEVC1410 TEVC1415 TEVC1610 TEVC1615
TEVC1810 TEVC1815 TEVC1820 TEVC2010
TEVC2015 TEVC2020
Introductor coaxial valvulado TEMNO Elite™
VC1410 VC1415 VC1610 VC1615
VC1810 VC1815 VC1820 VC2010
VC2015 VC2020
Kit de colector personalizado
K09T-10440D
Jeringa Medallion® COP y kits
K01-07826 K01-07944 K01-08064P K02-01587 K06-00316
Kit de procedimiento - Dilatador - Sin Vascular
K12-08322 K12-08323 K12-08324 K12-08325
Kit de gestión de residuos
K10-04750 K10-00230B K10-04843 K10-05180 K10-04750
Tubo de conexión de drenaje
K10-04129 K10-04130 K10-04131 K10-04132 K08-02027 K10-03450
Bandeja angiográfica para kit de colector
K09T-08952
Dispositivo de inflado digital
K05-03069 K05-03069A
Kits de conveniencia
KXX-YYYYA
'K' - indica que es un kit
'XX1' - designa el tipo de kit
'YYYYA' - es un número secuencial que lo identifica de forma única El kit "KXXT" indica que se trata de un paquete de procedimiento.
Es el carácter - (guión).
K01 = Medallón simple (jeringa).
K02 = Medallones múltiples (jeringa).
K04 = Tubo.
K05 = Dispositivo de inflado.
K06 = Jeringa de control simple.
K07 = Jeringa de control combinada con otras jeringas. K08 = Gestión de fluidos.

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Certificado para un gobierno extranjero - Nombre del producto (anexo) Página 12 de 17

K09 = Colectores
K10 = Gestión de residuos
K11 = Monitorización de presión
K12 = Kit de procedimientos
K13 = Bolígrafos y etiquetas
K14 = Kit de diálisis
K15 = Kit de introductor de vaina
K16 = Kit de microcatéter
K17 = Kit intervencionista
K18 = Kit de introductor de vaina
K19 = Ver paquetes combinados
K20 = Kit endoscópico personalizado es el carácter - (guión)

Nombre del fabricante
Centro de fabricación
Akita Sumitomo Bakelite Co., Ltd.
27-4, Aza Nakajimashita, Souzen-machi Tsuchizakiminato
Akita, Akita
JAPÓN 011-8510

Nombre del/de los producto(s)

Microcatéter dirigible SwiftNINJA®
MIV-20500 26SN24150ST 26SN24125ST
SwiftNINJA® dirigible Microcatéter coronario
SNCM125 26SNCM24125ST 26SNCM24150ST

Nombre del fabricante
Lugar de fabricación
PIOLAX MEDICAL DEVICES, INC.
2265-3 Kamiyabe-cho Totsuka-ku
Yokohama, Kanagawa
JAPÓN 2450053

Nombre del producto(s)
Alambre guía reconfigurable TrueForm™
TF14145S TF14165S TF14180S TF14180A

Nombre del fabricante
Lugar de fabricación
Paragon Medical - Mansfield
111 Forbes Blvd Suite 101
Mansfield, MA
EE. UU. 02048

Nombre del producto(s)
Sistema de catéter de acceso Surfer® inside-Out®
600200
Nombre del fabricante
Lugar de fabricación
HEALTH LINE INTERNATIONAL CORPORATION
260 North Ace Yeager Court
Unidad D
Salt Lake City, UT, EE. UU. 84116

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Certificado para un gobierno extranjero - Nombre del producto (anexo) Página 13 de 17

Nombre del producto(s)
Tapones desinfectantes DualCap® Solo™ con válvulas sin aguja
001-300 001-400 450-LB 460-DB
Tapones desinfectantes DualCap® con tiras para portasueros® con válvulas sin aguja
500-LB 550-LB 600-DB 660-DB

Nombre del fabricante
Centro de fabricación

BIOSPHERE MEDICAL, S.A.
Parc des Nations - París Norte 2, 383 rue de la Belle Etoile
95700 ROISSY-EN-FRANCE, FRANCIA
Roissy, Val-d'Oise
FRANCIA 95700

Dirección también conocida como
BIOSPHERE MEDICAL, S.A.
Parc des Nations, París Norte 2,
383 Rue de la Belle Etoile
Roissy-en-France, París
FRANCIA 95700

Nombre del producto(s)
Partículas de embolización Bearing™ nsPVA
V100EP V200EP V300EP V400EP V600EP V800EP V1100EP
Partículas de embolización Bearing nsPVA Express™
S100EP S200EP S300EP S400EP S600EP S800EP S1100EP

Nombre del fabricante
Centro de fabricación
KA Medical
1265 Grey Fox Road
Suite 550
Arden Hills, MN
EE. UU. 55112

Nombre del producto(s)
Tapón vascular SIEGE™
SVP2.5-0.021 SVP4-0.021 SVP6-0.027

Nombre del fabricante
Centro de fabricación
MERIT MEDICAL IRELAND, LTD
Parkmore Business Park West
Galway, Galway
IRLANDA 0000

Nombre del producto(s)
Dispositivo de inflado basixCOMPAK™
IN4130 IN4330 IN4352 IN4530
Dispositivo de inflado analógico Endotek
ENDO-AN2030
Paquete de angioplastia Merit™
MAPI01 MAPI02 MAPI04 MAP111
MAP112 MAP113 MAP150 MAP151
MAPI52 MAP152SD MAPI53 MAPI54
MAP220 MAP221 MAP222 MAP300
MAP301 MAP302 MAP350 MAP351

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Certificado para un gobierno extranjero - Nombre del producto (anexo) Página 14 de 17

MAP352 MAP353 MAP354 MAP400
MAP403 MAP450 MAP453
Válvula de hemostasia FLO40XR™
FLO40XR
FLO30™
FLO30
Guía Prelude®
SW35DE50SST SW35DE80SST SW38DE50SST SW38DE80SST
Sistema de lazo endovascular EN Snare®
EN1003004 EN2007030 EN2006015 EN2007045 EN1003008 EN2006010 EN2006020
Sistema de lazo endovascular ONE Snare®
ONE500 ONE2000 ONE3500 ONE1500 ONE1000 ONE2500 ONE4000 ONE3000
ONE1001 ONE2501 ONE6000 ONE1501
Sistema de microlazo ONE Snare®
ONE200 ONE400 ONE700
ONE201 ONE401 ONE701
Alambres guía InQwire® recubiertos de PTFE
6500-11 6682-L3 IQ35F150J1O5S IQ35F260J1O5
6500-31 6682-M1 IQ35F150J3 IQ35F260J1O5F
6609-13 6682-N3 IQ35F150J3F IQ35F260J1O5RS
6609-31 6682-R1 IQ35F150J3K IQ35F260J3
6609-33 6684-41 IQ35F150J3S IQ35F260J3S
6676-A1 6689-11 IQ35F150J3SHD IQ35F260S
6676-B3 6689-A1 IQ35F150J3SK IQ35F80B
6676-C1 6690-41 IQ35F150J6 IQ35F80J1O5RS
6676-D3 6690-61 IQ35F150NLLLT IQ35F80J3
6676-G1 6693-41 IQ35F150NLLT IQ38F150B
6676-H1 6693-61 IQ35F150NLT IQ38F150BC
6677-B1 6693-71 IQ35F150S IQ38F150J15
6678-71 6693-A1 IQ35F180B IQ38F150J1O5RS
6678-81 6694-21 IQ35F180BC IQ38F150J3
6678-B3 6695-31 IQ35F180BK IQ38F150J3F
6680-11 6697-11 IQ35F180BST IQ38F150J3S
6680-23 6697-21 IQ35F180J15 IQ38F150J6
6680-23J3 8818-73 IQ35F180J1O5 IQ38F150J6K
6680-31 8818-B1 IQ35F180J1O5RS IQ38F150S
6680-43 8818-G1 IQ35F180J3 IQ38F180J3F
6680-51 8818-F1 IQ35F180J3F IQ38F180J6F
6680-61 8819-K1 IQ35F180J3K IQ38F260J3
6680-71 8819-L1 IQ35F180J3S IQ38F260J3F
6682-21 IQ35F100J15 IQ35F180J6F IQ38F260S
6682-41 IQ35F150B IQ35F210J1O5 IQ38F50J3
6682-61 IQ35F150BC IQ35F210J1O5F IQ38F80J3
6682-81 IQ35F150BST IQ35F210J3 IQ35F100J3SHD
6682-B3 IQ35F150J15 IQ35F220J3 IQ35F260J3K
6682-E1 IQ35F150J1O5 IQ35F260B IQ35F210J3K
6682-K1 IQ35F150J1O5RS IQ35F260BST IQ35F80J3SHD 6680-93
Alambre guía con revestimiento de plástico Prelude®
SW21A45PW SW21A80PW SW25A45PW SW25A80PW
ALAMBRE GUÍA HIDRÓFILO MERIT LAUREATE™
LWSTDA3580 LWSTDS35150 LWSTFA3580 LWSTDA35260EX
LWSTDA35150 LWSTDS35180 LWSTFA35150 LWSTDS35260EX

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Asunción - Paraguay

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Certificado n.° 8311-5-2025-1
Certificado para un gobierno extranjero - Nombre del producto (anexo) Página 15 de 17

LWSTDA35180 LWSTDS35220 LWSTFA35180 LWSTFA35260EX
LWSTDA35220 LWSTDA38180 LWSTFA35220 LWSTFS35260EX
LWSTFS35180 LWSTDS38150 LWSTFA3880 LWSTFS35150
LWSTFS35220 LWSTDS38180 LWSTFA38150 LWSTFS38150
LWSTDA3880 LWSTDS25150 LWSTFA38180 LWSTFS38180
LWSTDA38120 LWSTDS25180 LWSTDA25260EX LWSTDA38260EX
LWSTDA38150 LWSTDA18180 LWSTDS25260EX LWSTDS38260EX
LWSTDA25150 LWSTFS3580 LWSTDS18150 LWSTDS18260EX
LWSTDA25180 LWSTDS3580 LWSTDS18180 LWSTDA18260EX
LWSTDA1880 LWSTDA18150 LWSTDS35110
InQwire® AMPLATZ
IQA500 IQA510 IQA519 IQA525
IQA501 IQA511 IQA520 IQA526
IQA502 IQA512 IQA521 IQA527
IQA503 IQA513 IQA522 IQA528
IQA504 IQA517 IQA523 IQA563
IQA509 IQA518 IQA524 IQA564
IQA505 IQA506 IQA507
Paquete de Angioplastia Merit™ PhD™ Válvula de Hemostasia
MAP800 MAP801 MAP802 MAP803
MAP804 MAP850 MAP851 MAP852
MAP853 MAP854
Guía dirigible recta flexible GO2WIRE™
G2WFS35145 G2WFS35145NE G2WFS35175 G2WFS35175NE
G2WFS35210 G2WFS35260 G2WFS35300
Guía dirigible intermedia GO2WIRE™ Mod J
G2WIJ35145 G2WIJ35145NE G2WIJ35175 G2WIJ35175NE
G2WIJ35210 G2WIJ35260 G2WIJ35300
Guía dirigible recta estándar GO2WIRE™
G2WSS35145 G2WSS35145NE G2WSS35175 G2WSS35175NE
G2WSS35210 G2WSS35260 G2WSS35300
Sistema de extensión GO2WIRE™ - Guía dirigible
G2WES35001
Guía hidrofílica SPLASHWire™
MSWSTDA1880 MSWSTDA18150 MSWSTDA18180 MSWSTDA18260EX
MSWSTDS18150 MSWSTDS18180 MSWSTDS18260EX MSWSTDA25150
MSWSTDA25180 MSWSTDA25260EX MSWSTDS25150 MSWSTDS25180
MSWSTDS25260EX MSWSTDA3580 MSWSTDA35150 MSWSTDA35180
MSWSTDA35220 MSWSTDA35260EX MSWSTDS3580 MSWSTDS35150
MSWSTDS35180 MSWSTDS35220 MSWSTDS35260EX MSWSTDA3880
MSWSTDA38120 MSWSTDA38150 MSWSTDA38180 MSWSTDA38260EX
MSWSTDS38150 MSWSTDS38180 MSWSTDS38260EX
MSWSTFA3580 MSWSTFA35150 MSWSTFA35180 MSWSTFA35220 MSWSTFA35260EX
MSWSTFS3580 MSWSTFS35150 MSWSTFS35180 MSWSTFS35220
MSWSTFS35260EX MSWSTFA3880 MSWSTFA38150 MSWSTFA38180
MSWSTFS38150 MSWSTFS38180
MIGHTYwire™ Guía
MW35904S MW351454S MW351457S MW351804S
MW351807S MW352304S MW352307S MW352604S
MW352607S MW353004S MW353007S MW35907S MW352304J
MW352604J MW353004J MW352604DC MW353004DC MW352604EDC
MW353004EDC
Aguja orientable Osseoflex® SN
OF-0020 OF-0231
Sistema de introducción vertebral del kit de acceso Osseoflex®
OS-0001
Balón orientable Osseoflex®
SB OF-0222 OF-0224

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Certificado para un gobierno extranjero - Nombre del producto (anexo) Página 16 de 17

Balón recto Osseoflex® SB
OT-0222 OT-0224
Sistema hidráulico de administración de cemento Osseoflex® CD-H
OF-0348
Troca manual recta Osseoflex®
OF-0217
Dispositivo de relleno óseo Osseoflex® BFD
O-0298
Sistema de biopsia ósea Westbrook™
KBD1110 KBD1115
Sistema de biopsia ósea con guía Kensington™
KBC1110 KBC1115
Introductor de hueso duro Preston™
KTP1110 KTP1115
Sistema de biopsia ósea con guía Bedford™
KBP1110 KBP1115
Aguja de biopsia ósea Preston™
CD1110 CD1115
Aguja de acceso óseo duro Preston™ con broca
ANP1165 ANP1185 ANP1110 ANP1115
Fresa larga Preston™
ML1110 ML1115
Sistema de biopsia ósea perforante Madison™ con fresa
KDPD1110 KDPD1115 KDPD1165 KDPD1185
KDPD139 KDP136
Introductor transpedicular Preston™
TV1110 TV813
Relleno óseo Preston™
CR1320 CR1020
Fresa transpedicular Preston™
MV1110
Sistema de biopsia ósea perforante guiada Huntington con fresa
OM1165 OM1110 OM1115

Nombre del fabricante
Sitio de fabricación
Merit Maquiladora México, S. DE R.L. DE C.V.
Avenida Sor Juana Inés de la Cruz
19970 Interior B, Edificio 2,
Parque Industrial Frontera Tijuana, Baja California
MÉXICO 22630
Nombre del producto(s)
Funda guía Prelude® Roadster
PG4F45S PG4F90S PG5F45MP PG5F45R
PG5F45S PG5F90MP PG5F90S PG6F45C
PG6F45HS PG6F45MP PG6F45R PG6F45S
PG6F65MP PG6F65S PG6F65SX PG6F90MP
PG6F90MPX PG6F90SX PG7F45MP PG7F45MPX PG7F45RX PG7F45S PG7F45SX PG7F65SX
PG7F90SX PG8F45MPX PG8F45S PG8F45SX PG8F65SX PG8F90SX PG5F45S018
PG5F90S018 PG6F45S018 PG6F90SX018
Catéter de hemodiálisis BioFlo DuraMax®

H965103028011	H965103028161	H965103038011	H965103038161	H965103029011
H965103028021	H965103028171	H965103038021	H965103038171	H965103029021
H965103028031	H965103028181	H965103038031	H965103038181	H965103029031

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JACK FACK S.R.L.

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Certificado para un gobierno extranjero - Nombre del producto (anexo) Página 17 de 17

H965103028041 H965103028191 H965103038041 H965103038191 H965103029041
H965103028051 H965103028201 H965103038051 H965103038201 H965103029051
H965103028061 H965103028211 H965103038061 H965103038211 H965103029061
H965103028070 H965103028220 H965103038070 H965103038220 H965103029071
H965103028080 H965103028230 H965103038080 H965103038230 H965103029081
H965103028090 H965103028240 H965103038090 H965103038240 H965103029091

Catéter de hemodiálisis DuraMax®

H787103028015 H787103028165 H787103029015
H787103028025 H787103028175 H787103029025
H787103028035 H787103028185 H787103029035
H787103028045 H787103028195 H787103029045
H787103028055 H787103028205 H787103029055
H787103028065 H787103028215 H787103029065
H787103028031 H787103028181 H787103029075
H787103028041 H787103028191 H787103029085
H787103028051 H787103028201 H787103029095
H787103028061 H787103028225 H787103029041
H787103028075 H787103028235
H787103028085 H787103028245
H787103028095

Catéter de hemodiálisis DuraFlow™ 2

H787103012145 H787103012185 H787103017015
H787103012125 H787103012195 H787103017025
H787103012015 H787103012205 H787103017035
H787103012025 H787103012215 H787103017045
H787103012035 H787103012225 H787103017055
H787103012045 H787103012235 H787103017155
H787103012011 H787103012245 H787103017145
H787103012021
H787103012031
H787103012041
H787103012055
H787103012155
H787103012115

EvenMore® Chronic Dialysis Catheter

H787103035115 H787103036015
H787103035125 H787103036025
H787103035015 H787103036035
H787103035025 H787103036065
H787103035035
H787103035045
H787103035055
H787103035065
H787103035075
H787103035085
H787103035095
H787103035105

Botón Perchick para accesorio de diálisis

H787138002015

Sistema de sellado de vías respiratorias Biosentry®

H787768022019S1

Sistema de microacceso avanzado Micro ACE™

ACE400SSS ACE401PTE ACE401PTS ACE421PTE
ACE500SSS ACE501PTE ACE501PTS ACE521PTE

----------**FIN DE LA LISTA DE PRODUCTOS**----------

QUIRNO CODAS THOMPSON LL.
Traductor Público
Matrícula N° 870

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los 31 días del mes de julio del 2025

2026-07-22 10:05:56.224342-03

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APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by CDR Cesar A. Perez

3. acting in the capacity of DRP2: Director, Division of Establishment Support Office of Regulatory Programs

4. bears the seal/stamp of U.S. Department of Health and Human Services

Certified

5. at Washington, D.C.

6. the seventh of August, 2025

7. by *Assistant Authentication Officer, United States Department of State*

8. No. 25072092-11

9. Seal/Stamp:

10. Signature:

Zelda Daley

FDA

Lote 33, 35, 36 - Item 1

JACK PACK SRL

2026-07-22 10:05:56.224342-03

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U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 9546-6-2025-1

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Four Pages)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections.The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from June 17, 2025 to June 16, 2027.

To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.

JACK FACK

2026-07-22 10:05:56.224342-03

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FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 9546-6-2025-1

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA
USA 01752

Name of Manufacturer
BOSTON SCIENTIFIC CORPORATION
302 Parkway, Global Park
La Aurora, Heredia
COSTA RICA

Name of Distributor
Boston Scientific Corp., Marina Bay Cust. Fulfillment Center
500 Commander Shea Boulevard
QUINCY, MA
USA 02171

---END OF MANUFACTURER/DISTRIBUTOR LIST---

JACK FACK S.R.L.

2026-07-22 10:05:56.224342-03

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U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

ertificate No. 9546-6-2025-1

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 4

Name of Owner Operator

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA
USA 01752

Name of Manufacturer

BOSTON SCIENTIFIC CORPORATION
302 Parkway, Global Park
La Aurora, Heredia
COSTA RICA

Name of Distributor

Boston Scientific Corp., Marina Bay Cust. Fulfillment Center
500 Commander Shea Boulevard
QUINCY, MA
USA 02171

Name of Product(s)

ChoICE™ Guidewire with ICE™ Hydrophilic Coating

UPN:	Description:
H74912116011	0.014", 300cm, Straight
H74912116012	0.014", 300cm, Straight, 5 pk
H7491211601J1	0.014", 300cm, J Tip
H7491211601J2	0.014", 300cm, J Tip, 5 pk
H74912117011	0.014", 300cm, Straight
H74912117012	0.014", 300cm, Straight, 5 pk
H7491211701J1	0.014", 300cm, J Tip
H7491211701J2	0.014", 300cm, J Tip, 5 pk
H74912118011	0.014", 300cm, Straight
H74912118012	0.014", 300cm, Straight, 5 pk
H7491211801J1	0.014", 300cm, J Tip
H7491211801J2	0.014", 300cm, J Tip, 5 pk
H74912119011	0.014", 300cm, Straight
H74912119012	0.014", 300cm, Straight, 5 pk
H7491211901J1	0.014", 300cm, J Tip
H7491211901J2	0.014", 300cm, J Tip, 5 pk
H74912132011	0.014", 182cm, Straight
H74912132012	0.014", 182cm, Straight, 5 pk
H7491213201J1	0.014", 182cm, J Tip
H7491213201J2	0.014", 182cm, J Tip, 5 pk
H74912133011	0.014", 182cm, Straight
H74912133012	0.014", 182cm, Straight, 5 pk
H7491213301J1	0.014", 182cm, J Tip
H7491213301J2	0.014", 182cm, J Tip, 5 pk
H74912134011	0.014", 182cm, Straight
H74912134012	0.014", 182cm, Straight, 5 pk
H7491213401J1	0.014", 182cm, J Tip
H7491213401J2	0.014", 182cm, J Tip, 5 pk
H74912135011	0.014", 182cm, Straight
H74912135012	0.014", 182cm, Straight, 5 pk
H7491213501J1	0.014", 182cm, J Tip
H7491213501J2	0.014", 182cm, J Tip, 5 pk

ChoICE™ Magnet Guidewire with ICE™ Hydrophilic Coating

UPN:	Description:
H7491213201M2	0.014", 182cm, Straight, 5 pk
H7491213201MJ2	0.014", 182cm, J Tip, 5 pk

JACK FACK S.R.L.

2026-07-22 10:05:56.224342-03

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U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
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www.fda.gov

ertificate No. 9546-6-2025-1

Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 4

H7491213501M2	0.014", 182cm, Straight, 5 pk
H7491213501MJ2	0.014", 182cm, J Tip, 5 pk
H7491213301M2	0.014", 182cm, Straight, 5 pk
H7491213301MJ2	0.014", 182cm, J Tip, 5 pk
H7491213401M2	0.014", 182cm, Straight, 5 pk
H7491213401MJ2	0.014", 182cm, J Tip, 5 pk

ChoICE™ PT Guidewire with ICE™ Hydrophilic Coating

UPN:	Description:
H74912154011	0.014", 300cm, Straight
H74912154012	0.014", 300cm, Straight, 5 pk
H7491215401J1	0.014", 300cm, J Tip
H7491215401J2	0.014", 300cm, J Tip, 5 pk
H74912155011	0.014", 300cm, Straight
H74912155012	0.014", 300cm, Straight, 5 pk
H7491215501J1	0.014", 300cm, J Tip
H7491215501J2	0.014", 300cm, J Tip, 5 pk
H74912160011	0.014", 182cm, Straight
H74912160012	0.014", 182cm, Straight, 5 pk
H7491216001J1	0.014", 182cm, J Tip
H7491216001J2	0.014", 182cm, J Tip, 5 pk
H74912161011	0.014", 182cm, Straight
H74912161012	0.014", 182cm, Straight, 5 pk
H7491216101J1	0.014", 182cm, J Tip
H7491216101J2	0.014", 182cm, J Tip, 5 pk

ChoICE™ PT Magnet Guidewire with ICE™ Hydrophilic Coating

UPN:	Description:
H7491216001M2	0.014", 182cm, Straight, 5 pk
H7491216001MJ2	0.014", 182cm, J Tip, 5 pk
H7491216101M2	0.014", 182cm, Straight, 5 pk
H7491216101MJ2	0.014", 182cm, J Tip, 5 pk

Luge™ Guidewire with ICE™ Hydrophilic Coating

UPN:	Description:
H74912100010	0.014", 300cm, Straight
H74912100012	0.014", 300cm, Straight, 5pk
H7491210001J0	0.014", 300cm, J Tip
H7491210001J2	0.014", 300cm, J Tip, 5pk
H74912130010	0.014", 182cm, Straight
H74912130012	0.014", 182cm, Straight, 5pk
H7491213001J0	0.014", 182cm, J Tip
H7491213001J2	0.014", 182cm, J Tip, 5pk

Luge™ Magnet Guidewire with ICE™ Hydrophilic Coating

UPN:	Description:
H7491213001M2	0.014", 182cm, Straight, 5 pk
H7491213001MJ2	0.014", 182cm, J Tip, 5 pk

Mailman™ Guidewire with ICE™ Hydrophilic Coating

UPN:	Description:
H74912120011	0.014", 300cm, Straight
H74912120012	0.014", 300cm, Straight, 5 pk
H7491212001J1	0.014", 300cm, J Tip
H7491212001J2	0.014", 300cm, J Tip, 5 pk
H74912136011	0.014", 182cm, Straight
H74912136012	0.014", 182cm, Straight, 5 pk
H7491213601J1	0.014", 182cm, J Tip

JACK HACK S.r.l.

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U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
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Certificate No. 9546-6-2025-1

Certificate to Foreign Government - Name of Product(s) Attachment Page 3 of 4

H7491213601J2	0.014", 182cm, J Tip, 5 pk

–

Mailman™ Magnet Guidewire with ICE™ Hydrophilic Coating

UPN:	Description:
H7491213601M2	0.014", 182cm, Straight, 5 pk
H7491213601MJ2	0.014", 182cm, J Tip, 5 pk

–

PT Graphix™ Guidewire with ICE™ Hydrophilic Coating

UPN:	Description:
H74914902011	0.014", 182cm, Straight
H74914902012	0.014", 182cm, Straight, 5 pk
H7491490201J1	0.014", 182cm, J Tip
H7491490201J2	0.014", 182cm, J Tip, 5 pk
H74914903011	0.014", 182cm, Straight
H74914903012	0.014", 182cm, Straight, 5 pk
H7491490301J1	0.014", 182cm, J Tip
H7491490301J2	0.014", 182cm, J Tip, 5 pk
H74914905011	0.014", 182cm, Straight
H74914905012	0.014", 182cm, Straight, 5 pk
H7491490501J1	0.014", 182cm, J Tip
H7491490501J2	0.014", 182cm, J Tip, 5 pk
H74914914011	0.014", 300cm, Straight
H74914914012	0.014", 300cm, Straight, 5 pk
H7491491401J1	0.014", 300cm, J Tip
H7491491401J2	0.014", 300cm, J Tip, 5 pk

–

PT Graphix™ Magnet Guidewire with ICE™ Hydrophilic Coating

UPN:	Description:
H7491490201M2	0.014", 182cm, Straight, 5 pk
H7491490201MJ2	0.014", 182cm, J Tip, 5 pk
H7491490501M2	0.014", 182cm, Straight, 5 pk
H7491490501MJ2	0.014", 182cm, J Tip, 5 pk
H7491490301M2	0.014", 182cm, Straight, 5 pk
H7491490301MJ2	0.014", 182cm, J Tip, 5 pk

–

PT2™ Guidewire

UPN:	Description:
H74938931010	0.014", Light, 185cm, Straight
H74938931012	0.014", Light, 185cm, Straight, 5 pk
H7493893101J0	0.014", Light, 185cm, J Tip
H7493893101J2	0.014", Light, 185cm, J Tip, 5 pk
H74938931020	0.014", Light, 300cm, Straight
H74938931022	0.014", Light, 300cm, Straight, 5 pk
H7493893102J0	0.014", Light, 300cm, J Tip
H7493893102J2	0.014", Light, 300cm, J Tip, 5 pk
H74938931030	0.014", Moderate, 185cm, Straight
H74938931032	0.014", Moderate, 185cm, Straight, 5 pk
H7493893103J0	0.014", Moderate, 185cm, J Tip
H7493893103J2	0.014", Moderate, 185cm, J Tip, 5 pk
H74938931040	0.014", Moderate, 300cm, Straight
H74938931042	0.014", Moderate, 300cm, Straight, 5 pk
H7493893104J0	0.014", Moderate, 300cm, J Tip
H7493893104J2	0.014", Moderate, 300cm, J Tip, 5 pk

–

wireClip™ Torquer Guidewire Manipulation Device

UPN:	Description:
H802221960032	WireClip Torquer, 5 pk
H802221960030	WireClip Torquer, 1 pk

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U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 9546-6-2025-1

Certificate to Foreign Government - Name of Product(s) Attachment Page 4 of 4

RotaWire™ and wireClip™ Torquer Guidewire and Guidewire Manipulation Device

UPN:	Description:
H802228240020	RotaWire, 330cm, Floppy GW/wireClip
H802228240022	RotaWire, 330cm, Floppy GW/wireClip, 5 pk
H802232390010	RotaWire, 330cm, Extra Sup Wire/wireClip
H802232390012	RotaWire, 330cm, Extra Sup Wire/wireClip, 5 pk

ROTAWIRE™ Drive and wireClip™ Torquer Guidewire and Guidewire Manipulation Device

UPN:	Description:
H74939463005	ROTAWIRE Drive, 330cm, Extra Support Wire/wireClip, 5pk
H74939462005	ROTAWIRE Drive, 330cm, Floppy GW/wireClip, 5pk
H74939463001	ROTAWIRE Drive, 330cm, Extra Support GW/wireClip
H74939462001	ROTAWIRE Drive, 330cm, Floppy GW/wireClip

----------END OF PRODUCT LIST----------

JACK

2026-07-22 10:05:56.224342-03

QUIRNO CODAS THOMPSON LLANO
Traductor Público Matriculado
Reclus 283
Tel.: 600 865 – Fax 612 314
Asunción - Paraguay

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APOSTILLA

(Convención de La Haya del 5 de octubre de 1961)

País: Estados Unidos de América

Este documento público

ha sido firmado por: CDR Cesar A. Perez

Actuando en calidad de: DRP2: Director, División de Apoyo al Establecimiento, Oficina de Programas Regulatorios

Lleva el sello/timbre de: Departamento de Salud y Servicios Humanos de los Estados Unidos

Certificado

En: Washington, D.C.

El: siete de agosto de 2025

Por: Oficial Asistente de Autenticación, Departamento de Estado de los Estados Unidos

N.º: 25072092-11

Sello/Timbre:

Firma: Zelda Daley

QUIRNO CODAS THOMPSON LL.
Traductor Público
Matrícula Nº 670

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los 29 días del mes de agosto del 2025

2026-07-22 10:05:56.224342-03

QUIRNO CODAS THOMPSON LLANO
Traductor Público Matriculado
Reclus 283
Tel.: 600 865 – Fax 612 314
Asunción - Paraguay

133

Certificado N° 9546-06-2025-1

CERTIFICADO PARA GOBIERNO EXTRANJERO

Para permitir la importación de productos estadounidenses a países extranjeros, la Administración de Alimentos y Medicamentos de los Estados Unidos (FDA) certifica la siguiente información sobre los productos que se exportarán y que se enumeran a continuación:

Nombre del/del producto(s)	**Nombre del fabricante/distribuidor, dirección**
Ver lista adjunta (Cuatro página)	Ver lista adjunta (una página)

El/los producto(s) descrito(s) anteriormente (y el/los centro(s) de fabricación/distribución que lo(s) producen/distribuyen) está(n) sujeto(s) a la jurisdicción de la FDA en virtud de la Ley Federal de Alimentos, Medicamentos y Cosméticos.

Se certifica que el/los producto(s) mencionado(s) puede(n) comercializarse y exportarse legalmente desde los Estados Unidos de América actualmente. La(s) planta(s) de fabricación donde se produce(n) el/los producto(s) está(n) sujeta(s) a inspecciones periódicas.

Atentamente,

CDR Cesar A. Perez, PhD, Director
DRP2: División de Apoyo al Establecimiento,
Oficina de Programas Regulatorios
Oficina de Evaluación y Calidad de Productos,
Centro de Dispositivos y Salud Radiológica,
Administración de Alimentos y Medicamentos de EE. UU., DHHS

Este certificado es válido desde el 17 de junio de 2025 hasta el 16 de junio de 2027.

QUIRNO CODAS THOMPSON LL.
Traductor Público
Matrícula Nº 670

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los 29 días del mes de agosto del 2025

2026-07-22 10:05:56.224342-03

QUIRNO CODAS THOMPSON LLANO
Traductor Público Matriculado
Reclus 283
Tel.: 600 865 – Fax 612 314
Asunción - Paraguay

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Certificado N° 9546-06-2025-1
Certificado para gobierno extranjero - Nombre del fabricante/distribuidor - Anexo, página 1 de 1

Nombre del propietario y operador
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA
EE. UU. 01752

Nombre del fabricante
Centro de fabricación
BOSTON SCIENTIFIC CORPORATION
302 Parkway, Global Park
La Aurora, Heredia
COSTA RICA

Nombre del distribuidor
Boston Scientific Corp., Marina Bay Cust. Fulfillment Center, 500 Commander Shea Boulevard
QUINCY, MA
EE. UU. 02171

-—FIN DE LA LISTA DE FABRICANTES/DISTRIBUIDORES-—

QUIRNO CODAS THOMPSON LL.
Traductor Publico
Matrícula N° 670

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los 29 días del mes de agosto del 2025

2026-07-22 10:05:56.224342-03

135

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by CDR Cesar A. Perez, PhD

3. acting in the capacity of Director, Division of Establishment Support Office of Regulatory Programs

4. bears the seal/stamp of U. S. Department of Health and Human Services

Certified

5. at Washington, D.C.

6. the twenty-first of February, 2025

7. by *Assistant Authentication Officer, United States Department of State*

8. No. 25028963-3

9. Seal/Stamp:

10. Signature: N. Skinner

Nekisha V. Skinner

- FDA
Lore 38 a1 60
Lore 124

JACK FACK SRI

2026-07-22 10:05:56.224342-03

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U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 1301-11-2024-1

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(22 Pages)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections.The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from November 15, 2024 to November 14, 2026.

To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.

2026-07-22 10:05:56.224342-03

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FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 1301-11-2024-1

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator
Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT
USA 84095

Name of Manufacturer
Manufacturing Site
Merit Medical Systems, Inc.
14646 Kirby Drive
Houston, TX
USA 77047

Manufacturing Site
MERIT MEDICAL SYSTEMS, INC.
12701 Kingston Avenue
Chester, VA
USA 23836

Manufacturing Site
Merit Maquiladora Mexico, S. DE R.L. DE C.V.
Avenida Sor Juana Ines de la Cruz
19970 Interior B, Edificio 2, Parque Industrial Frontera
Tijuana, Baja California
MEXICO 22630

Name of Manufacturer/Distributor
Legal Manufacturer/Distributor
MERIT MEDICAL SYSTEMS, INC.
1600 WEST MERIT PKWY.
South Jordan, UT
USA 84095

----END OF MANUFACTURER/DISTRIBUTOR LIST----

JACK FALK S.R.L.

2026-07-22 10:05:56.224342-03

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U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 1301-11-2024-1

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 22

Name of Manufacturer
Manufacturing Site

Merit Medical Systems, Inc.
14646 Kirby Drive
Houston, TX
USA 77047

Name of Product(s)

FEP PIGTAIL Angiographic Catheter
1308-25-0085 1308-35-0086 1310-21-0043 1310-25-0064 1308-35-0065 1308-35-0006
1310-21-0053 1310-25-0084 1308-35-0085 1308-38-0006 1310-21-0054 1310-25-0065
1308-35-0005 1308-35-0007 1310-21-0064 1310-25-0085 1308-38-0007 1310-25-0054
Vessel Sizing Angiographic Catheter
[redacted]535AVS20MHK 510035AVS20MHK 510035AVS20PIG 510035AVS2MHK
510035AVS2PIG 510035AVS2STR 56535AVS20MHK 56535AVS20PIG
56535AVS2MHK 56535AVS2PIG 56535AVS2STR 7602-11M
7602-11M65 7602-20M 7602-20M100SH 7602-20M65
7602-20M65SH 7602-2M 7602-2M65 7603-11M100
7603-11M65 7603-20M100SH 7603-20M65SH 7603-2M100
7603-2M65 7673-11M100SH 7673-11M65SH 7673-20M100SH
7673-20M65SH 7673-2M 7673-2M65 7674-2M
7674-2M65 7742-20M100SH 7742-20M65SH 7742-2M100SH
7742-2M65SH 7743-2M100SH 7743-2M65SH 7744-2M100SH
7744-2M65SH 7755-2M100 7755-2M65 7757-2MP65
7757-2MP65SH 7757-2MP65SHA 7757-2MP65SHTC 7757-2MP65SHTCB
7757-2MP80 7757-2MP80SH 7757-2MP80SHTC
Performa® AngiographicCatheter ✱
Performa® Angiographic Catheter Judkins Left
7521-A3 7521-B1 7521-C3
Performa® Angiographic Catheter Judkins Right
7523-A3 7701-50 7523-B1 7523-C3
Performa® Angiographic Catheter Left Coronary Bypass
7534-43
[redacted]rforma® Angiographic Catheter Right Coronary Bypass
7534-33
Performa® Angiographic Catheter Amplatz Left
7527-63 7527-73
Performa® Angiographic Catheter Amplatz Right
7526-21
Performa® Angiographic Catheter Multipurpose
7533-D3
Performa® Angiographic Catheter Headhunter
7715-B0 7715-50 7715-60
Performa® Angiographic Catheter Newton
7722-20 7722-E0
Performa® Angiographic Catheter Bentson
7721-30
Performa® Angiographic Catheter Osborn
7746-20
Performa® Angiographic Catheter Simmons
7720-F0 7720-80
Performa® Angiographic Catheter MW2
7745-B0
Performa® Angiographic Catheter Renal Double Curve
7713-A0 510038PRDC
Performa® Angiographic Catheter Reuter
7714-10 7714-B0
Performa® Angiographic Catheter KA Selective

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5582-23 5582-33
Performa® Angiographic Catheter DVS A1
5595-13 5595-23 5595-33 5595-43
Performa® Angiographic Catheter DVS A2
5595-A3 5595-B3 5595-C3 5595-D3
Performa® Angiographic Catheter Modified Hook
7603-A1 7603-B1 7603-C1 7603-D1
5585-C3 5585-D3 5585-E3
Performa® Angiographic Catheter Transradial Peripheral
PV612538U4 PV512538U3 PV512538U4 PV512538U45
PV612538PIG PV511038FH3 PV512538FH3 PV512538U1
PV512538U2 PV612538MP2SH PV512538BERN PV612538U2 PV512538U45SH
Performa® Angiographic Catheter Ultimate
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6110382ULT3 6110381ULT4-T40 6110381ULT4-T45
612538ULT1 512538ULT4-T40 412538ULT1 412538ULT3
Performa® Angiographic Catheter Vertebral
410035VER-PNB
Performa® Angiographic Catheter Uterine Artery
56535PUAC2
Performa® Angiographic Catheter Berenstein
7718-40
Performa® Angiographic Catheter UHF Pigtail
4653510PIG-PNB
Performa® Angiographic Catheter MIV™
4RPL110 4RPL110-NB 4RPL125 4RPL125-NB
4RPS110-NB 4RPS125 4RPS125-NB 5RPL110-NB
5RPL125-NB 6RPL110-NB 6RPL125 6RPL125-NB
6RPS110-NB 6RPS125 6RPS125-NB 5RPS125-NB
Performa® Angiographic Catheter Shepherd Hook
7712-D0
Performa® Custom Catheters
[redacted]623-A72M 1623-B62M 1623-C720M 1623-D1 1623-D2 1623-D3 1623-D4 1623-D5 1623-D6 1623-[redacted] 1623-E320M 1623-E93M
1623-F220M 1623-F320M 1623-F420M 1623-F620M 1623-F720M 1623-F820M 1624-69-20M 1624-71
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1624-D8 1624-D9 1624-E520M 1624-E75M 1624-E8 1624-E9 1625-26 1625-29 1625-31 1625-32
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1628-086 1628-092
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1628-163 1628-165 1628-167 1628-169 1628-171 1628-176 1628-180 1628-184 1628-187 1628-191 1628-193 1628-194
1628-201 1628-203 1628-211 1628-212 1628-214 1628-218 1628-229 1628-230 1628-233 1628-235 1628-242 1628-243
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1628-E1 1628-E2 1628-E8 1628-F1 1628-F2 1628-F6 1628-F7 1628-F8 1628-G4 1628-G5 1628-G6 1628-G8
1628-G9 1628-H1 1628-H2 1628-J1 1628-J2 1628-J3 1628-J5 1628-J8 1628-K1 1628-L3 1628-L7
1628-M1

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1628-M3 1628-N3 1628-N5 1628-N6 1628-N8 1628-N9 1628-P2 1628-P3 1628-Q5 1628-Q6 1628-Q7 1628-Q8
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1628-S4 1628-T6 1628-U2 1628-U5 1628-V5 1628-V6 1628-V7 1628-W2 1628-X8 1628-Y1 1628-Y5 1628-Y9
1628-Z1 1628-Z8 7440-11 7440-12 7440-13 7440-15 7440-16 7440-21 7440-26 7440-27 7440-28 7440-29
7440-30 7440-31 7440-32 7440-33 7440-34 7440-42 7440-45 7440-53 7440-56 7440-60 7440-61 7440-62
7440-64 7440-65 7440-75 7440-79 7440-80 7440-81 7440-82 7440-83 7440-84 7440-85 7440-87 7440-88
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7445-83 7445-84 7445-88 7445-94 7445-95 7445-99 7445-A2 7445-A3 7445-A7 7445-A8 7445-B1 7445-B3
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7445-H5 7445-H6 7445-J4 7445-J5 7445-J6 7445-J7 7445-J8 7445-J9 7445-K1 7445-K2 7445-K3
1623-G2
Performa® Transradial Angiographic Catheter
PV413538BERN PV415038BERN PV415038U1 PV513538BERN
PV513538U1 PV515038BERN PV515038U1
CONCIERGE Guiding Excellence™ Guiding Catheter
CONCIERGE Guiding Excellence™ Guiding Catheter Judkins Right
CGC5100JR30 CGC6100JR30 CGC7100JR30 CGC8100JR30 CGC5100JR35 CGC6100JR35 CGC7100JR35 CGC8100JR35
CGC5100JR35SH CGC6100JR35SH CGC7100JR35SH CGC8100JR35SH CGC5100JR40 CGC6100JR40 CGC7100JR40 CGC8100JR40SH
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CGC5100JR50SH CGC6100JR50SH CGC7100JR50SH CGC8100JR50SH CGC5100JR60 CGC6100JR60 CGC7100JR60 CGC8100JR60
CONCIERGE Guiding Excellence™ Guiding Catheter Judkins Left
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CGC5100JL50SH CGC6100JL50SH CGC7100JL50SH CGC8100JL50SH
CONCIERGE Guiding Excellence™ Guiding Catheter Amplatz Right
CGC5100AR1 CGC5100AR3 CGC6100AR2SH CGC7100AR2 CGC5100AR1SH CGC6100AR1 CGC6100AR3 CGC7100AR2SH
CGC5100AR2 CGC6100AR1SH CGC7100AR1 CGC7100AR3 CGC5100AR2SH CGC6100AR2 CGC7100AR1SH CGC8100AR1
CGC8100AR1SH CGC8100AR2 CGC8100AR2SH CGC8100AR3
CONCIERGE Guiding Excellence™ Guiding Catheter Amplatz Left

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CGC5100AL1 CGC5100AL3 CGC6100AL2SH CGC7100AL1SH CGC5100AL1SH CGC6100AL1
CGC6100AL3 CGC7100AL2
CGC5100AL2 CGC6100AL1SH CGC7100AL1 CGC7100AL2SH CGC5100AL2SH CGC6100AL2
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CGC7100MP1 CGC8100MP1SH CGC6100MP1
CONCIERGE Guiding Excellence™ Guiding Catheter Left Coronary Bypass
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CGC7100LCBSH CGC8100LCBSH
CONCIERGE Guiding Excellence™ Guiding Catheter Right Coronary Bypass
CGC5100RCB CGC6100RCB CGC7100RCB CGC8100RCB CGC5100RCBSH CGC6100RCBSH
CGC7100RCBSH CGC8100RCBSH
CONCIERGE Guiding Excellence™ Guiding Catheter Internal Mammary
CGC5100IM CGC6100IM CGC7100IM CGC8100IM CGC5100IMSH CGC6100IMSH CGC7100IMSH
CGC8100IMSH
CONCIERGE Guiding Excellence™ Guiding Catheter El Gamal
CGC5100EG CGC6100EG CGC7100EG CGC8100EG
CONCIERGE Guiding Excellence™ Guiding Catheter Hockey Stick
CGC5100HS CGC6100HS CGC7100HS CGC8100HS CGC7100HSSH CGC8100HSSH CGC5100HSSH
CGC6100HSSH
CONCIERGE Guiding Excellence™ Guiding Catheter Renal Double Curve
CGC6100RDC CGC7100RDC
CONCIERGE Guiding Excellence™ Guiding Catheter SBS
CGC5100SBS30 CGC6100SBS30 CGC7100SBS30 CGC8100SBS35 CGC5100SBS30SH
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CGC7100SBS375SH CGC5100SBSRCASH CGC5100SBSLAD40SH
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MSH CGC7100SBS35-M CGC8100SBS40-M CGC8100SBS375-M
CGC5100SBS375-M CGC7100SBS35-MSH CGC8100SBS40-MSH CGC8100SBS35-M CGC6100SBS35-M
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CGC6100SBS35-MSH CGC7100SBS45-MSH CGC6100SBS45-MSH CGC8100SBS45-M
CONCIERGE Guiding Excellence™ Guiding Catheter Ultimate
CGC5100ULT1 CGC6100ULT2 CGC7100ULT3 CGC6100ULT4-T45 CGC6100ULT1 CGC7100ULT2
CGC5100ULT4-T40 CGC7100ULT4-T45

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CGC7100ULT1 CGC8100ULT2 CGC6100ULT4-T40 CGC8100ULT3 CGC8100ULT1 CGC5100ULT3
CGC7100ULT4-T40
CGC5100ULT2 CGC6100ULT3 CGC5100ULT4-T45
Vessel Dilator
3339-21 3339-31 3339-41 3339-51
Impress® Angiographic Catheter
Impress® Angiographic Catheter Radial Internal Mammary
411038RADIM 511038RADIM
Impress® Angiographic Catheter Coronary Sinus
57538CS 1628-Y8M
Impress® Angiographic Catheter Fischook
PVI511038FH3 PVI512538FH3
Impress® Angiographic Catheter Headhunter
035HH1 410038HH3 510035HH1 512535HH1 410035HH3 412535HH1 510038HH3 512538HH1
410038HH1 510035HH3 510038HH1
410038HH1-H 412538HH1-H 510038HH1-H 512538HH1-H
Impress® Angiographic Catheter Newton
410038N1 510038N4 410038N3 510038N2 410038N4 410038N2 510038N3 510038N1
Impress® Angiographic Catheter Bentson
46535B1 410035B1 510038B1 510035B1
410035B2 510035B2 56535B1 410038B1
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Impress® Angiographic Catheter Mani
410035MANI 510035MANI 410038MANI 510038MANI
410038MANI-H 510038MANI-H
Impress® Angiographic Catheter Vertebral
46538VER 510038VER 56538VER 410038VER
412535VER 410035VER 512535VER 510035VER
56538VER-H 510038VER-H 46538VER-H 410038VER-H
Impress® Angiographic Catheter Modified Cerebral
410035MC 410038MC 510035MC 510038MC
Impress® Angiographic Catheter Berenstein
35BER 510035BER 410038BER 53035BER 56538BER 410035BER 512538BER 56535BER
38BER 510038BER 412538BER 43035BER
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412538BER-H 512538BER-H
Impress® Angiographic Catheter MW2
44038MW2 56538MW2
Impress® Angiographic Catheter Simmons
46535SIM1 410035SIM1 410038SIM2 56535SIM1 46538SIM1 410035SIM2 48035MODS 56538SIM1
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512535SIM1
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465352CB1 410038CB2 565352CB1 46538CB2
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56538CB2-H 510038CB2-H
Impress® Angiographic Catheter Modified Cobra
43035MODCB1 53035MODCB1
Impress® Angiographic Catheter Hook
465352HK0-8 565352HK0-8 465352HK1-0 565352HK1-0
Impress® Angiographic Catheter Shepherd Hook
465352SH0-8 465352SH1-0 565352SH0-8 565352SH1-0

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Impress® Angiographic Catheter Renal Vein Renin
56538IRG1 56538IRG2
Impress® Angiographic Catheter Renal Double Curve
465352RC 565352RC 46535RC 510038IRDC
Impress® Angiographic Catheter Amir Motarjeme™
46535MOT 410035MOT 56535MOT 510035MOT
Impress® Angiographic Catheter Amir Motarjeme™ Cane
46535MOTC 410035MOTC
Impress® Angiographic Catheter Reuter
48038RE 58035RE 58038RE
Impress® Angiographic Catheter Mikaelsson
48038MIK 58038MIK
Impress® Angiographic Catheter KA2
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44038KA2-H 46538KA2-H 54038KA2-H 56538KA2-H
Impress® Angiographic Catheter Hockey Stick
410038HS 510038HS
Impress® Angiographic Catheter Modified Hook
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58035MHK3 58035MHK2
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48038MHK3-H 58038MHK3-H
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Impress® Angiographic Catheter Straight Selective
46538STS 56538STS 511038STS 44035STS
411035STS 411038STS 511035STS 44038STS 54035STS 54038STS
46538STS-H 410038STS-H 56538STS-H 510038STS-H
412538STS-H 512538STS-H
Impress® Angiographic Catheter Straight
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4653510STF-NB 4903510STF-NB 5653510STF-NB 5903510STF-NB
Impress® Angiographic Catheter Renal, Bifurcation, Iliac
[redacted]65354RBI 565354RBI 510035RBI 56535RBI
[redacted]100354RBI 56538RBI-H
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Impress® Angiographic Catheter Mini RIM
56535MRIMST
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Impress® Angiographic Catheter Ultra Bolus Flush
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Impress® Angiographic Catheter Modified Bolus Flush
5653810MUBF-NB 4653810MUBF-NB
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41103510PIG-NB 5903810PIG-NB
51103510PIG-NB 5303510PIG-NB 4303510PIG-NB
Impress® Angiographic Catheter Osborn
410035OSB1 510035OSB1
Impress® Angiographic Catheter Multipurpose A1
410038MPA1 412538MPA1 46538MPA1 56538MPA1 510038MPA1 512538MPA1
410038MPA1-H 510038MPA1-H
Impress® Angiographic Catheter Ultimate
5IMP10038ULT1 5IMP100381ULT1 5IMP110381ULT2 5IMP11038ULT2
5IMP110381ULT4-T40 5IMP11038ULT4-T40
Impress® Angiographic Catheter Uterine Artery

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59035UAC 59038UAC 59035IUAC
Impress® Angiographic Catheter CPC
57538CARN5 57538CARN5S 57538CARN10 57538CARN10S 57538CARN15 57538CARN15S
Impress® UAC2™ Uterine Artery Catheter
59035IUACTMB-H
Impress® Angiographic Catheter 3D Curve
58038IRH1 58038IRH2
Impress® Custom Catheter
1623-E1 1623-E6 1623-F9 1623-G1 1624-B5 1624-B7 1624-C7 1624-D5 1624-E6 1628-001 1628-005 1628-015
1628-016 1628-017 1628-019 1628-021 1628-034 1628-035 1628-037 1628-042 1628-043 1628-044 1628-050 1628-054
1628-059 1628-060 1628-061 1628-062 1628-063 1628-064 1628-065 1628-073 1628-079 1628-083 1628-094 1628-095H
1628-100 1628-113 1628-118 1628-121 1628-128 1628-133 1628-148 1628-151 1628-152 1628-155 1628-164 1628-166
1628-168 1628-178 1628-179 1628-181 1628-182 1628-183 1628-189 1628-192 1628-197 1628-198 1628-199 1628-200
1628-202 1628-204 1628-205 1628-206 1628-206H 1628-207 1628-208 1628-209 1628-210 1628-213 1628-216 1628-217
1628-219 1628-220 1628-221 1628-222 1628-223 1628-224 1628-225 1628-228 1628-231 1628-232 1628-234 1628-236
1628-237 1628-238 1628-239 1628-240 1628-241 1628-248 1628-253 1628-261 1628-268 1628-269 1628-270 1628-272
1628-275 1628-W7 1628-Y7 1628-Y8 1628-Z4 1628-Z5 1628-Z7 1628-Z9 7440-E7 7440-F6 7440-F7 7440-G8
7440-H5 7440-H6 7440-H8 7440-H9 7440-J4 7440-J5 7440-J7 7440-J8 7440-K4 7440-K5 7440-L5 7440-L6
7440-M1 7440-M3 7440-M5 7440-M6 7440-N4 7440-N5 7440-N6 7440-N7 7440-N8 7440-N9 7440-P1 7440-P2
7440-P3 7440-P7 7440-P8 7440-P9 7440-Q1 7440-Q2 7440-Q3 7440-Q4 7440-Q5 7440-Q6 1628-017M 1628-019M
Impress® Angiographic Catheter Double Loop 3D Curve
57538IDLOOP
Worley™ VEIN SELECTOR Angiographic Catheter
57538CS-WOR 57538CSV-WOR 57538CSHK-WOR
Resolve® Repositioning Tool
RC-RTOOL
Resolve®NL Hydrophilic Coated Non-Locking Drainage Catheter
RNL-10-038J RNL-10-038S RNL-12-038J RNL-12-038S
RNL-6-038J RNL-6-038S RNL-7-038J RNL-7-038S
RNL-8-038J RNL-8-038S
Resolve® Hydrophilic Coated Locking Drainage Catheter
RLC-10-038 RLC-12-038 RLC-14-038 RLC-6-038
RLC-7-038 RLC-8-038 RLC15-10-038MB RLC15-12-038MB
RLC15-14-038MB RLC15-6-038MB RLC15-7-038MB RLC15-8-038MB
RLC40-10-038MB RLC40-12-038MB RLC40-14-038MB RLC40-6-038MB
RLC40-7-038MB RLC40-8-038MB RLC-10-038MB RLC-12-038MB
RLC-14-038MB RLC-6-038MB RLC-7-038MB RLC-8-038MB
RLC-NV-10 RLC-NV-12 RLC-NV-14 RLC-NV-6
RLC-NV-7 RLC-NV-8 RLCMB-NV-10 RLCMB-NV-12
RLCMB-NV-14 RLCMB-NV-6 RLCMB-NV-8 RLCMB-NV-7
Resolve® Hydrophilic Coated Biliary Locking Drainage Catheter
RBC-10-038 RBC-12-038 RBC-14-038 RBC-8-038
RBDC-10-038 RBDC-12-038 RBDC-14-038 RBDC-8-038
Resolve Mini™ Hydrophilic Coated Locking Drainage Catheter
RML17-10-038MB RML17-12-038MB RML17-14-038MB RML17-6-038MB
RML17-7-038MB RML17-8-038MB RML27-10-038MB RML27-12-038MB

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RML27-14-038MB RML27-6-038MB RML27-7-038MB RML27-8-038MB
RML42-10-038MB RML42-12-038MB RML42-14-038MB RML42-6-038MB
RML42-7-038MB RML42-8-038MB
Resolve®+
RBC-10-REV RBC-12-REV RBC-14-REV RBC-8-REV
RBDC-10-REV RBDC-12-REV RBDC-14-REV RBDC-8-REV
RBC-10-SFX RBC-12-SFX RBC-14-SFX RBC-8-SFX
RBDC-10-SFX RBDC-12-SFX RBDC-14-SFX RBDC-8-SFX
RLC-10-REV RLC-12-REV RLC-14-REV RLC-6-REV
RLC-7-REV RLC-8-REV RLCMB-10-REV RLCMB-12-REV
RLCMB-14-REV RLCMB-6-REV RLCMB-7-REV RLCMB-8-REV
RLC-10-SFX RLC-12-SFX RLC-14-SFX RLC-6-SFX
RLC-7-SFX RLC-8-SFX RLCMB-10-SFX RLCMB-12-SFX
RLCMB-14-SFX RLCMB-6-SFX RLCMB-7-SFX RLCMB-8-SFX
RLC-NV-10-REV RLC-NV-12-REV RLC-NV-14-REV RLC-NV-6-REV
RLC-NV-7-REV RLC-NV-8-REV RLCMB-NV-10-REV RLCMB-NV-12-REV
RLCMB-NV-14-REV RLCMB-NV-6-REV RLCMB-NV-7-REV RLCMB-NV-8-REV
RLC-NV-10-SFX RLC-NV-12-SFX RLC-NV-14-SFX RLC-NV-6-SFX
RLC-NV-7-SFX RLC-NV-8-SFX RLCMB-NV-10-SFX RLCMB-NV-12-SFX
RLCMB-NV-14-SFX RLCMB-NV-6-SFX RLCMB-NV-7-SFX RLCMB-NV-8-SFX
RML27-10-REV RML27-10-SFX RML27-12-REV RML27-12-SFX
RML27-14-REV RML27-14-SFX RML27-6-REV RML27-6-SFX
RML27-7-REV RML27-7-SFX RML27-8-REV RML27-8-SFX
Resolve ConvertX® Nephroureteral Stent System
RCX10-10-038 RCX10-8-038 RCX12-10-038 RCX12-8-038 RCX22-10-038 RCX22-8-038
RCX14-10-038 RCX14-8-038 RCX20-10-038 RCX20-8-038 RCX26-10-038 RCX26-8-038
RCX24-10-038 RCX24-8-038 RCX28-10-038 RCX28-8-038
Resolve ConvertX® Biliary Stent System
RCXB10-10-038 RCXB15-10-038 RCXB5-10-038 RCXB7-10-038
Merit SureCross™ Support Catheter
SC1465 SC1890 SC14135 SC18150 SC1490 SC3565 SC14150 SC35135 SC1865 SC3590 SC18135
SC35150
ULTIMAXX-ES™ Fully Covered Esophageal Stent
90129-201 90129-204 90129-207 90129-210 90129-202 90129-205 90129-208 90129-211
90129-203 90129-206 90129-209 90129-215 90129-212 90129-213 90129-214
EndoMAXX® Fully Covered Esophageal Stent
MAXX-197 MAXX-1912 MAXX-237 MAXX-2310 MAXX-1910 MAXX-1915 MAXX-2312 MAXX-2315
AERO® Fully Covered Tracheobronchial Stent
90129-201 90129-206 90129-211 90129-216 90129-202 90129-207 90129-212 90129-217
90129-203 90129-208 90129-213 90129-218 90129-204 90129-209 90129-214
90129-205 90129-210 90129-215
AERO DV® Fully Covered Tracheobronchial Stent
90129-301 90129-305 90129-312 90129-316 90129-302 90129-306 90129-313 90129-317
90129-303 90129-310 90129-314 90129-318 90129-304 90129-311 90129-315
AEROmini® Fully Covered Tracheobronchial Stent
AERO815 AERO1215 AERO1015 AERO1415 AERO820 AERO1210 AERO1010 AERO1410
AERO810 AERO610 AERO615
AEROSIZER® Tracheobronchial Stent Sizing Device
90129-501
HeartSpan® Transseptal Needle
FND-019-00 FND-019-02 FND-019-04 FND-019-06 FND-019-01 FND-019-03 FND-019-05 FND-019-07
HeartSpan® Fixed Curve Braided Transseptal Sheath
FCL-160-00 FCL-160-07 FCB8563MR0 FCB8563120 FCL-160-01 FCL-160-08 FCB8581MR0 FCB8581120
FCL-160-02 FCL-160-09 FCB8563ML0 FCB8563135 FCL-160-03 FCL-160-10 FCB8581ML0 FCB8581135
FCL-160-04 FCB856345 FCB856390 FCB8581ML1 FCL-160-05 FCB858145 FCB8563150 FCB8581150
FCL-160-06 FCB8563ML1 FCB858190 FCB8581ML2 FCB8560MP18 FCB8560MP28 FCB8561MUL
FCB8563ML2
HeartSpan® Steerable Sheath Introducer

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HST-085-00 HST-085-10 HST-085-20

Name of Manufacturer
Manufacturing Site

Merit Maquiladora Mexico, S. DE R.L. DE C.V.
Avenida Sor Juana Ines de la Cruz
19970 Interior B, Edificio 2, Parque Industrial Frontera
Tijuana, Baja California
MEXICO 22630

Name of Product(s)

Fluid Management System
FAS1048 FAS1060 FAS1072 FAS1108 FAS1160 FAS1172 FAS1260 FAS1272
FAS1372 FAS2072 FAS3072 FAS6072 FAS4060 FAS4072 FAS4108 FAS5048 FAS5060 FAS5072
FAS5108 FAS5248
Merit Miser® Contrast Burette Assembly
MISER1 MISER2 MISER3 MISER4
Merit Miser® Contrast Burette Spike Assembly
MISER5
CT Transfer Set
TS120 TS220
RADSTAT® Radial Artery Compression System
RADSTD RADSRT RADCDS RADCDO
Finale® Vascular Compression Device
FCD100 FCD200
Merit Drainage Depot™
MDD600 MDD600PML
Merit Disposal Depot™
MDD100 MDD220 MDD200H MDD500H MDD110 MDD220H MDD300H MDD520H MDD400H
Replaceable Pressure Infusor Bag/ Dual Setting Pressure Relief
PIB500 PIB1000 PIB3000
Single Use Pressure Infusor Bag/Dual Setting Pressure Relief
PIB500EU PIB1000EU PIB3000EU
Protura® Safety Scalpel
SMS210 SMS211 SMS215
DugOut® Disposal Basin
DUG100 DUG1SS
BackStop® Disposal Basin
MBS100
BackStop®+ Disposal Basin
MBSP100
ShortStop® Temporary Sharps Holder
SS10
ShortStop Advantage® Temporary Sharps Holder
SS20
Revolution™Catheter Securement Device
CFG624
StayFIX® Catheter Fixation Device
680ME 685ME
MERIT® MAK MINI ACCESS KIT
MAK401 MAK501N-E MAK501NPDEBT MAK501-PED
MAK501 MAK401-PED MAK4F-10 MAK401N-PED
MAK401N MAK505PD MAK5F-10 MAK501N-PED
MAK501N MAK401NEBT MAK5F-15 MAK501NPD
MAK501N-15 MAK501NEBT MAK501NBT MAK501NPD-E
MAK405 MAK405-E MAK401NPDBT MAK405-PED
MAK405PD MAK505-PED MAK501NPDBT
MAK401NBT MAK401NPD MAK505 MAK501-E MAK401NPD-E MAK401-E

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MAK401N-E MAK401NPDEBT MAK505-E
MERIT® S-MAK™ MINI ACCESS KIT
S-MAK405 S-MAK501N15BT S-MAK401N S-MAK501 S-MAK505 S-MAK4F-10 S-MAK501N S-MAK401NBT
S-MAK401NPDBT S-MAK5F-10 S-MAK501N-15 S-MAK501NBT
S-MAK501NPDBT S-MAK5F-15 S-MAK401 S-MAK401NPD S-MAK501NPD
MERIT® S-MAK XL™
S-MAK430NUS S-MAK430N S-MAK430NPD
MERIT® MAK
MAK001 MAK001N-60 MAK005 MAKSSPD
MAK001N MAK001N-80 MAK005-60 MAKNTPD
MERIT® MAKNV™
MAK-NV-001 MAK-NV-007 MAK-NV-013 MAK-NV-019
MAK-NV-002 MAK-NV-008 MAK-NV-014 MAK-NV-020
MAK-NV-003 MAK-NV-009 MAK-NV-015 MAK-NV-021 MAK-NV-004 MAK-NV-010 MAK-NV-016
MAK-NV-005 MAK-NV-011 MAK-NV-017 MAK-NV-006 MAK-NV-012 MAK-NV-018
Performa® AngiographicCatheter
Performa® Angiographic Catheter Judkins Left
7501-13 7501-H1 7521-83 7601-21 7501-21 7521-13 7521-F1 7601-33
7501-33 7521-21 7574-13 7601-43 7501-43 7521-33 7574-21 7700-10
7501-53 7521-43 7574-33 7700-20 7501-63 7521-53 7574-43 7700-30
7501-73 7521-63 7601-13 7700-40 7501-83 7521-73
7521-L3 7521-N3 7700-A0 7700-C0 7521-M3 7521-P3 7700-B0 7700-D0
Performa® Angiographic Catheter Judkins Left Short-Tip
7501-A3 7501-B1 7501-C3 7501-D3
Performa® Angiographic Catheter Judkins Right
7503-13 7503-73 7523-43 7523-93 7503-21 7503-83 7523-53 7701-10
7503-33 7503-93 7523-63 7701-20 7503-43 7523-13 7523-73 7701-30
7503-53 7523-21 7523-83 7701-40 7503-63 7523-33
7523-L3 7523-N3 7701-A0 7701-C0 7523-M3 7523-P3 7701-B0 7701-D0
Performa® Angiographic Catheter Judkins Right Short-Tip
7503-A3 7503-C3 7523-E3 7523-G3 7503-B1 7503-D3 7523-F1 7523-H3
Performa® Angiographic Catheter Modified Judkins Right
7502-13 7502-23 7502-33 7502-43
Performa® Angiographic Catheter MultiPACK plus™
5MP6SW-145 6MPPROW-145 6MPSW-145 5MPSW-SNB 6MPPRO-11-S
5MPPRO-W-145 6MPPROW-N 6MPSW-N 6MPPRO-11-W-145
5MPSW-145 6MPPROW-S 6MPSW-S 6MPPRO-11-W-NP-18
5MPSW-S 6MPS-11-W-NP-18 6MPSW-S-18G 6MPS-145
6MPS-S 5MPS-145 5MPS-S 5MPSW-S-18G 6MPPRO-N 5MPPRO-S 5MPPROW-145
5MPPROW-S 5MPS7-W-145 5MP6PROW-NP-18 5MPPRO-11-N
5MPPRO-N 5MPPROW-N 5MPSW-N 4MPPRO-11-W-145 4MPPRO-W-145 4MPS-145-18
Performa® Angiographic Catheter Left Coronary Bypass
7510-13 7534-13 7709-10
Performa® Angiographic Catheter Right Coronary Bypass
7510-23 7534-23 7709-20
Performa® Angiographic Catheter Amplatz Left
7507-13 7527-13 7703-30 7507-23 7527-23 7703-10 7703-40
7507-33 7527-33 7703-20 7703-B0 7507-43 7527-43
Performa® Angiographic Catheter Amplatz Right
7506-13 7508-33 7528-23 7702-20 7508-13 7526-11 7528-33 7702-30
7508-23 7528-13 7702-10 7702-40
Performa® Angiographic Catheter Progressive Right Coronary
7512-13 7532-13 7600-11 7707-10 7512-23 7572-11
Performa® Angiographic Catheter Internal Mammary
7511-13 7531-23 7531-33 7706-10 7531-13
Performa® Angiographic Catheter Cardiac Pigtail
7509-11 7569-11 7704-70 7776-B3 7509-43 7569-43 7776-11 7777-21
7529-11 7602-11 7776-21 7777-B1 7529-43 7704-10 7776-B1

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Performa® Angiographic Catheter Cardiac Pigtail 145 Degree
7509-23 7529-53 7602-23 7776-C3 7509-53 7569-23 7704-20 7777-33
7529-23 7569-53 7776-33 7777-C3
Performa® Angiographic Catheter Cardiac Pigtail 155 Degree
7704-30 7529-33 7569-33 7602-33 7529-63 7776-43 7509-33
7509-63 7569-63 7777-D3 7777-43
Performa® Angiographic Catheter Infant Pediatric Pigtail
7757-10 7757-20
Performa® Angiographic Catheter Standard Pediatric Pigtail
7756-10 7756-20
Performa® Angiographic Catheter Multipurpose
7513-13 7513-B3 7533-23 7708-10 7513-23 7513-C3 7533-33 7708-20
7513-33 7513-D3 7533-43 7708-30 7513-43 7513-E3 7533-53 7708-40
7513-53 7513-F3 7533-63 7708-50 7513-63 7533-13 7533-B3 7708-60 7513-A3
Performa® Angiographic Catheter Sones
7520-13 7530-13 7705-10 7705-20 7520-23 7530-23
Performa® Angiographic Catheter Cardiac Multipack
7560-13 7560-53 7660-13 7660-A3 7560-13K 7560-83 7660-23 7660-B3
7560-23 7560-A3 7660-33 7660-D3 7560-C3 7751-10
7560-33 7560-F3 7660-53 7751-20 7560-43 7560-G3 7660-63 7751-50
7560-43K 7560-H0K 7660-23K 7751-20K 7560-73 7560-L3K 7660-D3K 7751-40K
7560-F3K 7660-13K
Performa® Angiographic Catheter LBR
7240-10 7240-20 7240-30
Performa® Angiographic Catheter IML BR
7242-10 7242-20
Performa® Angiographic Catheter RBR
7241-10
Performa® Angiographic Catheter Headhunter
5575-13 5575-D3 7715-A0 5575-13S 5575-A3 7715-10
5575-23 5575-B3 7715-30 7715-D0 5575-33 5575-C3
Performa® Angiographic Catheter Newton
5577-13 5577-A3 7722-10 7722-A0 5577-23 5577-B3 7722-30 7722-B0
5577-33 5577-C3 7722-40 7722-C0 5577-43 5577-D3 7722-D0
5577-53 5577-E3 7722-50S
Performa® Angiographic Catheter Bentson
5578-13 5578-A3 7721-10 7721-B0 5578-23 5578-B3 7721-20 7721-C0
5578-33 5578-C3 7721-A0
Performa® Angiographic Catheter Vertebral
5583-13 5583-B3 7717-30 7717-B0 5583-23 7717-10 7717-A0 7717-C0 5583-A3 7717-20
Performa® Angiographic Catheter Mani
5579-13 5579-A3 7716-A0
Performa® Angiographic Catheter Osborn
7746-10 7746-A0 7746-B0 7746-C0 7746-30
Performa® Angiographic Catheter Simmons
5576-13 5576-C3 7720-20 7720-A0 5576-23 5576-D3 7720-30 7720-B0
5576-33 5576-E3 7720-40 7720-C0 5576-43 5576-F3 7720-50 7720-D0
5576-A3 5576-G3 7720-70 7720-E0 5576-B3 7720-10
Performa® Angiographic Catheter Cobra
5584-13 5584-B3 7710-10 7710-A0 5584-23 5584-C3 7710-20 7710-B0
5584-33 5584-D3 7710-30 7710-C0 5584-43 5584-E3 7710-40 7710-D0
5584-53 5584-F3 7710-50 7710-E0 5584-63 5596-13S 7710-60 7710-F0 5584-A3
Performa® Angiographic Catheter Hook
5585-13 5585-A3 7711-10 7711-A0
5585-23 5585-B3 7711-20 7711-B0
Performa® Angiographic Catheter Modified Hook
7755-20S
Performa® Angiographic Catheter Modified Cerebral Selective

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5588-13 5588-A3 7723-A0 7723-10
Performa® Angiographic Catheter Berenstein
5592-13 5592-A3 5592-23 5592-B3 7718-10 7718-A0 7718-20 7718-B0
5592-33 5592-43 5592-C3 7718-30 7718-C0
Performa® Angiographic Catheter Straight Selective
7748-A0 7748-10
Performa® Angiographic Catheter MW2
5590-13 5590-33 5590-23
Performa® Angiographic Catheter Modified MW2
7745-A0 7745-C0 7745-10
Performa® Angiographic Catheter Shepherd Hook
5586-13 5586-B3 7712-20 7712-A0 5586-23 5593-43S 7712-30 7712-B0
5586-43 7712-10 7712-40 7712-C0 5586-A3
Performa® Angiographic Catheter Renal Double Curve
5587-13 5587-A3 7713-20 7713-B0 5587-23 7713-10
Performa® Angiographic Catheter Hockey Stick
7752-10 7543-13 7541-13
Performa® Angiographic Catheter Amir Motarjeme™
5591-A3 5591-B3 5591-C3 5591-D3
7747-C0 7747-D0 7747-E0 7747-F0
Performa® Angiographic Catheter Amir Motarjeme™ Cane
7747-10 7747-20 7747-A0 7747-B0 5591-E3 5591-F3
Performa® Angiographic Catheter Reuter
5589-13 5589-A3 7714-A0 5589-23 5589-B3
Performa® Angiographic Catheter Mikaelsson
5594-13 7719-A0 7719-10
Performa® Angiographic Catheter KA2
5582-13 5582-43 7514-13 7514-23
Performa® Angiographic Catheter Shepherd Flush
7602-A1 7602-B1 7602-C1 7602-D1
Performa® Angiographic Catheter Ultra Bolus Flush
7674-11 7674-21 7674-31 7674-41
Performa® Angiographic Catheter UHF Pigtail
7602-41 7602-61 7602-81 7602-91
7602-51 7602-71 7742-20S
Performa® Angiographic Catheter Pigtail Flush
7749-A0 7749-40
Performa® Angiographic Catheter UHF Straight Flush
7673-11 7673-21 7673-31 7673-41 7673-51 7673-61
Radial MultiPACK plus™
RADMPP-1 RADMPP-3 RADMPP-5 RADMPP-7 RADMPP-10
RADMPP-2 RADMPP-4 RADMPP-6 RADMPP-8 RADMPP-11
Radial MultiPACK Premier™
RADMPP-12
Performa® Angiographic Catheter KGCA
7738-10S
Performa® Angiographic Catheter Transradial Peripheral
PV411038PIG PV412538U4 PV512538PIG PV512538U4SH
PV412538BERN PV412538U45 PV512538REN PV612538MP2SH
PV412538MP1 PV512538BERN PV512538U1SH PV612538U1
PV412538MP2SH PV512538COB2 PV512538U2SH PV612538U2
PV412538U1 PV512538MP1 PV512538U3SH PV612538U3
PV412538U2 PV512538MP2SH PV512538U45SH PV612538U45
PV412538U3 PV413538BERN PV415038BERN PV513538BERN
PV515038BERN
Performa® Angiographic Catheter Ultimate
4100381ULT1 5100381ULT1 510038ULT4-T40 512538ULT2
4100381ULT2 5100381ULT1K 510038ULT4-T40K 6100381ULT1

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4100381ULT4-T40 5100381ULT2 510038ULT4-T45 6100381ULT2
4100381ULT4-T45 5100381ULT4-T40 5110381ULT1 6100381ULT4-T40
4100382ULT3 5100381ULT4-T45 5110381ULT2 6100382ULT3
410038ULT1 5100382ULT3 5110381ULT4-T40 610038ULT1
410038ULT2 510038ULT1 5110381ULT4-T45 610038ULT2
410038ULT3 510038ULT1K 5110382ULT3 610038ULT3
410038ULT4-T40 510038ULT2 512538ULT1 610038ULT4-T40
410038ULT4-T45 510038ULT3 5125382ULT3 612538ULT3
412538ULT2 5125381ULT1 512538ULT3 612538ULT4-T40
412538ULT3 5125381ULT2 512538ULT4-T45 612538ULT4-T45
412538ULT4-T40 5125381ULT4-T40 612538ULT2
412538ULT4-T45 5125381ULT4-T45
Performa® Angiographic Catheter MIV™
[redacted]PS110 5RPL125 5RPS110-NB 6RPL110 5RPL110 5RPS110 5RPS125 6RPS110
Performa® Angiographic Catheter Judkins Left
7521-A3 7521-B1 7521-C3
Performa® Angiographic Catheter Judkins Right
7523-A3 7701-50 7523-B1 7523-C3
Performa® Angiographic Catheter Left Coronary Bypass
7534-43
Performa® Angiographic Catheter Right Coronary Bypass
7534-33
Performa® Angiographic Catheter Amplatz Left
7527-63 7527-73
Performa® Angiographic Catheter Amplatz Right
7526-21
Performa® Angiographic Catheter Multipurpose
7533-D3
Performa® Angiographic Catheter Headhunter
7715-B0 7715-50 7715-60
Performa® Angiographic Catheter Newton
7722-20 7722-E0
Performa® Angiographic Catheter Bentson
[redacted]21-30
Performa® Angiographic Catheter Osborn
7746-20
Performa® Angiographic Catheter Simmons
7720-F0 7720-80
Performa® Angiographic Catheter MW2
7745-B0
Performa® Angiographic Catheter Renal Double Curve
7713-A0 510038PRDC
Performa® Angiographic Catheter Reuter
7714-10 7714-B0
Performa® Angiographic Catheter KA Selective
5582-23 5582-33
Performa® Angiographic Catheter DVS A1
5595-13 5595-23 5595-33 5595-43
Performa® Angiographic Catheter DVS A2
5595-A3 5595-B3 5595-C3 5595-D3
Performa® Angiographic Catheter Modified Hook
7603-A1 7603-B1 7603-C1 7603-D1
5585-C3 5585-D3 5585-E3
Performa® Angiographic Catheter Transradial Peripheral
PV612538U4 PV512538U3 PV512538U4 PV512538U45
PV612538PIG PV511038FH3 PV512538FH3 PV512538U1
PV512538U2
Performa® Angiographic Catheter Ultimate

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610038ULT4-T45 6100381ULT4-T45 6110381ULT1 6110381ULT2
6110382ULT3 6110381ULT4-T40 6110381ULT4-T45
612538ULT1 512538ULT4-T40 412538ULT1 412538ULT3
Performa® Angiographic Catheter Vertebral
410035VER-PNB
Performa® Angiographic Catheter Uterine Artery
56535PUAC2
Performa® Angiographic Catheter Berenstein
7718-40
Performa® Angiographic Catheter UHF Pigtail
4653510PIG-PNB
Performa® Angiographic Catheter MIV™
4RPL110 4RPL110-NB 4RPL125 4RPL125-NB
4RPS110-NB 4RPS125 4RPS125-NB 5RPL110-NB
[redacted]L125-NB 6RPL110-NB 6RPL125 6RPL125-NB
6RPS110-NB 6RPS125 6RPS125-NB 5RPS125-NB
Performa® Angiographic Catheter Shepherd Hook
7712-D0
Performa® Custom Catheters
1623-A72M 1623-B62M 1623-C720M 1623-D1 1623-D2 1623-D3 1623-D4 1623-D5 1623-D6 1623-E2 1623-E320M 1623-E93M
1623-F220M 1623-F320M 1623-F420M 1623-F620M 1623-F720M 1623-F820M 1624-69-20M 1624-71
1624-832M 1624-972M 1624-A32M 1624-A42M
1624-B220M 1624-B420M 1624-C120M 1624-C220M 1624-C320M 1624-C620M 1624-C820M 1624-C920M 1624-D110M 1624-D320M 1624-D719M
1624-D8 1624-D9 1624-E520M 1624-E75M 1624-E8 1624-E9 1625-26 1625-29 1625-31 1625-32
1625-33 1625-34 1625-36
1625-37 1625-38 1628-003 1628-031 1628-032 1628-045 1628-047 1628-049 1628-082 1628-085
1628-086 1628-092
1628-098 1628-099 1628-101 1628-102 1628-103 1628-104 1628-105 1628-106 1628-110 1628-111 1628-112 1628-122
1628-123 1628-124 1628-132 1628-134 1628-140 1628-141 1628-145 1628-146 1628-149 1628-150 1628-157 1628-161
[redacted]8-163 1628-165 1628-167 1628-169 1628-171 1628-176 1628-180 1628-184 1628-187 1628-191 1628-193 1628-194
1628-201 1628-203 1628-211 1628-212 1628-214 1628-218 1628-229 1628-230 1628-233 1628-235 1628-242 1628-243
1628-244 1628-245 1628-246 1628-247 1628-249 1628-250 1628-251 1628-252 1628-254 1628-255 1628-256 1628-257
1628-258 1628-259 1628-260 1628-262 1628-264 1628-265 1628-266 1628-267 1628-271 1628-274 1628-C1 1628-D1
1628-E1 1628-E2 1628-E8 1628-F1 1628-F2 1628-F6 1628-F7 1628-F8 1628-G4 1628-G5
1628-G9 1628-H1 1628-H2 1628-J1 1628-J2 1628-J3 1628-J5 1628-J8 1628-K1 1628-L3
1628-M3 1628-N3 1628-N5 1628-N6 1628-N8 1628-N9 1628-P2 1628-P3 1628-Q5 1628-Q6
1628-Q9 1628-R1 1628-R2 1628-R4 1628-R5 1628-R6 1628-R7 1628-R8 1628-R9 1628-S1
1628-S4 1628-T6 1628-U2 1628-U5 1628-V5 1628-V6 1628-V7 1628-W2 1628-X8 1628-Y1
1628-Z1 1628-Z8 7440-11 7440-12 7440-13 7440-15 7440-16 7440-21 7440-26 7440-27
7440-30 7440-31 7440-32 7440-33 7440-34 7440-42 7440-45 7440-53 7440-56 7440-60
7440-64 7440-65 7440-75 7440-79 7440-80 7440-81 7440-82 7440-83 7440-84 7440-85
7440-89 7440-90 7440-91 7440-93 7440-94 7440-95 7440-96 7440-97 7440-98 7440-99
7440-B2 7440-C3 7440-C5 7440-C7 7440-D1 7440-D3 7440-D4 7440-D5 7440-D6 7440-G2
7440-K2 7440-K3 7440-K6 7440-K7 7440-K8 7440-L1 7440-L2 7440-L3 7440-L4 7440-L8
7440-M4 7440-M8 7440-M9 7440-N1 7440-N2 7440-N3 7440-P4 7440-P5 7440-P6 7445-73
7445-83 7445-84 7445-88 7445-94 7445-95 7445-99 7445-A2 7445-A3 7445-A7 7445-A8
7445-B7 7445-B8 7445-F4 7445-F6 7445-F7 7445-F9 7445-G1 7445-G2 7445-G3 7445-G9
7445-H5 7445-H6 7445-J4 7445-J5 7445-J6 7445-J7 7445-J8 7445-J9 7445-K1 7445-K2
7445-H3 7445-H4 7445-K3 1623-G2 7445-B1 7445-B3 7445-80 7445-81 7440-L9 7440-M2
7440-H4 7440-J1 7440-A1 7440-A6 7440-87 7440-88 7440-61 7440-62 7440-28 7440-29

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1628-Y5 1628-Y9 1628-S2 1628-S3 1628-Q7 1628-Q8 1628-L7 1628-M1 1628-G6 1628-G8
Performa® Transradial Angiographic Catheter
PV413538BERN PV415038BERN PV415038U1 PV513538BERN
PV513538U1 PV515038BERN PV515038U1
FEP PIGTAIL Angiographic Catheter
1308-25-0085 1308-35-0086 1310-21-0043 1310-25-0064 1308-35-0065 1308-35-0006
1310-21-0053 1310-25-0084 1308-35-0085 1308-38-0006 1310-21-0054 1310-25-0065
1308-35-0005 1308-35-0007 1310-21-0064 1310-25-0085 1308-38-0007 1310-25-0054
Vessel Sizing Angiographic Catheter
46535AVS20MHK 510035AVS20MHK 510035AVS20PIG 510035AVS2MHK
510035AVS2PIG 510035AVS2STR 56535AVS20MHK 56535AVS20PIG
56535AVS2MHK 56535AVS2PIG 56535AVS2STR 7602-11M
7602-11M65 7602-20M 7602-20M100SH 7602-20M65
7602-20M65SH 7602-2M 7602-2M65 7603-11M100
7603-11M65 7603-20M100SH 7603-20M65SH 7603-2M100
7603-2M65 7673-11M100SH 7673-11M65SH 7673-20M100SH
7673-20M65SH 7673-2M 7673-2M65 7674-2M
7674-2M65 7742-20M100SH 7742-20M65SH 7742-2M100SH
7742-2M65SH 7743-2M100SH 7743-2M65SH 7744-2M100SH
7744-2M65SH 7755-2M100 7755-2M65 7757-2MP65
7757-2MP65SH 7757-2MP65SHA 7757-2MP65SHTC 7757-2MP65SHTCB
7757-2MP80 7757-2MP80SH 7757-2MP80SHTC
PreludeSYNC DISTAL™ Radial Compression Device Syringe
SDRB10AC
PreludeSYNC™ Radial Compression Devices
SRB24AC SRB24MED SRB29AC SRB29MED
PreludeSYNC EVO™ Radial Compression Devices
SRB29LBAC SRB24LBAC
PreludeSYNC DISTAL™ Radial Compression Devices
SDRB-REG-LT SDRB-REG-RT
PreludeSYNC EZ™ Radial Compression Device
EZ-SML EZ-REG
SAFEGUARD FOCUS™ Compression Device
SGF1V SGF1A
SAFEGUARD FOCUS COOL™ Compression Device
SGF1AC SGF1VC
SAFEGUARD® Pressure Assisted Device
SG127AC SG2440AC
SAFEGUARD™ Syringe
SG40ACB SG40AC
DriPAD™ Sterile Super Absorbent Pad
DRI2332E DRI0909E
DriPAD™ Non-Sterile Super Absorbent Pad
DRI2332 DRI0909 DRI2320
PRESSURE MONITOR Tubing
PM6006 PM6012 PM6024 PM6036 PM6048 PM6060 PM6072 PM6106 PM6112 PM6124
PM6148-B PM6148-R PM6160-Y PM6172-Y PM6184 PM6196 PM6136 PM6148 PM6096
PM6160-R PM6160 PM6172 PM6172-R
High Pressure Tubing
HP5100E HP5101E HP5200E HP5201E HP5300E HP5301E HP5480E HP5481E HP9100E
HP9300E HP9301E HP9480E HP9481E HP9720E HP9721E HPC100E HPC101E HPC200E
HPC390E HPC391E HPC480E HPC481E HPC590E HPC591E HPC720E HPC721E HPF100E
HPF201E HPF201K HPF300E HPF300K HPF301E HPF301K HPF480E HPF480K HPF481E
HPF720E HPF720K HPF721E HPF721K HPT100E HPT101E HPT200E HPT201E HPT300E
HP9101E HP9200E HP9201E HPC201E HPC300E HPC301E HPF101E HPF200E HPF200K
HPF481K HPF600K HPF601K HPT301E HPT480E HPT481E HPT590E HPT591E
Evacuated Drainage Bottle
EVAC1000

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Aspira Peritoneal Drainage System
4992206 4992207 4992208 4992209
4992207B 4992204 4992224 4992224B
Aspira Pleural Drainage System
4992506 4992507 4992508 4992509
4992507B 4992524B 4992524 4992504
Aspira Drainage Accessories
4991503 4992301 4992305 4992306
4992307 ASP-4 ASP-10
Corvocet™ Biopsy System
CORA1410 CORA1410S CORCA1410 CORCA1825B CORA1415 CORA1415S CORCA1415
CORA1610 CORA1610S CORCA1610 CORCA2015B CORA1615 CORA1615S CORCA1615
CORA1810 CORA1810S CORCA1410S CORCA1810SB CORA1815 CORA1815S CORCA1415S
CORA1820 CORA1820S CORCA1610S CORCA1820SB CORA1825 CORA1825S CORCA1615S
CORA2010 CORA2010S CORCA1810B CORCA2010SB CORA2015 CORA2015S CORCA1815B
CORA2020 CORA2020S CORCA1820B CORCA2020SB CORCA2010B CORCA2020B CORCA1815SB
CORCA1825SB CORCA2015SB
Corvocet™ Coaxial Introducer
CORC1410 CORC1615 CORC1820B CORC2015B CORC1415 CORC1810B CORC1825B CORC2020B
CORC1610 CORC1815B CORC2010B
Tru-Cut® Biopsy Needles
2N2700X 2N2702X 2N2704X 2N2711X 2N2712X 2N2713X
Achieve® Programmable Automatic Biopsy System
A1411 A1415 A1420 A146 A149 A1611 A1615 A1620 A166 A169 A1811 A1815
A1820 A1825 A186 A189 A2011 A2015 A2020 A206 A209
CA1411 CA1415 CA1420 CA1611 CA1615 CA1620 CA1811 CA1815 CA1820 CA2011 CA2015 CA2020
Pink Achieve™ Programmable Automatic Biopsy System
BA1211 BA1215 BA129 BA1411 BA149 BCA1211 BCA1215 BCA1411
Adjustable Coaxial Temno™ A.C.T Biopsy Device
ACT1415 ACT1811 ACT1815 ACT1820 ACT2011 ACT2015 ACT2020 ACT2211 ACT2215
Temno® Biopsy Device
CT1411 CT1415 CT1420 CT1611 CT1615 CT1620 CT1811 CT1815 CT1820 CT2011 CT2015 CT2020
CT2215 CT2220
T1411 T1415 T1420 T146 T149 T1611 T1615 T1620 T166 T169 T1811 T1815
T1820 T186 T189 T1915 T2011 T2015 T2020 T206 T209 T2215 T226 T229
Temno Evolution® Biopsy Device
CTT1411 CTT1415 CTT1420 CTT1611 CTT1615 CTT1620 CTT1811 CTT1815 CTT1820 CTT2011
CTT2015 CTT2020
TT1411 TT1415 TT1420 TT146 TT1611 TT1615 TT1620 TT166 TT1811 TT1815 TT1820 TT186 TT2011
TT2015 TT2020 TT206
Temno® Coaxial Introducer
PP13510 PP1356 PP1510A PP1515A PP156 PP1710 PP1715 PP176
PP1910 PP1915 PP196 PP2010 PP2015 PP206
MERIT PAK™ PEDAL ACCESS KIT
PAKM4NPD4 PAKM4NPD7 PAKM5NPD4 PAKM5NPD7
MERIT PAK™ PEDAL ACCESS KIT Stiffened
PAKS4NPD4 PAKS4NPD7 PAKS5NPD4 PAKS5NPD7
Transvalvular Insertion Tool
MIS-105-00 MIS-099-00
Prelude SNAP Splittable Sheath Introducer
PLS-1006 PLS-1007 PLS-1008 PLS-1008.5 PLS-1009 PLS-1009.5 PLS-1010 PLS-1010.5
PLS-1012.5 PLS-2506 PLS-2507 PLS-2508 PLS-2509 PLS-2510 PLS-2510.5 PLS-2511
PLSX-1008 PLSX-1008.5 PLSX-1009 PLSX-1009.5 PLSX-1010 PLSX-1010.5 PLSX-1011
PLSX-2506 PLSX-2507 PLSX-2508 PLSX-2509 PLSX-2510 PLSX-2510.5 PLSX-2511
PLS-1011 PLS-1012 PLSX-1006 PLSX-1007 PLSX-1012 PLSX-1012.5
Hydrophilic Prelude SNAP Splittable Introducer
PLSH-1006 PLSH-1007 PLSH-1008 PLSH-1008.5 PLSH-1009 PLSH-1009.5 PLSH-1010 PLSH-1010.5
PLSH-1012 PLSH-1012.5 PLSH-2506 PLSH-2507 PLSH-2508 PLSH-2509 PLSH-2510 PLSH-2510.5

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PLSH-1011 PLSH-2511
Prelude SNAP Splittable Sheath Introducer
PLSS-1006 PLSS-1007 PLSS-1008 PLSS-1008.5 PLSS-1009 PLSS-1009.5 PLSS-1010 PLSS-1010.5
PLSS-1012 PLSS-1012.5 PLSS-2506 PLSS-2507 PLSS-2508 PLSS-2509 PLSS-2510 PLSS-2510.5
PLSS-1011 PLSS-2511
Prelude SNAP 165 Valved Splittable Sheath Introducer
PLS165
Classic Sheath Splittable Sheath Introducer
CLS-1006 CLS-1009.5 CLS-1012.5 CLS-2510 CLS-1007 CLS-1010 CLS-2506 CLS-2510.5
CLS-1008 CLS-1010.5 CLS-2507 CLS-2511 CLS-1008.5 CLS-1011 CLS-2508
CLS-1009 CLS-1012 CLS-2509
Worley™ Advanced CSG Coronary Sinus Guide
WOR-CSG-B1-09 WOR-CSG-B2-09 WOR-CSG-BL1-09 WOR-CSG-BR1-09 WOR-CSG-E-90
WOR-CSGS-B1-09 WOR-CSGS-B2-09 WOR-CSGS-BL1-09 WOR-CSGS-BR1-09
Worley™ Advanced LVI Lateral Vein Introducers
WORLVI-75-5-62-07-HO WORLVI-75-5-62-55-HO WORLVI-75-5-62-55-HS WORLVI-75-5-62-07-MP
WORLVI-75-5-62-07-HS WORLVI-75-5-62-55-RE WORLVI-75-5-62-55-MP WORLVI-75-5-62-07-RE
Prelude Prestige™ Splittable Sheath Introducer
PLP-1005 PLP-1006 PLP-1007 PLP-1008 PLP-1008.5 PLP-1009 PLP-1009.5 PLP-1010 PLP-1010.5
PLP-1013 PLP-1014 PLP-1015 PLP-1016 PLP-2505 PLP-2506 PLP-2507 PLP-2508 PLP-2509 PLP-2510
PLP-2513 PLP-2514 PLP-2515 PLP-2516 PLPS-1005 PLPS-1006 PLPS-1007 PLPS-1008 PLPS-1008.5
PLPS-1010.5 PLPS-1011 PLPS-1012 PLPS-1012.5 PLPS-1013 PLPS-1014 PLPS-1015 PLPS-1016
PLPS-2508 PLPS-2509 PLPS-2510 PLPS-2511 PLPS-2512 PLPS-2513 PLPS-2514 PLPS-2515
PLP-1012 PLP-1012.5 PLP-2511 PLP-2512 PLPS-1009.5 PLPS-1010 PLPS-2506 PLPS-2507
PLP-1011 PLPS-1009 PLPS-2505 PLPS-2516
Endotek BIG60® Inflation Device
ENDO-AN6012
BIG60 ALPHA™ Infaltion Device
EN-AL6012
Cultura™ Flex Swab Sterile Flocked Nasopharyngeal Collection Device
C100F C100FS
Worley™ Slitter
WC100
BasixCOMPAK™ Inflation Device
IN4130 IN4230 IN4330 IN4352 IN4430 IN4462 IN4463 IN4464 IN4465 IN4530 IN4802 IN4852
IN4901 IN4902 IN4903 IN4904 IN4905 IN4906 IN4907 IN4908 IN4909 IN4910 IN4911 IN4912
IN4913 IN4914 IN4915 IN4916 IN4917 IN4918 IN4919 IN4952 ENDO-AN2030
ONE1STEP™ Centesis Catheter
OSC-4F-10 OSC-4F-10L OSC-4F-10LNH OSC-4F-10NH OSC-4F-10S OSC-4F-12PL OSC-4F-12PS
OSC-4F-17PS OSC-4F-7 OSC-4F-7L OSC-4F-7LNH OSC-4F-7NH OSC-4F-7S OSC-5F-10 OSC-5F-10L
OSC-5F-10LNH OSC-5F-10NH OSC-5F-10S OSC-5F-12PL OSC-5F-12PS OSC-5F-15 OSC-5F-15L
OSC-5F-15NH OSC-5F-15S OSC-5F-17PL OSC-5F-17PS OSC-5F-7 OSC-5F-7L OSC-5F-7LNH
OSC-5F-7S OSC-6F-10L OSC-6F-10S OSC-6F-12PL OSC-6F-12PS OSC-6F-15L OSC-6F-15S
OSC-6F-17PS OSC-6F-7L OSC-6F-7S OSC-8F-10L OSC-8F-10S OSC-8F-12PL OSC-8F-12PS
OSC-8F-15S OSC-8F-17PL OSC-8F-17PS OSC-8F-7L OSC-8F-7S OSC-6F-17PL OSC-8F-15L
OSC-4F-17PL OSC-5F-15LNH OSC-5F-7NH
ONE1STEP™ Valved Centesis Catheter
OSC-4F-10LT OSC-4F-10T OSC-4F-12PLT OSC-4F-12PT OSC-4F-17PLT OSC-4F-17PT OSC-4F-7LT
OSC-5F-10LT OSC-5F-10T OSC-5F-12PLT OSC-5F-12PT OSC-5F-15LT OSC-5F-15T OSC-5F-17PLT
OSC-5F-7LT OSC-5F-7T OSC-6F-10LT OSC-6F-10T OSC-6F-12PLT OSC-6F-12PT OSC-6F-15LT
OSC-6F-17PLT OSC-6F-17PT OSC-6F-7LT OSC-6F-7T OSC-8F-10LT OSC-8F-10T OSC-8F-12PLT
OSC-8F-15LT OSC-8F-15T OSC-8F-17PLT OSC-8F-17PT OSC-8F-7LT OSC-8F-7T OSC-8F-12PT
OSC-5F-17PT OSC-4F-7T OSC-6F-15T OSC410T OSC510T
BasixTOUCH™ Inflation Device
IN8100 IN8112 IN8130 IN8152 IN8302 IN8352 IN8353 IN8403 IN8802 IN8852 IN8952
BasixTOUCH40™ Inflation Device
IN8140
Stabilit Touch™

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IN8KVCF IN8VCF
Contamination Sleeve
CON-006-01 CON-006-02
Cen-Step™ Centesis Catheter
CSC-5F-7S CSC-5F-15S CSC-5F-10S CSC-4F-7S CSC-4F-10S
Merit Angioplasty Pack™
MAP101 MAP102 MAP104 MAP111 MAP112 MAP113 MAP150 MAP151 MAP152 MAP152SD
MAP153 MAP154 MAP220 MAP221 MAP222 MAP300 MAP301 MAP302 MAP350 MAP351
MAP352 MAP353 MAP354 MAP400 MAP403 MAP450 MAP453 MAP900 MAP952
Merit Angioplasty Pack™ PhD™ Hemostasis Valve
MAP800 MAP801 MAP802 MAP803 MAP804 MAP850 MAP851 MAP852 MAP853 MAP854
FLO40XR™ Hemostasis Valve
FLO40XR FLO40XR51 FLO40XR52 FLO40XR53 FLO40XR54
Resolve® Repositioning Tool
-RTOOL
Resolve®NL Hydrophilic Coated Non-Locking Drainage Catheter
RNL-10-038J RNL-10-038S RNL-12-038J RNL-12-038S
RNL-6-038J RNL-6-038S RNL-7-038J RNL-7-038S
RNL-8-038J RNL-8-038S
Resolve® Hydrophilic Coated Locking Drainage Catheter
RLC-10-038 RLC-12-038 RLC-14-038 RLC-6-038
RLC-7-038 RLC-8-038 RLC15-10-038MB RLC15-12-038MB
RLC15-14-038MB RLC15-6-038MB RLC15-7-038MB RLC15-8-038MB
RLC40-10-038MB RLC40-12-038MB RLC40-14-038MB RLC40-6-038MB
RLC40-7-038MB RLC40-8-038MB RLC-10-038MB RLC-12-038MB
RLC-14-038MB RLC-6-038MB RLC-7-038MB RLC-8-038MB
RLC-NV-10 RLC-NV-12 RLC-NV-14 RLC-NV-6
RLC-NV-7 RLC-NV-8 RLCMB-NV-10 RLCMB-NV-12
RLCMB-NV-14 RLCMB-NV-6 RLCMB-NV-8 RLCMB-NV-7
Resolve® Hydrophilic Coated Biliary Locking Drainage Catheter
RBC-10-038 RBC-12-038 RBC-14-038 RBC-8-038
RBDC-10-038 RBDC-12-038 RBDC-14-038 RBDC-8-038
Resolve Mini™ Hydrophilic Coated Locking Drainage Catheter
L17-10-038MB RML17-12-038MB RML17-14-038MB RML17-6-038MB
RML17-7-038MB RML17-8-038MB RML27-10-038MB RML27-12-038MB
RML27-14-038MB RML27-6-038MB RML27-7-038MB RML27-8-038MB
RML42-10-038MB RML42-12-038MB RML42-14-038MB RML42-6-038MB
RML42-7-038MB RML42-8-038MB
Resolve ConvertX® Biliary Stent System
RCXB10-10-038 RCXB15-10-038 RCXB5-10-038 RCXB7-10-038
Resolve®+
RBC-10-REV RBC-12-REV RBC-14-REV RBC-8-REV
RBDC-10-REV RBDC-12-REV RBDC-14-REV RBDC-8-REV
RBC-10-SFX RBC-12-SFX RBC-14-SFX RBC-8-SFX
RBDC-10-SFX RBDC-12-SFX RBDC-14-SFX RBDC-8-SFX
RLC-10-REV RLC-12-REV RLC-14-REV RLC-6-REV
RLC-7-REV RLC-8-REV RLCMB-10-REV RLCMB-12-REV
RLCMB-14-REV RLCMB-6-REV RLCMB-7-REV RLCMB-8-REV
RLC-10-SFX RLC-12-SFX RLC-14-SFX RLC-6-SFX
RLC-7-SFX RLC-8-SFX RLCMB-10-SFX RLCMB-12-SFX
RLCMB-14-SFX RLCMB-6-SFX RLCMB-7-SFX RLCMB-8-SFX
RLC-NV-10-REV RLC-NV-12-REV RLC-NV-14-REV RLC-NV-6-REV
RLC-NV-7-REV RLC-NV-8-REV RLCMB-NV-10-REV RLCMB-NV-12-REV
RLCMB-NV-14-REV RLCMB-NV-6-REV RLCMB-NV-7-REV RLCMB-NV-8-REV
RLC-NV-10-SFX RLC-NV-12-SFX RLC-NV-14-SFX RLC-NV-6-SFX
RLC-NV-7-SFX RLC-NV-8-SFX RLCMB-NV-10-SFX RLCMB-NV-12-SFX
RLCMB-NV-14-SFX RLCMB-NV-6-SFX RLCMB-NV-7-SFX RLCMB-NV-8-SFX
RML27-10-REV RML27-10-SFX RML27-12-REV RML27-12-SFX

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RML27-14-REV RML27-14-SFX RML27-6-REV RML27-6-SFX
RML27-7-REV RML27-7-SFX RML27-8-REV RML27-8-SFX
Impress® Angiographic Catheter
Impress® Angiographic Catheter Radial Internal Mammary
411038RADIM 511038RADIM
Impress® Angiographic Catheter Coronary Sinus
57538CS 1628-Y8M
Impress® Angiographic Catheter Fischook
PVI511038FH3 PVI512538FH3
Impress® Angiographic Catheter Headhunter
410035HH1 410038HH3 510035HH1 512535HH1 410035HH3 412535HH1 510038HH3 512538HH1
410038HH1 510035HH3 510038HH1
410038HH1-H 412538HH1-H 510038HH1-H 512538HH1-H
Impress® Angiographic Catheter Newton
[redacted]0038N1 510038N4 410038N3 510038N2 410038N4 410038N2 510038N3 510038N1
Impress® Angiographic Catheter Bentson
46535B1 410035B1 510038B1 510035B1
410035B2 510035B2 56535B1 410038B1
410038B1-H 510038B1-H 410038B2-H 510038B2-H
Impress® Angiographic Catheter Mani
410035MANI 510035MANI 410038MANI 510038MANI
410038MANI-H 510038MANI-H
Impress® Angiographic Catheter Vertebral
46538VER 510038VER 56538VER 410038VER
412535VER 410035VER 512535VER 510035VER
56538VER-H 510038VER-H 46538VER-H 410038VER-H
Impress® Angiographic Catheter Modified Cerebral
410035MC 410038MC 510035MC 510038MC
Impress® Angiographic Catheter Berenstein
46535BER 510035BER 410038BER 53035BER 56538BER 410035BER 512538BER 56535BER
46538BER 510038BER 412538BER 43035BER
46538BER-H 410038BER-H 56538BER-H 510038BER-H
412538BER-H 512538BER-H
[redacted]press® Angiographic Catheter MW2
44038MW2 56538MW2
Impress® Angiographic Catheter Simmons
46535SIM1 410035SIM1 410038SIM2 56535SIM1 46538SIM1 410035SIM2 48035MODS 56538SIM1
46538SIM2 410038SIM1 48038MODS 56538SIM2 512535SIM1
510035SIM1 510035SIM2 510038SIM1 510038SIM2
410038SIM1-H 510038SIM1-H 410038SIM2-H 510038SIM2-H
Impress® Angiographic Catheter Cobra
465352CB1 410038CB2 565352CB1 46538CB2
465352CB2 510038CB1 565352CB2 410038CB1
46535CB2 510038CB2 565382CB1 56538CB1
465382CB1 465382CB2 565382CB2 56538CB2
46538CB1
46538CB1-H 56538CB1-H 46538CB2-H 410038CB2-H
56538CB2-H 510038CB2-H
Impress® Angiographic Catheter Modified Cobra
43035MODCB1 53035MODCB1
Impress® Angiographic Catheter Hook
465352HK0-8 565352HK0-8 465352HK1-0 565352HK1-0
Impress® Angiographic Catheter Shepherd Hook
465352SH0-8 465352SH1-0 565352SH0-8 565352SH1-0
Impress® Angiographic Catheter Renal Vein Renin
56538IRG1 56538IRG2
Impress® Angiographic Catheter Renal Double Curve
465352RC 565352RC 46535RC 510038IRDC

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Impress® Angiographic Catheter Amir Motarjeme™
46535MOT 410035MOT 56535MOT 510035MOT
Impress® Angiographic Catheter Amir Motarjeme™ Cane
46535MOTC 410035MOTC
Impress® Angiographic Catheter Reuter
48038RE 58035RE 58038RE
Impress® Angiographic Catheter Mikaelsson
48038MIK 58038MIK
Impress® Angiographic Catheter KA2
56538KA2 44038KA2 46538KA2 54038KA2 53035KA2 43035KA2
44038KA2-H 46538KA2-H 54038KA2-H 56538KA2-H
Impress® Angiographic Catheter Hockey Stick
410038HS 510038HS
Impress® Angiographic Catheter Modified Hook
035MHK1 48035MHK2 48035MHK3 58035MHK1
58035MHK3 58035MHK2
48038MHK1-H 58038MHK1-H 48038MHK2-H 58038MHK2-H
48038MHK3-H 58038MHK3-H
465356MHK-NB 490356MHK-NB 590386MHK-NB 565356MHK-NB 565386MHK-NB
Impress® Angiographic Catheter Straight Selective
46538STS 56538STS 511038STS 44035STS
411035STS 411038STS 511035STS 44038STS 54035STS 54038STS
46538STS-H 410038STS-H 56538STS-H 510038STS-H
412538STS-H 512538STS-H
Impress® Angiographic Catheter Straight
53035STR 43035STR
4653510STF-NB 4903510STF-NB 5653510STF-NB 5903510STF-NB
Impress® Angiographic Catheter Renal, Bifurcation, Iliac
465354RBI 565354RBI 510035RBI 56535RBI
5100354RBI 56538RBI-H
Impress® Angiographic Catheter RIM
56535RIM 46535RIM 44035RIM 54035RIM
53035RIM 43035RIM
ress® Angiographic Catheter Mini RIM
56535MRIMST
Impress® Angiographic Catheter Shepherd Flush
465356SHP-NB 490356SHP-NB 565356SHP-NB
Impress® Angiographic Catheter Ultra Bolus Flush
4653510UBF-NB 5653510UBF-NB 4903510UBF-NB 5903510UBF-NB
Impress® Angiographic Catheter Modified Bolus Flush
5653810MUBF-NB 4653810MUBF-NB
Impress® Angiographic Catheter Pigtail Flush
4653510PIG-NB 51103810PIG-NB 5653810PIG-NB 5903510PIG-NB 5653510PIG-NB 4903510PIG-NB
51103510PIG-NB 5303510PIG-NB 4303510PIG-NB 41103510PIG-NB 5903810PIG-NB
Impress® Angiographic Catheter Osborn
410035OSB1 510035OSB1
Impress® Angiographic Catheter Multipurpose A1
410038MPA1 412538MPA1 46538MPA1 56538MPA1 510038MPA1 512538MPA1
410038MPA1-H 510038MPA1-H
Impress® Angiographic Catheter Ultimate
5IMP10038ULT1 5IMP100381ULT1 5IMP110381ULT2 5IMP11038ULT2
5IMP110381ULT4-T40 5IMP11038ULT4-T40
Impress® Angiographic Catheter Uterine Artery
59035UAC 59038UAC 59035IUAC
Impress® Angiographic Catheter CPC
57538CARN5 57538CARN5S 57538CARN10 57538CARN10S 57538CARN15 57538CARN15S
Impress® UAC2™ Uterine Artery Catheter
59035IUACTMB-H

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Impress® Angiographic Catheter 3D Curve
58038IRH1 58038IRH2
Impress® Custom Catheter
1623-E1 1623-E6 1623-F9 1623-G1 1624-B5 1624-B7 1624-C7 1624-D5 1624-E6 1628-001 1628-005
1628-016 1628-017 1628-019 1628-021 1628-034 1628-035 1628-037 1628-042 1628-043 1628-044
1628-059 1628-060 1628-061 1628-062 1628-063 1628-064 1628-065 1628-073 1628-079 1628-083
1628-100 1628-113 1628-118 1628-121 1628-128 1628-133 1628-148 1628-151 1628-152 1628-155
1628-168 1628-178 1628-179 1628-181 1628-182 1628-183 1628-189 1628-192 1628-197 1628-198
1628-202 1628-204 1628-205 1628-206 1628-206H 1628-207 1628-208 1628-209 1628-210 1628-213
1628-219 1628-220 1628-221 1628-222 1628-223 1628-224 1628-225 1628-228 1628-231 1628-232
1628-237 1628-238 1628-239 1628-240 1628-241 1628-248 1628-253 1628-261 1628-268 1628-269
1628-275 1628-W7 1628-Y7 1628-Y8 1628-Z4 1628-Z5 1628-Z7 1628-Z9 7440-E7 7440-F6 7440-F7
7440-H5 7440-H6 7440-H8 7440-H9 7440-J4 7440-J5 7440-J7 7440-J8 7440-K4 7440-K5 7440-L5
7440-M1 7440-M3 7440-M5 7440-M6 7440-N4 7440-N5 7440-N6 7440-N7 7440-N8 7440-N9 7440-P1
7440-P3 7440-P7 7440-P8 7440-P9 7440-Q1 7440-Q2 7440-Q3 7440-Q4 7440-Q5 7440-Q6 1628-017M
1628-015 1628-054 1628-095H 1628-166 1628-200 1628-217 1628-236 1628-272 7440-G8
7440-P2 1628-019M 7440-L6 1628-050 1628-094 1628-164 1628-199 1628-216 1628-234 1628-270
Impress® Angiographic Catheter Double Loop 3D Curve
57538IDLOOP
HeartSpan® Transseptal Needle
FND-019-00 FND-019-02 FND-019-04 FND-019-06 FND-019-01 FND-019-03 FND-019-05 FND-019-07
Resolve ConvertX® Nephroureteral Stent System
RCX10-10-038 RCX10-8-038 RCX12-10-038 RCX12-8-038 RCX22-10-038 RCX22-8-038
RCX14-10-038 RCX14-8-038 RCX20-10-038 RCX20-8-038 RCX26-10-038 RCX26-8-038
RCX24-10-038 RCX24-8-038 RCX28-10-038 RCX28-8-038
Vessel Dilator
3339-21 3339-31 3339-41 3339-51
Worley™ VEIN SELECTOR Angiographic Catheter
57538CS-WOR 57538CSV-WOR 57538CSHK-WOR

Name of Manufacturer
Manufacturing Site
MERIT MEDICAL SYSTEMS, INC
1701 Kingston Avenue
Chester, VA
USA 23836

Name of Product(s)
PERICARDIOCENTESIS KIT
PC101 PC801 PC201 PC802 PC804EU
Waste Management Kit
BRC-BAL-INT-FL BRC-BAL-INT-SL
OUTAKE® Catheter Extraction Device
CET100 CET200 CET300
ReSolve® Thoracostomy Tray
RTT14038MB RTT14038MBND
Angiography Tray 1
K09T-08878
Convenience Kits
KXX-YYYYY
'K' - indicates that it is a Kit 'XX' - designates the Kit type
YYYYY' - is a sequential number uniquely identifying the Kit 'KXXT' - indicates that it is a Procedure Pack
'-' is the character - (dash) K05 = Inflation Kit K09 = Manifold K10 = Waste Collection (Disposable Depots, Drainage Kits)

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K11 = Pressure Monitoring (MeritTrans™) K12 = Miscellaneous K17 = Electrophysiology Kit K20 = Bronchoscopy Kit

----------END OF PRODUCT LIST----------

sacosta

QUIRNO CODAS THOMPSON LLANO
Traductor Público Matriculado
Reclus 283
Tel.: 600 865 – Fax 612 314
Asunción - Paraguay

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APOSTILLA

(Convención de La Haya del 5 de octubre de 1961)

1. País: Estados Unidos de América

2. Este documento público

2. ha sido firmado por el CDR Cesar A. Pérez, PhD, Director

3. actuando en calidad de DRP2: División de Apoyo a Establecimientos, Oficina de Programas Regulatorios

4. lleva el sello/timbre del Departamento de Salud y Servicios Humanos de los Estados Unidos

Certificado

5. en Washington, D.C.

6. el dos de diciembre de 2023

7. por el Oficial de Autenticación del Departamento de Estado de los Estados Unidos

8. No. 23073510-2

9. Seal/Stamp:

10. Firma

Nekisha V. Skinner

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los días del mes de julio del 2025

QUIRNO CODAS THOMPSON LL.
Traductor Público
Matrícula N° 670

2026-07-22 10:05:56.224342-03

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Traductor Público Matriculado
Reclus 283
Tel.: 600 865 – Fax 612 314
Asunción - Paraguay

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CERTIFICADO N°1301-11-2024

CERTIFICADO AL GOBIERNO EXTRANJERO

Para permitir la importación de productos estadounidenses a países extranjeros, el Departamento de Alimentos y Medicamentos de EE.UU. (FDA) certifica la siguiente información relativa al producto(s) a exportar que se enumeran a continuación:

Nombre del producto(s)
Ver lista adjunta
(22 Paginas)

Nombre del fabricante/distribuidor, dirección
Ver lista adjunta
(una página)

Los productos descritos anteriormente (y los sitios de fabricación/distribución que los producen/distribuyen) están sujetos a la jurisdicción de la FDA según la Ley Federal de Alimentos, Medicamentos y Cosméticos.

Se certifica que los productos anteriores pueden comercializarse y exportarse legalmente desde los Estados Unidos de América.
América en este momento. Las plantas de fabricación en las que se produce el producto están sujetas a controles periódicos inspecciones. La última inspección de este tipo mostró que la(s) planta(s), en ese momento, parecían estar en condiciones sustanciales. Cumplimiento de los requisitos actuales de buenas prácticas de fabricación para los productos enumerados anteriormente.

Atentamente

CDR Cesar A. Perez, PhD, Director
DRP2: División de apoyo al establecimiento
Oficina de Programas Regulatorios
Oficina de Evaluación y Calidad de Producto Centro de Dispositivos y Salud Radiológica
Administración de Alimentos y Medicamentos de EE. UU., DHHS

Este certificado tiene una vigencia del 15 de noviembre de 2024 al 14 de noviembre de 2026.

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay a los días del mes de agosto del 2025

QUIRNO CODAS THOMPSON LL.
Traductor Público
Matrícula Nº 670

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Traductor Público Matriculado
Reclus 283
Tel.: 600 865 – Fax 612 314
Asunción - Paraguay

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Certificado N° **1301-11-2024-1**

Nombre del propietario operador
Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT
USA 84095

Nombre del fabricante
Sitio de fabricación
Merit Medical Systems, Inc.
14646 Kirby Drive
Houston, TX
USA 77047

Sitio de fabricación
MERIT MEDICAL SYSTEMS, INC
12701 Kingston Avenue
Chester, VA
USA 23836

Sitio de fabricación

Merit Maquiladora Mexico, S. DE R.L. DE C.V.
Avenida Sor Juana Ines de la Cruz
19970 Interior B, Edificio 2, Parque Industrial Frontera
Tijuana, Baja California
MEXICO 22630

Nombre del fabricante/distribuidor
Fabricante/Distribuidor legal
MERIT MEDICAL SYSTEMS, INC.
1600 WEST MERIT PKWY.
South Jordan, UT
USA 84095

----FIN DE LA LISTA DE FABRICANTES/DISTRIBUIDORES----

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los 05 días del mes de agosto del 2025

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Traductor Público
Matrícula Nº 670

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Traductor Público Matriculado
Reclus 283
Tel.: 600 865 – Fax 612 314
Asunción - Paraguay

Certificado N° 1301-11-2024-1
Nombre del fabricante
Sitio de fabricación
Merit Medical Systems, Inc.
14646 Kirby Drive
Houston, TX
USA 77047

Nombre del producto(s)

FEP PIGTAIL Angiographic Catheter
1308-25-0085 1308-35-0086 1310-21-0043 1310-25-0064 1308-35-0065 1308-35-0006
1310-21-0053 1310-25-0084 1308-35-0085 1308-38-0006 1310-21-0054 1310-25-0065
1308-35-0005 1308-35-0007 1310-21-0064 1310-25-0085 1308-38-0007 1310-25-0054
Vessel Sizing Angiographic Catheter
46535AVS20MHK 510035AVS20MHK 510035AVS20PIG 510035AVS2MHK
510035AVS2PIG 510035AVS2STR 56535AVS20MHK 56535AVS20PIG
56535AVS2MHK 56535AVS2PIG 56535AVS2STR 7602-11M
7602-11M65 7602-20M 7602-20M100SH 7602-20M65
7602-20M65SH 7602-2M 7602-2M65 7603-11M100
7603-11M65 7603-20M100SH 7603-20M65SH 7603-2M100
7603-2M65 7673-11M100SH 7673-11M65SH 7673-20M100SH
7673-20M65SH 7673-2M 7673-2M65 7674-2M
7674-2M65 7742-20M100SH 7742-20M65SH 7742-2M100SH
7742-2M65SH 7743-2M100SH 7743-2M65SH 7744-2M100SH
7744-2M65SH 7755-2M100 7755-2M65 7757-2MP65
7757-2MP65SH 7757-2MP65SHA 7757-2MP65SHTC 7757-2MP65SHTCB
7757-2MP80 7757-2MP80SH 7757-2MP80SHTC
Performa® AngiographicCatheter
Performa® Angiographic Catheter Judkins Left
7521-A3 7521-B1 7521-C3
Performa® Angiographic Catheter Judkins Right
7523-A3 7701-50 7523-B1 7523-C3
Performa® Angiographic Catheter Left Coronary Bypass
7534-43
Performa® Angiographic Catheter Right Coronary Bypass
7534-33
Performa® Angiographic Catheter Amplatz Left
7527-63 7527-73
Performa® Angiographic Catheter Amplatz Right
7526-21
Performa® Angiographic Catheter Multipurpose
7533-D3
Performa® Angiographic Catheter Headhunter
7715-B0 7715-50 7715-60
Performa® Angiographic Catheter Newton
7722-20 7722-E0
Performa® Angiographic Catheter Bentson
7721-30
Performa® Angiographic Catheter Osborn
7746-20

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HOMPSON LL.
Público
Matrícula N° 670

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Performa® Angiographic Catheter Simmons
7720-F0 7720-80
Performa® Angiographic Catheter MW2
7745-B0
Performa® Angiographic Catheter Renal Double Curve
7713-A0 510038PRDC
Performa® Angiographic Catheter Reuter
7714-10 7714-B0
Performa® Angiographic Catheter KA Selective

Performa® Angiographic Catheter DVS A1
5595-13 5595-23 5595-33 5595-43
Performa® Angiographic Catheter DVS A2
5595-A3 5595-B3 5595-C3 5595-D3
Performa® Angiographic Catheter Modified Hook
7603-A1 7603-B1 7603-C1 7603-D1
5585-C3 5585-D3 5585-E3
Performa® Angiographic Catheter Transradial Peripheral
PV612538U4 PV512538U3 PV512538U4 PV512538U45
PV612538PIG PV511038FH3 PV512538FH3 PV512538U1
PV512538U2 PV612538MP2SH PV512538BERN PV612538U2 PV512538U45SH
Performa® Angiographic Catheter Ultimate
610038ULT4-T45 6100381ULT4-T45 6110381ULT1 6110381ULT2
6110382ULT3 6110381ULT4-T40 6110381ULT4-T45
612538ULT1 512538ULT4-T40 412538ULT1 412538ULT3
Performa® Angiographic Catheter Vertebral
410035VER-PNB
Performa® Angiographic Catheter Uterine Artery
56535PUAC2
Performa® Angiographic Catheter Berenstein
7718-40
Performa® Angiographic Catheter UHF Pigtail
4653510PIG-PNB
Performa® Angiographic Catheter MIV™
4RPL110 4RPL110-NB 4RPL125 4RPL125-NB
4RPS110-NB 4RPS125 4RPS125-NB 5RPL110-NB
5RPL125-NB 6RPL110-NB 6RPL125 6RPL125-NB
6RPS110-NB 6RPS125 6RPS125-NB 5RPS125-NB
Performa® Angiographic Catheter Shepherd Hook
7712-D0
Performa® Custom Catheters
1623-A72M 1623-B62M 1623-C720M 1623-D1 1623-D2 1623-D3 1623-D4 1623-D5 1623-D6 1623-E2 1623-E320M 1623-E93M
1623-F220M 1623-F320M 1623-F420M 1623-F620M 1623-F720M 1623-F820M 1624-69-20M 1624-71
1624-832M 1624-972M 1624-A32M 1624-A42M
1624-B220M 1624-B420M 1624-C120M 1624-C220M 1624-C320M 1624-C620M 1624-C820M 1624-C920M 1624-D110M 1624-D320M 1624-D719M
1624-D8 1624-D9 1624-E520M 1624-E75M 1624-E8 1624-E9 1625-26 1625-29 1625-31 1625-32
1625-33 1625-34 1625-36
1625-37 1625-38 1628-003 1628-031 1628-032 1628-045 1628-047 1628-049 1628-082 1628-085

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1628-086 1628-092
1628-098 1628-099 1628-101 1628-102 1628-103 1628-104 1628-105 1628-106 1628-110 1628-111 1628-112 1628-122
1628-123 1628-124 1628-132 1628-134 1628-140 1628-141 1628-145 1628-146 1628-149 1628-150 1628-157 1628-161
1628-163 1628-165 1628-167 1628-169 1628-171 1628-176 1628-180 1628-184 1628-187 1628-191 1628-193 1628-194
1628-201 1628-203 1628-211 1628-212 1628-214 1628-218 1628-229 1628-230 1628-233 1628-235 1628-242 1628-243
1628-244 1628-245 1628-246 1628-247 1628-249 1628-250 1628-251 1628-252 1628-254 1628-255 1628-256 1628-257
1628-258 1628-259 1628-260 1628-262 1628-264 1628-265 1628-266 1628-267 1628-271 1628-274 1628-C1 1628-D1
1628-E1 1628-E2 1628-E8 1628-F1 1628-F2 1628-F6 1628-F7 1628-F8 1628-G4 1628-G5 1628-G6 1628-G8
1628-G9 1628-H1 1628-H2 1628-J1 1628-J2 1628-J3 1628-J5 1628-J8 1628-K1 1628-L3 1628-L7 1628-M1
1628-M3 1628-N3 1628-N5 1628-N6 1628-N8 1628-N9 1628-P2 1628-P3 1628-Q5 1628-Q6 1628-Q7 1628-Q8
1628-Q9 1628-R1 1628-R2 1628-R4 1628-R5 1628-R6 1628-R7 1628-R8 1628-R9 1628-S1 1628-S2 1628-S3
1628-S4 1628-T6 1628-U2 1628-U5 1628-V5 1628-V6 1628-V7 1628-W2 1628-X8 1628-Y1 1628-Y5 1628-Y9
1628-Z1 1628-Z8 7440-11 7440-12 7440-13 7440-15 7440-16 7440-21 7440-26 7440-27 7440-28 7440-29
7440-30 7440-31 7440-32 7440-33 7440-34 7440-42 7440-45 7440-53 7440-56 7440-60 7440-61 7440-62
7440-64 7440-65 7440-75 7440-79 7440-80 7440-81 7440-82 7440-83 7440-84 7440-85 7440-87 7440-88
7440-89 7440-90 7440-91 7440-93 7440-94 7440-95 7440-96 7440-97 7440-98 7440-99 7440-A1 7440-A6
7440-B2 7440-C3 7440-C5 7440-C7 7440-D1 7440-D3 7440-D4 7440-D5 7440-D6 7440-G2 7440-H4 7440-J1
7440-K2 7440-K3 7440-K6 7440-K7 7440-K8 7440-L1 7440-L2 7440-L3 7440-L4 7440-L8 7440-L9 7440-M2
7440-M4 7440-M8 7440-M9 7440-N1 7440-N2 7440-N3 7440-P4 7440-P5 7440-P6 7445-73 7445-80 7445-81
7445-83 7445-84 7445-88 7445-94 7445-95 7445-99 7445-A2 7445-A3 7445-A7 7445-A8 7445-B1 7445-B3
7445-B7 7445-B8 7445-F4 7445-F6 7445-F7 7445-F9 7445-G1 7445-G2 7445-G3 7445-G9 7445-H3 7445-H4
7445-H5 7445-H6 7445-J4 7445-J5 7445-J6 7445-J7 7445-J8 7445-J9 7445-K1 7445-K2 7445-K3
1623-G2

Performa® Transradial Angiographic Catheter
PV413538BERN PV415038BERN PV415038U1 PV513538BERN
PV513538U1 PV515038BERN PV515038U1
CONCIERGE Guiding Excellence™ Guiding Catheter
CONCIERGE Guiding Excellence™ Guiding Catheter Judkins Right
CGC5100JR30 CGC6100JR30 CGC7100JR30 CGC8100JR30 CGC5100JR35 CGC6100JR35
CGC7100JR35 CGC8100JR35
CGC5100JR35SH CGC6100JR35SH CGC7100JR35SH CGC8100JR35SH CGC5100JR40 CGC6100JR40

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CGC7100JR40 CGC8100JR40SH
CGC5100JR40SH CGC6100JR40SH CGC7100JR40SH CGC8100JR40 CGC5100JR50 CGC6100JR50
CGC7100JR50 CGC8100JR50
CGC5100JR50SH CGC6100JR50SH CGC7100JR50SH CGC8100JR50SH CGC5100JR60 CGC6100JR60
CGC7100JR60 CGC8100JR60
CONCIERGE Guiding Excellence™ Guiding Catheter Judkins Left
CGC5100JL30 CGC6100JL30 CGC7100JL30 CGC8100JL30 CGC5100JL35 CGC6100JL35 CGC7100JL35
CGC8100JL35
CGC5100JL35SH CGC6100JL35SH CGC7100JL35SH CGC8100JL35SH CGC5100JL35ST
CGC6100JL35ST CGC7100JL35ST CGC8100JL35ST
CGC5100JL40 CGC6100JL40 CGC7100JL40 CGC8100JL40 CGC5100JL40SH CGC6100JL40SH
CGC7100JL40SH CGC8100JL40SH
CGC5100JL40ST CGC6100JL40ST CGC7100JL40ST CGC8100JL40ST CGC5100JL45 CGC6100JL45
CGC7100JL45 CGC8100JL45
CGC5100JL45SH CGC6100JL45SH CGC7100JL45SH CGC8100JL45SH CGC5100JL50 CGC6100JL50
CGC7100JL50 CGC8100JL50
CGC5100JL50SH CGC6100JL50SH CGC7100JL50SH CGC8100JL50SH
CONCIERGE Guiding Excellence™ Guiding Catheter Amplatz Right
CGC5100AR1 CGC5100AR3 CGC6100AR2SH CGC7100AR2 CGC5100AR1SH CGC6100AR1
CGC6100AR3 CGC7100AR2SH
CGC5100AR2 CGC6100AR1SH CGC7100AR1 CGC7100AR3 CGC5100AR2SH CGC6100AR2
CGC7100AR1SH CGC8100AR1
CGC8100AR1SH CGC8100AR2 CGC8100AR2SH CGC8100AR3
CONCIERGE Guiding Excellence™ Guiding Catheter Amplatz Left

CGC5100AL1 CGC5100AL3 CGC6100AL2SH CGC7100AL1SH CGC5100AL1SH CGC6100AL1
CGC6100AL3 CGC7100AL2
CGC5100AL2 CGC6100AL1SH CGC7100AL1 CGC7100AL2SH CGC5100AL2SH CGC6100AL2
CGC8100AL1 CGC8100AL1SH
CGC7100AL3 CGC8100AL2 CGC8100AL2SH CGC8100AL3 CGC5100AL75 CGC7100AL75SH
CGC5100AL75SH CGC7100AL75
CGC8100AL75 CGC6100AL75 CGC8100AL75SH CGC6100AL75SH
CONCIERGE Guiding Excellence™ Guiding Catheter Multipurpose
CGC5100MP1 CGC6100MP1SH CGC7100MP1SH CGC5100MP1SH CGC6100MPA2SH CGC8100MP1
CGC7100MP1 CGC8100MP1SH CGC6100MP1
CONCIERGE Guiding Excellence™ Guiding Catheter Left Coronary Bypass
CGC5100LCB CGC6100LCB CGC7100LCB CGC8100LCB CGC5100LCBSH CGC6100LCBSH
CGC7100LCBSH CGC8100LCBSH
CONCIERGE Guiding Excellence™ Guiding Catheter Right Coronary Bypass
CGC5100RCB CGC6100RCB CGC7100RCB CGC8100RCB CGC5100RCBSH CGC6100RCBSH
CGC7100RCBSH CGC8100RCBSH
CONCIERGE Guiding Excellence™ Guiding Catheter Internal Mammary
CGC5100IM CGC6100IM CGC7100IM CGC8100IM CGC5100IMSH CGC6100IMSH CGC7100IMSH
CGC8100IMSH
CONCIERGE Guiding Excellence™ Guiding Catheter El Gamal
CGC5100EG CGC6100EG CGC7100EG CGC8100EG
CONCIERGE Guiding Excellence™ Guiding Catheter Hockey Stick
CGC5100HS CGC6100HS CGC7100HS CGC8100HS CGC7100HSSH CGC8100HSSH CGC5100HSSH
CGC6100HSSH
CONCIERGE Guiding Excellence™ Guiding Catheter Renal Double Curve
CGC6100RDC CGC7100RDC
CONCIERGE Guiding Excellence™ Guiding Catheter SBS
CGC5100SBS30 CGC6100SBS30 CGC7100SBS30 CGC8100SBS35 CGC5100SBS30SH
CGC6100SBS30SH CGC7100SBS30SH CGC8100SBS35SH
CGC5100SBS35 CGC6100SBS35 CGC7100SBS35 CGC8100SBS40 CGC5100SBS35SH

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Matrícula N° 670

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CGC6100SBS35SH CGC7100SBS35SH CGC8100SBS40SH
CGC5100SBS40 CGC6100SBS40 CGC8100SBS30 CGC7100SBS40 CGC5100SBS40SH
CGC6100SBS40SH CGC8100SBS30SH CGC7100SBS40SH
CGC8100SBS45SH CGC7100SBS45 CGC5100SBSLAD45SH CGC6100SBSLAD45SH CGC8100SBS45
CGC8100SBSLAD45SH CGC5100SBSLAD45 CGC7100SBSLAD45
CGC7100SBSLAD45SH CGC6100SBS45SH CGC7100SBS45SH CGC6100SBSLAD35SH
CGC6100SBSLAD45 CGC5100SBS45 CGC6100SBS45 CGC6100SBSRCASH
CGC5100SBS45SH CGC8100SBSLAD45 CGC6100SBSLAD35 CGC7100SBSLAD35SH
CGC6100SBSLAD30 CGC8100SBS375SH CGC6100SBSRCA CGC7100SBSRCASH
CGC6100SBSLAD40 CGC6100SBSLAD30SH CGC7100SBSLAD35 CGC8100SBSLAD35SH
CGC7100SBSLAD30 CGC6100SBSLAD40SH CGC7100SBSRCA CGC8100SBSRCASH
CGC7100SBSLAD40 CGC7100SBSLAD30SH CGC8100SBSLAD35 CGC6100SBS375SH
CGC8100SBSLAD30 CGC7100SBSLAD40SH CGC8100SBSRCA CGC5100SBSLAD30SH
CGC8100SBSLAD40 CGC8100SBSLAD30SH CGC6100SBS375 CGC5100SBSLAD30 CGC5100SBS375
CGC8100SBSLAD40SH CGC8100SBS375 CGC5100SBSLAD35
CGC7100SBS375 CGC5100SBS375SH CGC5100SBSLAD35SH CGC5100SBSRCA CGC5100SBSLAD40
CGC7100SBS375SH CGC5100SBSRCASH CGC5100SBSLAD40SH
CONCIERGE Guiding Excellence™ Guiding Catheter SBS Modified
CGC5100SBS35-M CGC6100SBS375-M CGC7100SBS40-MSH CGC7100SBS45-M CGC5100SBS35-MSH
CGC6100SBS40-M CGC5100SBS45-M CGC6100SBS45-M
CGC5100SBS40-M CGC6100SBS40-MSH CGC8100SBS45-MSH CGC7100SBS375-M CGC5100SBS40-
MSH CGC7100SBS35-M CGC8100SBS40-M CGC8100SBS375-M
CGC5100SBS375-M CGC7100SBS35-MSH CGC8100SBS40-MSH CGC8100SBS35-M CGC6100SBS35-M
CGC7100SBS40-M CGC5100SBS45-MSH CGC8100SBS35-MSH
CGC6100SBS35-MSH CGC7100SBS45-MSH CGC6100SBS45-MSH CGC8100SBS45-M
CONCIERGE Guiding Excellence™ Guiding Catheter Ultimate
CGC5100ULT1 CGC6100ULT2 CGC7100ULT3 CGC6100ULT4-T45 CGC6100ULT1 CGC7100ULT2
CGC5100ULT4-T40 CGC7100ULT4-T45

CGC7100ULT1 CGC8100ULT2 CGC6100ULT4-T40 CGC8100ULT3 CGC8100ULT1 CGC5100ULT3
CGC7100ULT4-T40
CGC5100ULT2 CGC6100ULT3 CGC5100ULT4-T45
Vessel Dilator
3339-21 3339-31 3339-41 3339-51
Impress® Angiographic Catheter
Impress® Angiographic Catheter Radial Internal Mammary
411038RADIM 511038RADIM
Impress® Angiographic Catheter Coronary Sinus
57538CS 1628-Y8M
Impress® Angiographic Catheter Fischook
PVI511038FH3 PVI512538FH3
Impress® Angiographic Catheter Headhunter
410035HH1 410038HH3 510035HH1 512535HH1 410035HH3 412535HH1 510038HH3 512538HH1
410038HH1 510035HH3 510038HH1
410038HH1-H 412538HH1-H 510038HH1-H 512538HH1-H
Impress® Angiographic Catheter Newton
410038N1 510038N4 410038N3 510038N2 410038N4 410038N2 510038N3 510038N1
Impress® Angiographic Catheter Bentson
46535B1 410035B1 510038B1 510035B1
410035B2 510035B2 56535B1 410038B1
410038B1-H 510038B1-H 410038B2-H 510038B2-H
Impress® Angiographic Catheter Mani
410035MANI 510035MANI 410038MANI 510038MANI
410038MANI-H 510038MANI-H

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Impress® Angiographic Catheter Vertebral
46538VER 510038VER 56538VER 410038VER
412535VER 410035VER 512535VER 510035VER
56538VER-H 510038VER-H 46538VER-H 410038VER-H
Impress® Angiographic Catheter Modified Cerebral
410035MC 410038MC 510035MC 510038MC
Impress® Angiographic Catheter Berenstein
46535BER 510035BER 410038BER 53035BER 56538BER 410035BER 512538BER 56535BER
46538BER 510038BER 412538BER 43035BER
46538BER-H 410038BER-H 56538BER-H 510038BER-H
412538BER-H 512538BER-H
Impress® Angiographic Catheter MW2
44038MW2 56538MW2
Impress® Angiographic Catheter Simmons
46535SIM1 410035SIM1 410038SIM2 56535SIM1 46538SIM1 410035SIM2 48035MODS 56538SIM1
46538SIM2 410038SIM1 48038MODS 56538SIM2
510035SIM1 510035SIM2 510038SIM1 510038SIM2
410038SIM1-H 510038SIM1-H 410038SIM2-H 510038SIM2-H
512535SIM1
Impress® Angiographic Catheter Cobra
465352CB1 410038CB2 565352CB1 46538CB2
465352CB2 510038CB1 565352CB2 410038CB1
46535CB2 510038CB2 565382CB1 56538CB1
465382CB1 465382CB2 565382CB2 56538CB2
46538CB1
46538CB1-H 56538CB1-H 46538CB2-H 410038CB2-H
56538CB2-H 510038CB2-H
Impress® Angiographic Catheter Modified Cobra
43035MODCB1 53035MODCB1
Impress® Angiographic Catheter Hook
465352HK0-8 565352HK0-8 465352HK1-0 565352HK1-0
Impress® Angiographic Catheter Shepherd Hook
465352SH0-8 465352SH1-0 565352SH0-8 565352SH1-0

Impress® Angiographic Catheter Renal Vein Renin
56538IRG1 56538IRG2
Impress® Angiographic Catheter Renal Double Curve
465352RC 565352RC 46535RC 510038IRDC
Impress® Angiographic Catheter Amir Motarjeme™
46535MOT 410035MOT 56535MOT 510035MOT
Impress® Angiographic Catheter Amir Motarjeme™ Cane
46535MOTC 410035MOTC
Impress® Angiographic Catheter Reuter
48038RE 58035RE 58038RE
Impress® Angiographic Catheter Mikaelsson
48038MIK 58038MIK
Impress® Angiographic Catheter KA2
56538KA2 44038KA2 46538KA2 54038KA2 53035KA2 43035KA2
44038KA2-H 46538KA2-H 54038KA2-H 56538KA2-H
Impress® Angiographic Catheter Hockey Stick
410038HS 510038HS
Impress® Angiographic Catheter Modified Hook
48035MHK1 48035MHK2 48035MHK3 58035MHK1
58035MHK3 58035MHK2
48038MHK1-H 58038MHK1-H 48038MHK2-H 58038MHK2-H

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48038MHK3-H 58038MHK3-H
465356MHK-NB 490356MHK-NB 590386MHK-NB 565356MHK-NB 565386MHK-NB
Impress® Angiographic Catheter Straight Selective
46538STS 56538STS 511038STS 44035STS
411035STS 411038STS 511035STS 44038STS 54035STS 54038STS
46538STS-H 410038STS-H 56538STS-H 510038STS-H
412538STS-H 512538STS-H
Impress® Angiographic Catheter Straight
53035STR 43035STR
4653510STF-NB 4903510STF-NB 5653510STF-NB 5903510STF-NB
Impress® Angiographic Catheter Renal, Bifurcation, Iliac
465354RBI 565354RBI 510035RBI 56535RBI
5100354RBI 56538RBI-H
Impress® Angiographic Catheter RIM
56535RIM 46535RIM 44035RIM 54035RIM
53035RIM 43035RIM
Impress® Angiographic Catheter Mini RIM
56535MRIMST
Impress® Angiographic Catheter Shepherd Flush
465356SHP-NB 490356SHP-NB 565356SHP-NB
Impress® Angiographic Catheter Ultra Bolus Flush
4653510UBF-NB 5653510UBF-NB 4903510UBF-NB 5903510UBF-NB
Impress® Angiographic Catheter Modified Bolus Flush
5653810MUBF-NB 4653810MUBF-NB
Impress® Angiographic Catheter Pigtail Flush
4653510PIG-NB 51103810PIG-NB 5653810PIG-NB 5903510PIG-NB 5653510PIG-NB 4903510PIG-NB
41103510PIG-NB 5903810PIG-NB
51103510PIG-NB 5303510PIG-NB 4303510PIG-NB
Impress® Angiographic Catheter Osborn
410035OSB1 510035OSB1
Impress® Angiographic Catheter Multipurpose A1
410038MPA1 412538MPA1 46538MPA1 56538MPA1 510038MPA1 512538MPA1
410038MPA1-H 510038MPA1-H
Impress® Angiographic Catheter Ultimate
5IMP10038ULT1 5IMP100381ULT1 5IMP110381ULT2 5IMP11038ULT2
5IMP110381ULT4-T40 5IMP11038ULT4-T40
Impress® Angiographic Catheter Uterine Artery

59035UAC 59038UAC 59035IUAC
Impress® Angiographic Catheter CPC
57538CARN5 57538CARN5S 57538CARN10 57538CARN10S 57538CARN15 57538CARN15S
Impress® UAC2™ Uterine Artery Catheter
59035IUACTMB-H
Impress® Angiographic Catheter 3D Curve
58038IRH1 58038IRH2
Impress® Custom Catheter
1623-E1 1623-E6 1623-F9 1623-G1 1624-B5 1624-B7 1624-C7 1624-D5 1624-E6 1628-001 1628-005 1628-015
1628-016 1628-017 1628-019 1628-021 1628-034 1628-035 1628-037 1628-042 1628-043 1628-044 1628-050 1628-054
1628-059 1628-060 1628-061 1628-062 1628-063 1628-064 1628-065 1628-073 1628-079 1628-083 1628-094 1628-095H
1628-100 1628-113 1628-118 1628-121 1628-128 1628-133 1628-148 1628-151 1628-152 1628-155 1628-164 1628-166
1628-168 1628-178 1628-179 1628-181 1628-182 1628-183 1628-189 1628-192 1628-197 1628-198

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1628-199 1628-200
1628-202 1628-204 1628-205 1628-206 1628-206H 1628-207 1628-208 1628-209 1628-210 1628-213 1628-216 1628-217
1628-219 1628-220 1628-221 1628-222 1628-223 1628-224 1628-225 1628-228 1628-231 1628-232 1628-234 1628-236
1628-237 1628-238 1628-239 1628-240 1628-241 1628-248 1628-253 1628-261 1628-268 1628-269 1628-270 1628-272
1628-275 1628-W7 1628-Y7 1628-Y8 1628-Z4 1628-Z5 1628-Z7 1628-Z9 7440-E7 7440-F6 7440-F7 7440-G8
7440-H5 7440-H6 7440-H8 7440-H9 7440-J4 7440-J5 7440-J7 7440-J8 7440-K4 7440-K5 7440-L5 7440-L6
7440-M1 7440-M3 7440-M5 7440-M6 7440-N4 7440-N5 7440-N6 7440-N7 7440-N8 7440-N9 7440-P1 7440-P2
7440-P3 7440-P7 7440-P8 7440-P9 7440-Q1 7440-Q2 7440-Q3 7440-Q4 7440-Q5 7440-Q6 1628-017M 1628-019M
Impress® Angiographic Catheter Double Loop 3D Curve
57538IDLOOP
Worley™ VEIN SELECTOR Angiographic Catheter
57538CS-WOR 57538CSV-WOR 57538CSHK-WOR
Resolve® Repositioning Tool
RC-RTOOL
Resolve®NL Hydrophilic Coated Non-Locking Drainage Catheter
RNL-10-038J RNL-10-038S RNL-12-038J RNL-12-038S
RNL-6-038J RNL-6-038S RNL-7-038J RNL-7-038S
RNL-8-038J RNL-8-038S
Resolve® Hydrophilic Coated Locking Drainage Catheter
RLC-10-038 RLC-12-038 RLC-14-038 RLC-6-038
RLC-7-038 RLC-8-038 RLC15-10-038MB RLC15-12-038MB
RLC15-14-038MB RLC15-6-038MB RLC15-7-038MB RLC15-8-038MB
RLC40-10-038MB RLC40-12-038MB RLC40-14-038MB RLC40-6-038MB
RLC40-7-038MB RLC40-8-038MB RLC-10-038MB RLC-12-038MB
RLC-14-038MB RLC-6-038MB RLC-7-038MB RLC-8-038MB
RLC-NV-10 RLC-NV-12 RLC-NV-14 RLC-NV-6
RLC-NV-7 RLC-NV-8 RLCMB-NV-10 RLCMB-NV-12
RLCMB-NV-14 RLCMB-NV-6 RLCMB-NV-8 RLCMB-NV-7
Resolve® Hydrophilic Coated Biliary Locking Drainage Catheter
RBC-10-038 RBC-12-038 RBC-14-038 RBC-8-038
RBDC-10-038 RBDC-12-038 RBDC-14-038 RBDC-8-038
Resolve Mini™ Hydrophilic Coated Locking Drainage Catheter
RML17-10-038MB RML17-12-038MB RML17-14-038MB RML17-6-038MB
RML17-7-038MB RML17-8-038MB RML27-10-038MB RML27-12-038MB

RML27-14-038MB RML27-6-038MB RML27-7-038MB RML27-8-038MB
RML42-10-038MB RML42-12-038MB RML42-14-038MB RML42-6-038MB
RML42-7-038MB RML42-8-038MB
Resolve®+
RBC-10-REV RBC-12-REV RBC-14-REV RBC-8-REV
RBDC-10-REV RBDC-12-REV RBDC-14-REV RBDC-8-REV
RBC-10-SFX RBC-12-SFX RBC-14-SFX RBC-8-SFX
RBDC-10-SFX RBDC-12-SFX RBDC-14-SFX RBDC-8-SFX
RLC-10-REV RLC-12-REV RLC-14-REV RLC-6-REV
RLC-7-REV RLC-8-REV RLCMB-10-REV RLCMB-12-REV
RLCMB-14-REV RLCMB-6-REV RLCMB-7-REV RLCMB-8-REV
RLC-10-SFX RLC-12-SFX RLC-14-SFX RLC-6-SFX
RLC-7-SFX RLC-8-SFX RLCMB-10-SFX RLCMB-12-SFX

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RLCMB-14-SFX RLCMB-6-SFX RLCMB-7-SFX RLCMB-8-SFX
RLC-NV-10-REV RLC-NV-12-REV RLC-NV-14-REV RLC-NV-6-REV
RLC-NV-7-REV RLC-NV-8-REV RLCMB-NV-10-REV RLCMB-NV-12-REV
RLCMB-NV-14-REV RLCMB-NV-6-REV RLCMB-NV-7-REV RLCMB-NV-8-REV
RLC-NV-10-SFX RLC-NV-12-SFX RLC-NV-14-SFX RLC-NV-6-SFX
RLC-NV-7-SFX RLC-NV-8-SFX RLCMB-NV-10-SFX RLCMB-NV-12-SFX
RLCMB-NV-14-SFX RLCMB-NV-6-SFX RLCMB-NV-7-SFX RLCMB-NV-8-SFX
RML27-10-REV RML27-10-SFX RML27-12-REV RML27-12-SFX
RML27-14-REV RML27-14-SFX RML27-6-REV RML27-6-SFX
RML27-7-REV RML27-7-SFX RML27-8-REV RML27-8-SFX
Resolve ConvertX® Nephroueteral Stent System
RCX10-10-038 RCX10-8-038 RCX12-10-038 RCX12-8-038 RCX22-10-038 RCX22-8-038
RCX14-10-038 RCX14-8-038 RCX20-10-038 RCX20-8-038 RCX26-10-038 RCX26-8-038
RCX24-10-038 RCX24-8-038 RCX28-10-038 RCX28-8-038
Resolve ConvertX® Biliary Stent System
RCXB10-10-038 RCXB15-10-038 RCXB5-10-038 RCXB7-10-038
Merit SureCross™ Support Catheter
SC1465 SC1890 SC14135 SC18150 SC1490 SC3565 SC14150 SC35135 SC1865 SC3590 SC18135
SC35150
ALIMAXX-ES™ Fully Covered Esophageal Stent
80129-201 80129-204 80129-207 80129-210 80129-202 80129-205 80129-208 80129-211
80129-203 80129-206 80129-209 80129-215 80129-212 80129-213 80129-214
EndoMAXX® Fully Covered Esophageal Stent
MAXX-197 MAXX-1912 MAXX-237 MAXX-2310 MAXX-1910 MAXX-1915 MAXX-2312 MAXX-2315
AERO® Fully Covered Tracheobronchial Stent
90129-201 90129-206 90129-211 90129-216 90129-202 90129-207 90129-212 90129-217
90129-203 90129-208 90129-213 90129-218 90129-204 90129-209 90129-214
90129-205 90129-210 90129-215
AERO DV® Fully Covered Tracheobronchial Stent
90129-301 90129-305 90129-312 90129-316 90129-302 90129-306 90129-313 90129-317
90129-303 90129-310 90129-314 90129-318 90129-304 90129-311 90129-315
AEROmini® Fully Covered Tracheobronchial Stent
AERO815 AERO1215 AERO1015 AERO1415 AERO820 AERO1210 AERO1010 AERO1410
AERO810 AERO610 AERO615
AEROSIZER® Tracheobronchial Stent Sizing Device
90129-501
HeartSpan® Transseptal Needle
FND-019-00 FND-019-02 FND-019-04 FND-019-06 FND-019-01 FND-019-03 FND-019-05 FND-019-07
HeartSpan® Fixed Curve Braided Transseptal Sheath
FCL-160-00 FCL-160-07 FCB8563MR0 FCB8563120 FCL-160-01 FCL-160-08 FCB8581MR0 FCB8581120
FCL-160-02 FCL-160-09 FCB8563ML0 FCB8563135 FCL-160-03 FCL-160-10 FCB8581ML0 FCB8581135
FCL-160-04 FCB856345 FCB856390 FCB8581ML1 FCL-160-05 FCB858145 FCB8563150 FCB8581150
FCL-160-06 FCB8563ML1 FCB858190 FCB8581ML2 FCB8560MP18 FCB8560MP28 FCB8561MUL
FCB8563ML2
HeartSpan® Steerable Sheath Introducer
HST-085-00 HST-085-10 HST-085-20

Nombre del fabricante
Sitio de fabricación
Merit Maquiladora Mexico, S. DE R.L. DE C.V.
Avenida Sor Juana Ines de la Cruz
19970 Interior B, Edificio 2, Parque Industrial Frontera
Tijuana, Baja California
MEXICO 22630

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Nombre del producto(s)
Fluid Management System
FAS1048 FAS1060 FAS1072 FAS1108 FAS1160 FAS1172 FAS1260 FAS1272
FAS1372 FAS2072 FAS3072 FAS6072 FAS4060 FAS4072 FAS4108 FAS5048 FAS5060 FAS5072
FAS5108 FAS5248
Merit Miser® Contrast Burette Assembly
MISER1 MISER2 MISER3 MISER4
Merit Miser® Contrast Burette Spike Assembly
MISER5
CT Transfer Set
TS120 TS220
RADSTAT® Radial Artery Compression System
RADSTD RADSRT RADCDS RADCDO
Finale® Vascular Compression Device
FCD100 FCD200
Merit Drainage Depot™
MDD600 MDD600PML
Merit Disposal Depot™
MDD100 MDD220 MDD200H MDD500H MDD110 MDD220H MDD300H MDD520H MDD400H
Replaceable Pressure Infusor Bag/ Dual Setting Pressure Relief
PIB500 PIB1000 PIB3000
Single Use Pressure Infusor Bag/Dual Setting Pressure Relief
PIB500EU PIB1000EU PIB3000EU
Futura® Safety Scalpel
SMS210 SMS211 SMS215
DugOut® Disposal Basin
DUG100 DUG1SS
BackStop® Disposal Basin
MBS100
BackStop®+ Disposal Basin
MBSP100
ShortStop® Temporary Sharps Holder
SS10
ShortStop Advantage® Temporary Sharps Holder
SS20
Revolution™Catheter Securement Device
CFG624
StayFIX® Catheter Fixation Device
680ME 685ME
MERIT® MAK MINI ACCESS KIT
MAK401 MAK501N-E MAK501NPDEBT MAK501-PED
MAK501 MAK401-PED MAK4F-10 MAK401N-PED
MAK401N MAK505PD MAK5F-10 MAK501N-PED
MAK501N MAK401NEBT MAK5F-15 MAK501NPD
MAK501N-15 MAK501NEBT MAK501NBT MAK501NPD-E
MAK405 MAK405-E MAK401NPDBT MAK405-PED
MAK405PD MAK505-PED MAK501NPDBT
MAK401NBT MAK401NPD MAK505 MAK501-E MAK401NPD-E MAK401-E

MAK401N-E MAK401NPDEBT MAK505-E
MERIT® S-MAK™ MINI ACCESS KIT

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S-MAK405 S-MAK501N15BT S-MAK401N S-MAK501 S-MAK505 S-MAK4F-10 S-MAK501N S-MAK401NBT
S-MAK401NPDBT S-MAK5F-10 S-MAK501N-15 S-MAK501NBT
S-MAK501NPDBT S-MAK5F-15 S-MAK401 S-MAK401NPD S-MAK501NPD
MERIT-® S-MAK XL™
S-MAK430NUS S-MAK430N S-MAK430NPD
MERIT® MAK
MAK001 MAK001N-60 MAK005 MAKSSPD
MAK001N MAK001N-80 MAK005-60 MAKNTPD
MERIT® MAKNV™
MAK-NV-001 MAK-NV-007 MAK-NV-013 MAK-NV-019
MAK-NV-002 MAK-NV-008 MAK-NV-014 MAK-NV-020
MAK-NV-003 MAK-NV-009 MAK-NV-015 MAK-NV-021 MAK-NV-004 MAK-NV-010 MAK-NV-016
MAK-NV-005 MAK-NV-011 MAK-NV-017 MAK-NV-006 MAK-NV-012 MAK-NV-018
Performa® AngiographicCatheter
Performa® Angiographic Catheter Judkins Left
7501-13 7501-H1 7521-83 7601-21 7501-21 7521-13 7521-F1 7601-33
7501-33 7521-21 7574-13 7601-43 7501-43 7521-33 7574-21 7700-10
7501-53 7521-43 7574-33 7700-20 7501-63 7521-53 7574-43 7700-30
7501-73 7521-63 7601-13 7700-40 7501-83 7521-73
7521-L3 7521-N3 7700-A0 7700-C0 7521-M3 7521-P3 7700-B0 7700-D0
Performa® Angiographic Catheter Judkins Left Short-Tip
7501-A3 7501-B1 7501-C3 7501-D3
Performa® Angiographic Catheter Judkins Right
7503-13 7503-73 7523-43 7523-93 7503-21 7503-83 7523-53 7701-10
7503-33 7503-93 7523-63 7701-20 7503-43 7523-13 7523-73 7701-30
7503-53 7523-21 7523-83 7701-40 7503-63 7523-33
7523-L3 7523-N3 7701-A0 7701-C0 7523-M3 7523-P3 7701-B0 7701-D0
Performa® Angiographic Catheter Judkins Right Short-Tip
7503-A3 7503-C3 7523-E3 7523-G3 7503-B1 7503-D3 7523-F1 7523-H3
Performa® Angiographic Catheter Modified Judkins Right
7502-13 7502-23 7502-33 7502-43
Performa® Angiographic Catheter MultiPACK plus™
5MP6SW-145 6MPPROW-145 6MPSW-145 5MPSW-SNB 6MPPRO-11-S
5MPPRO-W-145 6MPPROW-N 6MPSW-N 6MPPRO-11-W-145
5MPSW-145 6MPPROW-S 6MPSW-S 6MPPRO-11-W-NP-18
5MPSW-S 6MPS-11-W-NP-18 6MPSW-S-18G 6MPS-145
6MPS-S 5MPS-145 5MPS-S 5MPSW-S-18G 6MPPRO-N 5MPPRO-S 5MPPROW-145
5MPPROW-S 5MPS7-W-145 5MP6PROW-NP-18 5MPPRO-11-N
5MPPRO-N 5MPPROW-N 5MPSW-N 4MPPRO-11-W-145 4MPPRO-W-145 4MPS-145-18
Performa® Angiographic Catheter Left Coronary Bypass
7510-13 7534-13 7709-10
Performa® Angiographic Catheter Right Coronary Bypass
7510-23 7534-23 7709-20
Performa® Angiographic Catheter Amplatz Left
7507-13 7527-13 7703-30 7507-23 7527-23 7703-10 7703-40
7507-33 7527-33 7703-20 7703-B0 7507-43 7527-43
Performa® Angiographic Catheter Amplatz Right
7506-11 7508-33 7528-23 7702-20 7508-13 7526-11 7528-33 7702-30
7508-23 7528-13 7702-10 7702-40
Performa® Angiographic Catheter Progressive Right Coronary
7512-13 7532-13 7600-11 7707-10 7512-23 7572-11

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Performa® Angiographic Catheter Internal Mammary
7511-13 7531-23 7531-33 7706-10 7531-13
Performa® Angiographic Catheter Cardiac Pigtail
7509-11 7569-11 7704-70 7776-B3 7509-43 7569-43 7776-11 7777-21
7529-11 7602-11 7776-21 7777-B1 7529-43 7704-10 7776-B1

Performa® Angiographic Catheter Cardiac Pigtail 145 Degree
7509-23 7529-53 7602-23 7776-C3 7509-53 7569-23 7704-20 7777-33
7529-23 7569-53 7776-33 7777-C3
Performa® Angiographic Catheter Cardiac Pigtail 155 Degree
7704-30 7529-33 7569-33 7602-33 7529-63 7776-43 7509-33
7509-63 7569-63 7777-D3 7777-43
Performa® Angiographic Catheter Infant Pediatric Pigtail
7757-10 7757-20
Performa® Angiographic Catheter Standard Pediatric Pigtail
7756-10 7756-20
Performa® Angiographic Catheter Multipurpose
7513-13 7513-B3 7533-23 7708-10 7513-23 7513-C3 7533-33 7708-20
7513-33 7513-D3 7533-43 7708-30 7513-43 7513-E3 7533-53 7708-40
7513-53 7513-F3 7533-63 7708-50 7513-63 7533-13 7533-B3 7708-60 7513-A3
Performa® Angiographic Catheter Sones
7520-13 7530-13 7705-10 7705-20 7520-23 7530-23
Performa® Angiographic Catheter Cardiac Multipack
7560-13 7560-53 7660-13 7660-A3 7560-13K 7560-83 7660-23 7660-B3
7560-23 7560-A3 7660-33 7660-D3 7560-C3 7751-10
7560-33 7560-F3 7660-53 7751-20 7560-43 7560-G3 7660-63 7751-50
7560-43K 7560-H0K 7660-23K 7751-20K 7560-73 7560-L3K 7660-D3K 7751-40K
7560-F3K 7660-13K
Performa® Angiographic Catheter LBR
7240-10 7240-20 7240-30
Performa® Angiographic Catheter IML BR
7242-10 7242-20
Performa® Angiographic Catheter RBR
7241-10
Performa® Angiographic Catheter Headhunter
5575-13 5575-D3 7715-A0 5575-13S 5575-A3 7715-10
5575-23 5575-B3 7715-30 7715-D0 5575-33 5575-C3
Performa® Angiographic Catheter Newton
5577-13 5577-A3 7722-10 7722-A0 5577-23 5577-B3 7722-30 7722-B0
5577-33 5577-C3 7722-40 7722-C0 5577-43 5577-D3 7722-D0
5577-53 5577-E3 7722-50S
Performa® Angiographic Catheter Bentson
5578-13 5578-A3 7721-10 7721-B0 5578-23 5578-B3 7721-20 7721-C0
5578-33 5578-C3 7721-A0
Performa® Angiographic Catheter Vertebral
5583-13 5583-B3 7717-30 7717-B0 5583-23 7717-10 7717-A0 7717-C0 5583-A3 7717-20
Performa® Angiographic Catheter Mani
5579-13 5579-A3 7716-A0
Performa® Angiographic Catheter Osborn
7746-10 7746-A0 7746-B0 7746-C0 7746-30
Performa® Angiographic Catheter Simmons
5576-13 5576-C3 7720-20 7720-A0 5576-23 5576-D3 7720-30 7720-B0
5576-33 5576-E3 7720-40 7720-C0 5576-43 5576-F3 7720-50 7720-D0
5576-A3 5576-G3 7720-70 7720-E0 5576-B3 7720-10
Performa® Angiographic Catheter Cobra

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5584-13 5584-B3 7710-10 7710-A0 5584-23 5584-C3 7710-20 7710-B0
5584-33 5584-D3 7710-30 7710-C0 5584-43 5584-E3 7710-40 7710-D0
5584-53 5584-F3 7710-50 7710-E0 5584-63 5596-13S 7710-60 7710-F0 5584-A3
Performa® Angiographic Catheter Hook
5585-13 5585-A3 7711-10 7711-A0
5585-23 5585-B3 7711-20 7711-B0
Performa® Angiographic Catheter Modified Hook
7755-20S
Performa® Angiographic Catheter Modified Cerebral Selective

5588-13 5588-A3 7723-A0 7723-10
Performa® Angiographic Catheter Berenstein
5592-13 5592-A3 5592-23 5592-B3 7718-10 7718-A0 7718-20 7718-B0
5592-33 5592-43 5592-C3 7718-30 7718-C0
Performa® Angiographic Catheter Straight Selective
7748-A0 7748-10
Performa® Angiographic Catheter MW2
5590-13 5590-33 5590-23
Performa® Angiographic Catheter Modified MW2
7745-A0 7745-C0 7745-10
Performa® Angiographic Catheter Shepherd Hook
5586-13 5586-B3 7712-20 7712-A0 5586-23 5593-43S 7712-30 7712-B0
5586-43 7712-10 7712-40 7712-C0 5586-A3
Performa® Angiographic Catheter Renal Double Curve
5587-13 5587-A3 7713-20 7713-B0 5587-23 7713-10
Performa® Angiographic Catheter Hockey Stick
7752-10 7543-13 7541-13
Performa® Angiographic Catheter Amir Motarjeme™
5591-A3 5591-B3 5591-C3 5591-D3
7747-C0 7747-D0 7747-E0 7747-F0
Performa® Angiographic Catheter Amir Motarjeme™ Cane
7747-10 7747-20 7747-A0 7747-B0 5591-E3 5591-F3
Performa® Angiographic Catheter Reuter
5589-13 5589-A3 7714-A0 5589-23 5589-B3
Performa® Angiographic Catheter Mikaelsson
5594-13 7719-A0 7719-10
Performa® Angiographic Catheter KA2
5582-13 5582-43 7514-13 7514-23
Performa® Angiographic Catheter Shepherd Flush
7602-A1 7602-B1 7602-C1 7602-D1
Performa® Angiographic Catheter Ultra Bolus Flush
7674-11 7674-21 7674-31 7674-41
Performa® Angiographic Catheter UHF Pigtail
7602-41 7602-61 7602-81 7602-91
7602-51 7602-71 7742-20S
Performa® Angiographic Catheter Pigtail Flush
7749-A0 7749-40
Performa® Angiographic Catheter UHF Straight Flush
7673-11 7673-21 7673-31 7673-41 7673-51 7673-61
Radial MultiPACK plus™
RADMPP-1 RADMPP-3 RADMPP-5 RADMPP-7 RADMPP-10
RADMPP-2 RADMPP-4 RADMPP-6 RADMPP-8 RADMPP-11
Radial MultiPACK Premier™
RADMPP-12
Performa® Angiographic Catheter KGCA

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7738-10S
Performa® Angiographic Catheter Transradial Peripheral
PV411038PIG PV412538U4 PV512538PIG PV512538U4SH
PV412538BERN PV412538U45 PV512538REN PV612538MP2SH
PV412538MP1 PV512538BERN PV512538U1SH PV612538U1
PV412538MP2SH PV512538COB2 PV512538U2SH PV612538U2
PV412538U1 PV512538MP1 PV512538U3SH PV612538U3
PV412538U2 PV512538MP2SH PV512538U4SSH PV612538U45
PV412538U3 PV413538BERN PV415038BERN PV513538BERN
PV515038BERN
Performa® Angiographic Catheter Ultimate
4100381ULT1 5100381ULT1 510038ULT4-T40 512538ULT2
4100381ULT2 5100381ULT1K 510038ULT4-T40K 6100381ULT1

4100381ULT4-T40 5100381ULT2 510038ULT4-T45 6100381ULT2
4100381ULT4-T45 5100381ULT4-T40 5110381ULT1 6100381ULT4-T40
4100382ULT3 5100381ULT4-T45 5110381ULT2 6100382ULT3
410038ULT1 5100382ULT3 5110381ULT4-T40 610038ULT1
410038ULT2 510038ULT1 5110381ULT4-T45 610038ULT2
410038ULT3 510038ULT1K 5110382ULT3 610038ULT3
410038ULT4-T40 510038ULT2 512538ULT1 610038ULT4-T40
410038ULT4-T45 510038ULT3 5125382ULT3 612538ULT3
412538ULT2 5125381ULT1 512538ULT3 612538ULT4-T40
412538ULT3 5125381ULT2 512538ULT4-T45 612538ULT4-T45
412538ULT4-T40 5125381ULT4-T40 612538ULT2
412538ULT4-T45 5125381ULT4-T45
Performa® Angiographic Catheter MIV™
4RPS110 5RPL125 5RPS110-NB 6RPL110 5RPL110 5RPS110 5RPS125 6RPS110
Performa® Angiographic Catheter Judkins Left
7521-A3 7521-B1 7521-C3
Performa® Angiographic Catheter Judkins Right
7523-A3 7701-50 7523-B1 7523-C3
Performa® Angiographic Catheter Left Coronary Bypass
7534-43
Performa® Angiographic Catheter Right Coronary Bypass
7534-33
Performa® Angiographic Catheter Amplatz Left
7527-63 7527-73
Performa® Angiographic Catheter Amplatz Right
7526-21
Performa® Angiographic Catheter Multipurpose
7533-D3
Performa® Angiographic Catheter Headhunter
7715-B0 7715-50 7715-60
Performa® Angiographic Catheter Newton
7722-20 7722-E0
Performa® Angiographic Catheter Bentson
7721-30
Performa® Angiographic Catheter Osborn
7746-20
Performa® Angiographic Catheter Simmons
7720-F0 7720-80
Performa® Angiographic Catheter MW2
7745-B0
Performa® Angiographic Catheter Renal Double Curve

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7713-A0 510038PRDC
Performa® Angiographic Catheter Reuter
7714-10 7714-B0
Performa® Angiographic Catheter KA Selective
5582-23 5582-33
Performa® Angiographic Catheter DVS A1
5595-13 5595-23 5595-33 5595-43
Performa® Angiographic Catheter DVS A2
5595-A3 5595-B3 5595-C3 5595-D3
Performa® Angiographic Catheter Modified Hook
7603-A1 7603-B1 7603-C1 7603-D1
5585-C3 5585-D3 5585-E3
Performa® Angiographic Catheter Transradial Peripheral
PV612538U4 PV512538U3 PV512538U4 PV512538U45
PV612538PIG PV511038FH3 PV512538FH3 PV512538U1
PV512538U2
Performa® Angiographic Catheter Ultimate

610038ULT4-T45 6100381ULT4-T45 6110381ULT1 6110381ULT2
6110382ULT3 6110381ULT4-T40 6110381ULT4-T45
612538ULT1 512538ULT4-T40 412538ULT1 412538ULT3
Performa® Angiographic Catheter Vertebral
410035VER-PNB
Performa® Angiographic Catheter Uterine Artery
56535PUAC2
Performa® Angiographic Catheter Berenstein
7718-40
Performa® Angiographic Catheter UHF Pigtail
4653510PIG-PNB
Performa® Angiographic Catheter MIV™
4RPL110 4RPL110-NB 4RPL125 4RPL125-NB
4RPS110-NB 4RPS125 4RPS125-NB 5RPL110-NB
5RPL125-NB 6RPL110-NB 6RPL125 6RPL125-NB
6RPS110-NB 6RPS125 6RPS125-NB 5RPS125-NB
Performa® Angiographic Catheter Shepherd Hook
7712-D0
Performa® Custom Catheters
1623-A72M 1623-B62M 1623-C720M 1623-D1 1623-D2 1623-D3 1623-D4 1623-D5 1623-D6 1623-E2 1623-E320M 1623-E93M
1623-F220M 1623-F320M 1623-F420M 1623-F620M 1623-F720M 1623-F820M 1624-69-20M 1624-71 1624-832M 1624-972M 1624-A32M 1624-A42M
1624-B220M 1624-B420M 1624-C120M 1624-C220M 1624-C320M 1624-C620M 1624-C820M 1624-C920M 1624-D110M 1624-D320M 1624-D719M
1624-D8 1624-D9 1624-E520M 1624-E75M 1624-E8 1624-E9 1625-26 1625-29 1625-31 1625-32 1625-33 1625-34 1625-36
1625-37 1625-38 1628-003 1628-031 1628-032 1628-045 1628-047 1628-049 1628-082 1628-085 1628-086 1628-092
1628-098 1628-099 1628-101 1628-102 1628-103 1628-104 1628-105 1628-106 1628-110 1628-111 1628-112 1628-122
1628-123 1628-124 1628-132 1628-134 1628-140 1628-141 1628-145 1628-146 1628-149 1628-150 1628-157 1628-161
1628-163 1628-165 1628-167 1628-169 1628-171 1628-176 1628-180 1628-184 1628-187 1628-191 1628-193 1628-194
1628-201 1628-203 1628-211 1628-212 1628-214 1628-218 1628-229 1628-230 1628-233 1628-235 1628-242 1628-243

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1628-244 1628-245 1628-246 1628-247 1628-249 1628-250 1628-251 1628-252 1628-254 1628-255 1628-256 1628-257
1628-258 1628-259 1628-260 1628-262 1628-264 1628-265 1628-266 1628-267 1628-271 1628-274 1628-C1 1628-D1
1628-E1 1628-E2 1628-E8 1628-F1 1628-F2 1628-F6 1628-F7 1628-F8 1628-G4 1628-G5
1628-G9 1628-H1 1628-H2 1628-J1 1628-J2 1628-J3 1628-J5 1628-J8 1628-K1 1628-L3
1628-M3 1628-N3 1628-N5 1628-N6 1628-N8 1628-N9 1628-P2 1628-P3 1628-Q5 1628-Q6
1628-Q9 1628-R1 1628-R2 1628-R4 1628-R5 1628-R6 1628-R7 1628-R8 1628-R9 1628-S1
1628-S4 1628-T6 1628-U2 1628-U5 1628-V5 1628-V6 1628-V7 1628-W2 1628-X8 1628-Y1
1628-Z1 1628-Z8 7440-11 7440-12 7440-13 7440-15 7440-16 7440-21 7440-26 7440-27
7440-30 7440-31 7440-32 7440-33 7440-34 7440-42 7440-45 7440-53 7440-56 7440-60
7440-64 7440-65 7440-75 7440-79 7440-80 7440-81 7440-82 7440-83 7440-84 7440-85
7440-89 7440-90 7440-91 7440-93 7440-94 7440-95 7440-96 7440-97 7440-98 7440-99
7440-B2 7440-C3 7440-C5 7440-C7 7440-D1 7440-D3 7440-D4 7440-D5 7440-D6 7440-G2
7440-K2 7440-K3 7440-K6 7440-K7 7440-K8 7440-L1 7440-L2 7440-L3 7440-L4 7440-L8
7440-M4 7440-M8 7440-M9 7440-N1 7440-N2 7440-N3 7440-P4 7440-P5 7440-P6 7445-73
7445-83 7445-84 7445-88 7445-94 7445-95 7445-99 7445-A2 7445-A3 7445-A7 7445-A8
7445-B7 7445-B8 7445-F4 7445-F6 7445-F7 7445-F9 7445-G1 7445-G2 7445-G3 7445-G9
7445-H5 7445-H6 7445-J4 7445-J5 7445-J6 7445-J7 7445-J8 7445-J9 7445-K1 7445-K2
7445-H3 7445-H4 7445-K3 1623-G2 7445-B1 7445-B3 7445-80 7445-81 7440-L9 7440-M2
7440-H4 7440-J1 7440-A1 7440-A6 7440-87 7440-88 7440-61 7440-62 7440-28 7440-29
1628-Y5 1628-Y9 1628-S2 1628-S3 1628-Q7 1628-Q8 1628-L7 1628-M1 1628-G6 1628-G8
Performa® Transradial Angiographic Catheter
PV413538BERN PV415038BERN PV415038U1 PV513538BERN
PV513538U1 PV515038BERN PV515038U1
FEP PIGTAIL Angiographic Catheter
1308-25-0085 1308-35-0086 1310-21-0043 1310-25-0064 1308-35-0065 1308-35-0006
1310-21-0053 1310-25-0084 1308-35-0085 1308-38-0006 1310-21-0054 1310-25-0065
1308-35-0005 1308-35-0007 1310-21-0064 1310-25-0085 1308-38-0007 1310-25-0054
Vessel Sizing Angiographic Catheter
46535AVS20MHK 510035AVS20MHK 510035AVS20PIG 510035AVS2MHK
510035AVS2PIG 510035AVS2STR 56535AVS20MHK 56535AVS20PIG
56535AVS2MHK 56535AVS2PIG 56535AVS2STR 7602-11M
7602-11M65 7602-20M 7602-20M100SH 7602-20M65
7602-20M65SH 7602-2M 7602-2M65 7603-11M100
7603-11M65 7603-20M100SH 7603-20M65SH 7603-2M100
7603-2M65 7673-11M100SH 7673-11M65SH 7673-20M100SH
7673-20M65SH 7673-2M 7673-2M65 7674-2M
7674-2M65 7742-20M100SH 7742-20M65SH 7742-2M100SH
7742-2M65SH 7743-2M100SH 7743-2M65SH 7744-2M100SH
7744-2M65SH 7755-2M100 7755-2M65 7757-2MP65
7757-2MP65SH 7757-2MP65SHA 7757-2MP65SHTC 7757-2MP65SHTCB
7757-2MP80 7757-2MP80SH 7757-2MP80SHTC
PreludeSYNC DISTAL™ Radial Compression Device Syringe
SDRB10AC
PreludeSYNC™ Radial Compression Devices
SRB24AC SRB24MED SRB29AC SRB29MED
PreludeSYNC EVO™ Radial Compression Devices
SRB29LBAC SRB24LBAC
PreludeSYNC DISTAL™ Radial Compression Devices
SDRB-REG-LT SDRB-REG-RT
PreludeSYNC EZ™ Radial Compression Device
EZ-SML EZ-REG
SAFEGUARD FOCUS™ Compression Device
SGF1V SGF1A

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SAFEGUARD FOCUS COOL™ Compression Device
SGF1AC SGF1VC
SAFEGUARD® Pressure Assisted Device
SG127AC SG2440AC
SAFEGUARD™ Syringe
SG40ACB SG40AC
DriPAD™ Sterile Super Absorbent Pad
DRI2332E DRI0909E
DriPAD™ Non-Sterile Super Absorbent Pad
DRI2332 DRI0909 DRI2320
PRESSURE MONITOR Tubing
PM6006 PM6012 PM6024 PM6036 PM6048 PM6060 PM6072 PM6106 PM6112 PM6124
PM6148-B PM6148-R PM6160-Y PM6172-Y PM6184 PM6196 PM6136 PM6148 PM6096
PM6160-R PM6160 PM6172 PM6172-R
High Pressure Tubing
HP5100E HP5101E HP5200E HP5201E HP5300E HP5301E HP5480E HP5481E HP9100E
HP9300E HP9301E HP9480E HP9481E HP9720E HP9721E HPC100E HPC101E HPC200E
HPC390E HPC391E HPC480E HPC481E HPC590E HPC591E HPC720E HPC721E HPF100E
HPF201E HPF201K HPF300E HPF300K HPF301E HPF301K HPF480E HPF480K HPF481E
HPF720E HPF720K HPF721E HPF721K HPT100E HPT101E HPT200E HPT201E HPT300E
HP9101E HP9200E HP9201E HPC201E HPC300E HPC301E HPF101E HPF200E HPF200K
HPF481K HPF600K HPF601K HPT301E HPT480E HPT481E HPT590E HPT591E
Evacuated Drainage Bottle
EVAC1000
Aspira Peritoneal Drainage System
4992206 4992207 4992208 4992209
4992207B 4992204 4992224 4992224B
Aspira Pleural Drainage System
4992506 4992507 4992508 4992509
4992507B 4992524B 4992524 4992504
Aspira Drainage Accessories
4991503 4992301 4992305 4992306
4992307 ASP-4 ASP-10
Corvocet™ Biopsy System
CORA1410 CORA1410S CORCA1410 CORCA1825B CORA1415 CORA1415S CORCA1415
CORA1610 CORA1610S CORCA1610 CORCA2015B CORA1615 CORA1615S CORCA1615
CORA1810 CORA1810S CORCA1410S CORCA1810SB CORA1815 CORA1815S CORCA1415S
CORA1820 CORA1820S CORCA1610S CORCA1820SB CORA1825 CORA1825S CORCA1615S
CORA2010 CORA2010S CORCA1810B CORCA2010SB CORA2015 CORA2015S CORCA1815B
CORA2020 CORA2020S CORCA1820B CORCA2020SB CORCA2010B CORCA2020B CORCA1815SB
CORCA1825SB CORCA2015SB
Corvocet™ Coaxial Introducer
CORC1410 CORC1615 CORC1820B CORC2015B CORC1415 CORC1810B CORC1825B CORC2020B
CORC1610 CORC1815B CORC2010B
Tru-Cut® Biopsy Needles
2N2700X 2N2702X 2N2704X 2N2711X 2N2712X 2N2713X
Achieve® Programmable Automatic Biopsy System
A1411 A1415 A1420 A146 A149 A1611 A1615 A1620 A166 A169 A1811 A1815
A1820 A1825 A186 A189 A2011 A2015 A2020 A206 A209
CA1411 CA1415 CA1420 CA1611 CA1615 CA1620 CA1811 CA1815 CA1820 CA2011 CA2015 CA2020
Pink Achieve™ Programmable Automatic Biopsy System
BA1211 BA1215 BA129 BA1411 BA149 BCA1211 BCA1215 BCA1411
Adjustable Coaxial Temno™ A.C.T Biopsy Device
ACT1415 ACT1811 ACT1815 ACT1820 ACT2011 ACT2015 ACT2020 ACT2211 ACT2215
Temno® Biopsy Device

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CT1411 CT1415 CT1420 CT1611 CT1615 CT1620 CT1811 CT1815 CT1820 CT2011 CT2015 CT2020 CT2215 CT2220
T1411 T1415 T1420 T146 T149 T1611 T1615 T1620 T166 T169 T1811 T1815 T1820 T186 T189 T1915 T2011 T2015 T2020 T206 T209 T2215 T226 T229
Temno Evolution® Biopsy Device
CTT1411 CTT1415 CTT1420 CTT1611 CTT1615 CTT1620 CTT1811 CTT1815 CTT1820 CTT2011 CTT2015 CTT2020
TT1411 TT1415 TT1420 TT146 TT1611 TT1615 TT1620 TT166 TT1811 TT1815 TT1820 TT186 TT2011 TT2015 TT2020 TT206
Temno® Coaxial Introducer
PP13510 PP1356 PP1510A PP1515A PP156 PP1710 PP1715 PP176 PP1910 PP1915 PP196 PP2010 PP2015 PP206
MERIT PAK™ PEDAL ACCESS KIT
PAKM4NPD4 PAKM4NPD7 PAKM5NPD4 PAKM5NPD7
MERIT PAK™ PEDAL ACCESS KIT Stiffened
PAKS4NPD4 PAKS4NPD7 PAKS5NPD4 PAKS5NPD7
Transvalvular Insertion Tool
MIS-105-00 MIS-099-00
Prelude SNAP Splittable Sheath Introducer
PLS-1006 PLS-1007 PLS-1008 PLS-1008.5 PLS-1009 PLS-1009.5 PLS-1010 PLS-1010.5 PLS-1012.5 PLS-2506 PLS-2507 PLS-2508 PLS-2509 PLS-2510 PLS-2510.5 PLS-2511
PLSX-1008 PLSX-1008.5 PLSX-1009 PLSX-1009.5 PLSX-1010 PLSX-1010.5 PLSX-1011 PLSX-2506 PLSX-2507 PLSX-2508 PLSX-2509 PLSX-2510 PLSX-2510.5 PLSX-2511
PLS-1011 PLS-1012 PLSX-1006 PLSX-1007 PLSX-1012 PLSX-1012.5
Hydrophilic Prelude SNAP Splittable Introducer
PLSH-1006 PLSH-1007 PLSH-1008 PLSH-1008.5 PLSH-1009 PLSH-1009.5 PLSH-1010 PLSH-1010.5 PLSH-1012 PLSH-1012.5 PLSH-2506 PLSH-2507 PLSH-2508 PLSH-2509 PLSH-2510 PLSH-2510.5 PLSH-1011 PLSH-2511
Prelude SNAP Splittable Sheath Introducer
PLSS-1006 PLSS-1007 PLSS-1008 PLSS-1008.5 PLSS-1009 PLSS-1009.5 PLSS-1010 PLSS-1010.5 PLSS-1012 PLSS-1012.5 PLSS-2506 PLSS-2507 PLSS-2508 PLSS-2509 PLSS-2510 PLSS-2510.5 PLSS-1011 PLSS-2511
Prelude SNAP 165 Valved Splittable Sheath Introducer
PLS165
Classic Sheath Splittable Sheath Introducer
CLS-1006 CLS-1009.5 CLS-1012.5 CLS-2510 CLS-1007 CLS-1010 CLS-2506 CLS-2510.5 CLS-1008 CLS-1010.5 CLS-2507 CLS-2511 CLS-1008.5 CLS-1011 CLS-2508 CLS-1009 CLS-1012 CLS-2509
Worley™ Advanced CSG Coronary Sinus Guide
WOR-CSG-B1-09 WOR-CSG-B2-09 WOR-CSG-BL1-09 WOR-CSG-BR1-09 WOR-CSG-E-90 WOR-CSGS-B1-09 WOR-CSGS-B2-09 WOR-CSGS-BL1-09 WOR-CSGS-BR1-09
Worley™ Advanced LVI Lateral Vein Introducers
WORLVI-75-5-62-07-HO WORLVI-75-5-62-55-HO WORLVI-75-5-62-55-HS WORLVI-75-5-62-07-MP WORLVI-75-5-62-07-HS WORLVI-75-5-62-55-RE WORLVI-75-5-62-55-MP WORLVI-75-5-62-07-RE
Prelude Prestige™ Splittable Sheath Introducer
PLP-1005 PLP-1006 PLP-1007 PLP-1008 PLP-1008.5 PLP-1009 PLP-1009.5 PLP-1010 PLP-1010.5 PLP-1013 PLP-1014 PLP-1015 PLP-1016 PLP-2505 PLP-2506 PLP-2507 PLP-2508 PLP-2509 PLP-2510 PLP-2513 PLP-2514 PLP-2515 PLP-2516 PLPS-1005 PLPS-1006 PLPS-1007 PLPS-1008 PLPS-1008.5 PLPS-1010.5 PLPS-1011 PLPS-1012 PLPS-1012.5 PLPS-1013 PLPS-1014 PLPS-1015 PLPS-1016 PLPS-2508 PLPS-2509 PLPS-2510 PLPS-2511 PLPS-2512 PLPS-2513 PLPS-2514 PLPS-2515 PLP-1012 PLP-1012.5 PLP-2511 PLP-2512 PLPS-1009.5 PLPS-1010 PLPS-2506 PLPS-2507 PLP-1011 PLPS-1009 PLPS-2505 PLPS-2516
Endotek BIG60® Inflation Device
ENDO-AN6012
BIG60 ALPHA™ Infaltion Device

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los 19 días del mes de agosto del 2025.

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EN-AL6012
Cultura™ Flex Swab Sterile Flocked Nasopharyngeal Collection Device
C100F C100FS
Worley™ Slitter
WC100
BasixCOMPAK™ Inflation Device
IN4130 IN4230 IN4330 IN4352 IN4430 IN4462 IN4463 IN4464 IN4465 IN4530 IN4802 IN4852 IN4901 IN4902 IN4903 IN4904 IN4905 IN4906 IN4907 IN4908 IN4909 IN4910 IN4911 IN4912 IN4913 IN4914 IN4915 IN4916 IN4917 IN4918 IN4919 IN4952 ENDO-AN2030
ONE1STEP™ Centesis Catheter
OSC-4F-10 OSC-4F-10L OSC-4F-10LNH OSC-4F-10NH OSC-4F-10S OSC-4F-12PL OSC-4F-12PS OSC-4F-17PS OSC-4F-7 OSC-4F-7L OSC-4F-7LNH OSC-4F-7NH OSC-4F-7S OSC-5F-10 OSC-5F-10L OSC-5F-10LNH OSC-5F-10NH OSC-5F-10S OSC-5F-12PL OSC-5F-12PS OSC-5F-15 OSC-5F-15L OSC-5F-15NH OSC-5F-15S OSC-5F-17PL OSC-5F-17PS OSC-5F-7 OSC-5F-7L OSC-5F-7LNH OSC-5F-7S OSC-6F-10L OSC-6F-10S OSC-6F-12PL OSC-6F-12PS OSC-6F-15L OSC-6F-15S OSC-6F-17PS OSC-6F-7L OSC-6F-7S OSC-8F-10L OSC-8F-10S OSC-8F-12PL OSC-8F-12PS OSC-8F-15S OSC-8F-17PL OSC-8F-17PS OSC-8F-7L OSC-8F-7S OSC-6F-17PL OSC-8F-15L OSC-4F-17PL OSC-5F-15LNH OSC-5F-7NH
ONE1STEP™ Valved Centesis Catheter
OSC-4F-10LT OSC-4F-10T OSC-4F-12PLT OSC-4F-12PT OSC-4F-17PLT OSC-4F-17PT OSC-4F-7LT OSC-5F-10LT OSC-5F-10T OSC-5F-12PLT OSC-5F-12PT OSC-5F-15LT OSC-5F-15T OSC-5F-17PLT OSC-5F-7LT OSC-5F-7T OSC-6F-10LT OSC-6F-10T OSC-6F-12PLT OSC-6F-12PT OSC-6F-15LT OSC-6F-17PLT OSC-6F-17PT OSC-6F-7LT OSC-6F-7T OSC-8F-10LT OSC-8F-10T OSC-8F-12PLT OSC-8F-15LT OSC-8F-15T OSC-8F-17PLT OSC-8F-17PT OSC-8F-7LT OSC-8F-7T OSC-8F-12PT OSC-5F-17PT OSC-4F-7T OSC-6F-15T OSC410T OSC510T
BasixTOUCH™ Inflation Device
IN8100 IN8112 IN8130 IN8152 IN8302 IN8352 IN8353 IN8403 IN8802 IN8852 IN8952
BasixTOUCH40™ Inflation Device
IN8140
Stabilit Touch™
IN8KVCF IN8VCF
Contamination Sleeve
CON-006-01 CON-006-02
Cen-Step™ Centesis Catheter
CSC-5F-7S CSC-5F-15S CSC-5F-10S CSC-4F-7S CSC-4F-10S
Merit Angioplasty Pack™
MAP101 MAP102 MAP104 MAP111 MAP112 MAP113 MAP150 MAP151 MAP152 MAP152SD MAP153 MAP154 MAP220 MAP221 MAP222 MAP300 MAP301 MAP302 MAP350 MAP351 MAP352 MAP353 MAP354 MAP400 MAP403 MAP450 MAP453 MAP900 MAP952
Merit Angioplasty Pack™ PhD™ Hemostasis Valve
MAP800 MAP801 MAP802 MAP803 MAP804 MAP850 MAP851 MAP852 MAP853 MAP854
FLO40XR™ Hemostasis Valve
FLO40XR FLO40XR51 FLO40XR52 FLO40XR53 FLO40XR54
Resolve® Repositioning Tool
RC-RTOOL
Resolve®NL Hydrophilic Coated Non-Locking Drainage Catheter
RNL-10-038J RNL-10-038S RNL-12-038J RNL-12-038S
RNL-6-038J RNL-6-038S RNL-7-038J RNL-7-038S
RNL-8-038J RNL-8-038S
Resolve® Hydrophilic Coated Locking Drainage Catheter
RLC-10-038 RLC-12-038 RLC-14-038 RLC-6-038
RLC-7-038 RLC-8-038 RLC15-10-038MB RLC15-12-038MB
RLC15-14-038MB RLC15-6-038MB RLC15-7-038MB RLC15-8-038MB
RLC40-10-038MB RLC40-12-038MB RLC40-14-038MB RLC40-6-038MB
RLC40-7-038MB RLC40-8-038MB RLC-10-038MB RLC-12-038MB

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RLC-14-038MB RLC-6-038MB RLC-7-038MB RLC-8-038MB
RLC-NV-10 RLC-NV-12 RLC-NV-14 RLC-NV-6
RLC-NV-7 RLC-NV-8 RLCMB-NV-10 RLCMB-NV-12
RLCMB-NV-14 RLCMB-NV-6 RLCMB-NV-8 RLCMB-NV-7
Resolve® Hydrophilic Coated Biliary Locking Drainage Catheter
RBC-10-038 RBC-12-038 RBC-14-038 RBC-8-038
RBDC-10-038 RBDC-12-038 RBDC-14-038 RBDC-8-038
Resolve Mini™ Hydrophilic Coated Locking Drainage Catheter
RML17-10-038MB RML17-12-038MB RML17-14-038MB RML17-6-038MB
RML17-7-038MB RML17-8-038MB RML27-10-038MB RML27-12-038MB
RML27-14-038MB RML27-6-038MB RML27-7-038MB RML27-8-038MB
RML42-10-038MB RML42-12-038MB RML42-14-038MB RML42-6-038MB
RML42-7-038MB RML42-8-038MB
Resolve ConvertX® Biliary Stent System
RCXB10-10-038 RCXB15-10-038 RCXB5-10-038 RCXB7-10-038
Resolve®+
RBC-10-REV RBC-12-REV RBC-14-REV RBC-8-REV
RBDC-10-REV RBDC-12-REV RBDC-14-REV RBDC-8-REV
RBC-10-SFX RBC-12-SFX RBC-14-SFX RBC-8-SFX
RBDC-10-SFX RBDC-12-SFX RBDC-14-SFX RBDC-8-SFX
RLC-10-REV RLC-12-REV RLC-14-REV RLC-6-REV
RLC-7-REV RLC-8-REV RLCMB-10-REV RLCMB-12-REV
RLCMB-14-REV RLCMB-6-REV RLCMB-7-REV RLCMB-8-REV
RLC-10-SFX RLC-12-SFX RLC-14-SFX RLC-6-SFX
RLC-7-SFX RLC-8-SFX RLCMB-10-SFX RLCMB-12-SFX
RLCMB-14-SFX RLCMB-6-SFX RLCMB-7-SFX RLCMB-8-SFX
RLC-NV-10-REV RLC-NV-12-REV RLC-NV-14-REV RLC-NV-6-REV
RLC-NV-7-REV RLC-NV-8-REV RLCMB-NV-10-REV RLCMB-NV-12-REV
RLCMB-NV-14-REV RLCMB-NV-6-REV RLCMB-NV-7-REV RLCMB-NV-8-REV
RLC-NV-10-SFX RLC-NV-12-SFX RLC-NV-14-SFX RLC-NV-6-SFX
RLC-NV-7-SFX RLC-NV-8-SFX RLCMB-NV-10-SFX RLCMB-NV-12-SFX
RLCMB-NV-14-SFX RLCMB-NV-6-SFX RLCMB-NV-7-SFX RLCMB-NV-8-SFX
RML27-10-REV RML27-10-SFX RML27-12-REV RML27-12-SFX
RML27-14-REV RML27-14-SFX RML27-6-REV RML27-6-SFX
RML27-7-REV RML27-7-SFX RML27-8-REV RML27-8-SFX
Impress® Angiographic Catheter
Impress® Angiographic Catheter Radial Internal Mammary
411038RADIM 511038RADIM
Impress® Angiographic Catheter Coronary Sinus
57538CS 1628-Y8M
Impress® Angiographic Catheter Fischook
PVI511038FH3 PVI512538FH3
Impress® Angiographic Catheter Headhunter
410035HH1 410038HH3 510035HH1 512535HH1 410035HH3 412535HH1 510038HH3 512538HH1
410038HH1 510035HH3 510038HH1
410038HH1-H 412538HH1-H 510038HH1-H 512538HH1-H
Impress® Angiographic Catheter Newton
410038N1 510038N4 410038N3 510038N2 410038N4 410038N2 510038N3 510038N1
Impress® Angiographic Catheter Bentson
46535B1 410035B1 510038B1 510035B1
410035B2 510035B2 56535B1 410038B1
410038B1-H 510038B1-H 410038B2-H 510038B2-H
Impress® Angiographic Catheter Mani
410035MANI 510035MANI 410038MANI 510038MANI
410038MANI-H 510038MANI-H

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los 19 días del mes de agosto del 2025.

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Impress® Angiographic Catheter Vertebral
46538VER 510038VER 56538VER 410038VER
412535VER 410035VER 512535VER 510035VER
56538VER-H 510038VER-H 46538VER-H 410038VER-H
Impress® Angiographic Catheter Modified Cerebral
410035MC 410038MC 510035MC 510038MC
Impress® Angiographic Catheter Berenstein
46535BER 510035BER 410038BER 53035BER 56538BER 410035BER 512538BER 56535BER
46538BER 510038BER 412538BER 43035BER
46538BER-H 410038BER-H 56538BER-H 510038BER-H
412538BER-H 512538BER-H
Impress® Angiographic Catheter MW2
44038MW2 56538MW2
Impress® Angiographic Catheter Simmons
46535SIM1 410035SIM1 410038SIM2 56535SIM1 46538SIM1 410035SIM2 48035MODS 56538SIM1
46538SIM2 410038SIM1 48038MODS 56538SIM2 512535SIM1
510035SIM1 510035SIM2 510038SIM1 510038SIM2
410038SIM1-H 510038SIM1-H 410038SIM2-H 510038SIM2-H
Impress® Angiographic Catheter Cobra
465352CB1 410038CB2 565352CB1 46538CB2
465352CB2 510038CB1 565352CB2 410038CB1
46535CB2 510038CB2 565382CB1 56538CB1
465382CB1 465382CB2 565382CB2 56538CB2
46538CB1
46538CB1-H 56538CB1-H 46538CB2-H 410038CB2-H
56538CB2-H 510038CB2-H
Impress® Angiographic Catheter Modified Cobra
43035MODCB1 53035MODCB1
Impress® Angiographic Catheter Hook
465352HK0-8 565352HK0-8 465352HK1-0 565352HK1-0
Impress® Angiographic Catheter Shepherd Hook
465352SH0-8 465352SH1-0 565352SH0-8 565352SH1-0
Impress® Angiographic Catheter Renal Vein Renin
56538IRG1 56538IRG2
Impress® Angiographic Catheter Renal Double Curve
465352RC 565352RC 46535RC 510038IRDC

Impress® Angiographic Catheter Amir Motarjeme™
46535MOT 410035MOT 56535MOT 510035MOT
Impress® Angiographic Catheter Amir Motarjeme™ Cane
46535MOTC 410035MOTC
Impress® Angiographic Catheter Reuter
48038RE 58035RE 58038RE
Impress® Angiographic Catheter Mikaelsson
48038MIK 58038MIK
Impress® Angiographic Catheter KA2
56538KA2 44038KA2 46538KA2 54038KA2 53035KA2 43035KA2
44038KA2-H 46538KA2-H 54038KA2-H 56538KA2-H
Impress® Angiographic Catheter Hockey Stick
410038HS 510038HS
Impress® Angiographic Catheter Modified Hook
48035MHK1 48035MHK2 48035MHK3 58035MHK1
58035MHK3 58035MHK2
48038MHK1-H 58038MHK1-H 48038MHK2-H 58038MHK2-H
48038MHK3-H 58038MHK3-H

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465356MHK-NB 490356MHK-NB 590386MHK-NB 565356MHK-NB 565386MHK-NB
Impress® Angiographic Catheter Straight Selective
46538STS 56538STS 511038STS 44035STS
411035STS 411038STS 511035STS 44038STS 54035STS 54038STS
46538STS-H 410038STS-H 56538STS-H 510038STS-H
412538STS-H 512538STS-H
Impress® Angiographic Catheter Straight
53035STR 43035STR
4653510STF-NB 4903510STF-NB 5653510STF-NB 5903510STF-NB
Impress® Angiographic Catheter Renal, Bifurcation, Iliac
465354RBI 565354RBI 510035RBI 56535RBI
5100354RBI 56538RBI-H
Impress® Angiographic Catheter RIM
56535RIM 46535RIM 44035RIM 54035RIM
53035RIM 43035RIM
Impress® Angiographic Catheter Mini RIM
56535MRIMST
Impress® Angiographic Catheter Shepherd Flush
465356SHP-NB 490356SHP-NB 565356SHP-NB
Impress® Angiographic Catheter Ultra Bolus Flush
4653510UBF-NB 5653510UBF-NB 4903510UBF-NB 5903510UBF-NB
Impress® Angiographic Catheter Modified Bolus Flush
5653810MUBF-NB 4653810MUBF-NB
Impress® Angiographic Catheter Pigtail Flush
4653510PIG-NB 51103810PIG-NB 5653810PIG-NB 5903510PIG-NB 5653510PIG-NB 4903510PIG-NB
51103510PIG-NB 5303510PIG-NB 4303510PIG-NB 41103510PIG-NB 5903810PIG-NB
Impress® Angiographic Catheter Osborn
410035OSB1 510035OSB1
Impress® Angiographic Catheter Multipurpose A1
410038MPA1 412538MPA1 46538MPA1 56538MPA1 510038MPA1 512538MPA1
410038MPA1-H 510038MPA1-H
Impress® Angiographic Catheter Ultimate
5IMP10038ULT1 5IMP100381ULT1 5IMP110381ULT2 5IMP11038ULT2
5IMP110381ULT4-T40 5IMP11038ULT4-T40
Impress® Angiographic Catheter Uterine Artery
59035UAC 59038UAC 59035IUAC
Impress® Angiographic Catheter CPC
57538CARN5 57538CARN5S 57538CARN10 57538CARN10S 57538CARN15 57538CARN15S
Impress® UAC2™ Uterine Artery Catheter
59035IUACTMB-H
Impress® Angiographic Catheter 3D Curve
58038IRH1 58038IRH2
Impress® Custom Catheter
1623-E1 1623-E6 1623-F9 1623-G1 1624-B5 1624-B7 1624-C7 1624-D5 1624-E6 1628-001 1628-005
1628-016 1628-017 1628-019 1628-021 1628-034 1628-035 1628-037 1628-042 1628-043 1628-044
1628-059 1628-060 1628-061 1628-062 1628-063 1628-064 1628-065 1628-073 1628-079 1628-083
1628-100 1628-113 1628-118 1628-121 1628-128 1628-133 1628-148 1628-151 1628-152 1628-155
1628-168 1628-178 1628-179 1628-181 1628-182 1628-183 1628-189 1628-192 1628-197 1628-198
1628-202 1628-204 1628-205 1628-206 1628-206H 1628-207 1628-208 1628-209 1628-210 1628-213
1628-219 1628-220 1628-221 1628-222 1628-223 1628-224 1628-225 1628-228 1628-231 1628-232
1628-237 1628-238 1628-239 1628-240 1628-241 1628-248 1628-253 1628-261 1628-268 1628-269
1628-275 1628-W7 1628-Y7 1628-Y8 1628-Z4 1628-Z5 1628-Z7 1628-Z9 7440-E7 7440-F6 7440-F7
7440-H5 7440-H6 7440-H8 7440-H9 7440-J4 7440-J5 7440-J7 7440-J8 7440-K4 7440-K5 7440-L5
7440-M1 7440-M3 7440-M5 7440-M6 7440-N4 7440-N5 7440-N6 7440-N7 7440-N8 7440-N9 7440-P1
7440-P3 7440-P7 7440-P8 7440-P9 7440-Q1 7440-Q2 7440-Q3 7440-Q4 7440-Q5 7440-Q6 1628-017M

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1628-015 1628-054 1628-095H 1628-166 1628-200 1628-217 1628-236 1628-272 7440-G8
7440-P2 1628-019M 7440-L6 1628-050 1628-094 1628-164 1628-199 1628-216 1628-234 1628-270
Impress® Angiographic Catheter Double Loop 3D Curve
57538IDLOOP
HeartSpan® Transseptal Needle
FND-019-00 FND-019-02 FND-019-04 FND-019-06 FND-019-01 FND-019-03 FND-019-05 FND-019-07
Resolve ConvertX® Nephroueteral Stent System
RCX10-10-038 RCX10-8-038 RCX12-10-038 RCX12-8-038 RCX22-10-038 RCX22-8-038
RCX14-10-038 RCX14-8-038 RCX20-10-038 RCX20-8-038 RCX26-10-038 RCX26-8-038
RCX24-10-038 RCX24-8-038 RCX28-10-038 RCX28-8-038
Vessel Dilator
3339-21 3339-31 3339-41 3339-51
Worley™ VEIN SELECTOR Angiographic Catheter
57538CS-WOR 57538CSV-WOR 57538CSHK-WOR

Nombre del fabricante
Sitio de fabricación
MERIT MEDICAL SYSTEMS, INC
12701 Kingston Avenue
Chester, VA
USA 23836

Nombre del producto(s)

PERICARDIOCENTESIS KIT
PC101 PC801 PC201 PC802 PC804EU
Waste Management Kit
BRC-BAL-INT-FL BRC-BAL-INT-SL
OUTAKE® Catheter Extraction Device
CET100 CET200 CET300
ReSolve® Thoracostomy Tray
RTT14038MB RTT14038MBND
Angiography Tray 1
K09T-08878

Kits de conveniencia
KXX-AAAAAA
'K' - indica que es un Kit 'XX' - designa el tipo de Kit
YYYY': es un número secuencial que identifica de forma exclusiva el kit. 'KXXT': indica que se trata de un paquete de procedimientos.
'-' es el carácter - (guión) K05 = Kit de inflado K09 = Colector K10 = Recolección de desechos (desechable Depósitos, Kits de Drenaje)

K11 = Monitoreo de presión (MeritTrans™) K12 = Varios K17 = Kit de electrofisiología K20 = Kit de broncoscopia

----------FIN DE LA LISTA DE PRODUCTOS----------

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APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by Cesar A. Perez

3. acting in the capacity of Director, Division of Establishment Support

4. bears the seal/stamp of U. S. Department of Health and Human Services

Certified

5. at Washington, D.C.

6. the thirtieth of September, 2025

7. by *Assistant Authentication Officer, United States Department of State*

8. No. 25085586-6

9. Seal/Stamp:

10. Signature: Matthews

Veda Matthews

FDA-5 Lote 67-69-71-74-79-81-85
87-89-91-97-99-101

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FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

187
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 12854-9-2024-3

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Four Pages)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections.The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from September 12, 2024 to September 11, 2026.

To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.

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U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

ertificate No. 12854-9-2024-3

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA
USA 01752

Name of Manufacturer
Contract Manufacturer
AvailMed S.A.De C.V.
C.Industrial Lt.001 Mz.105
No. 20905 Int.A. Col. Cd. Industrial
Tijuana, Baja California
MEXICO C.P. 22444

Name of Distributor
Boston Scientific Corp., Marina Bay Cust. Fulfillment Center
500 Commander Shea Boulevard
QUINCY, MA
USA 02171

---END OF MANUFACTURER/DISTRIBUTOR LIST---

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U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 12854-9-2024-3

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 4

Name of Owner Operator
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA
USA 01752

Name of Manufacturer
Contract Manufacturer
AvailMed S.A.De C.V.
C.Industrial Lt.001 Mz.105
No. 20905 Int.A. Col. Cd. Industrial
Tijuana, Baja California
MEXICO C.P. 22444

Name of Distributor
Boston Scientific Corp., Marina Bay Cust. Fulfillment Center
500 Commander Shea Boulevard
QUINCY, MA
USA 02171

Name of Product(s)
RunWay™ Guide Catheters

UPN:	Description:
H74938969010	6F RunWay FR3.5
H74938969020	6F RunWay FR4
H74938969030	6F RunWay FR5
H74938969040	6F RunWay FR6
H74938969050	6F RunWay FL3
H74938969060	6F RunWay FL3.5
H74938969070	6F RunWay FL4
H74938969080	6F RunWay FL4.5
H74938969090	6F RunWay FL5
H74938969100	6F RunWay FL6
H749389691220	6F RunWay IM 85cm
H749389691230	6F RunWay IM 110cm
H749389691260	6F RunWay RCB SH (SIDE HOLES)
H749389691270	6F RunWay LCB SH (SIDE HOLES)
H749389691290	6F RunWay IM SH (SIDE HOLES)
H749389691380	6F RunWay MP1 SH (SIDE HOLES)
H749389691410	6F RunWay HS SH (SIDE HOLES)
H74938969170	6F RunWay AR1
H74938969180	6F RunWay AR2
H74938969190	6F RunWay AL1
H74938969200	6F RunWay AL2
H74938969210	6F RunWay AL3
H74938969220	6F RunWay AL.75
H74938969240	6F RunWay RCB
H74938969250	6F RunWay LCB
H74938969260	6F RunWay IM
H749389692720	6F RunWay FCL3.5
H749389692730	6F RunWay FCL4
H749389692790	6F RunWay FCR3.5
H749389692800	6F RunWay FCR4
H74938969280	6F RunWay FL3.5 ST
H74938969290	6F RunWay FL4 ST
H749389692930	6F RunWay Q3.5
H749389692940	6F RunWay Q4
H749389692950	6F RunWay Q4.5

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Certificate No. 12854-9-2024-3

Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 4

H749389692960	6F RunWay Q5
H749389692970	6F RunWay Q3.5 SH (SIDE HOLES)
H749389692980	6F RunWay Q4 SH (SIDE HOLES)
H74938969300	6F RunWay FL4.5 ST
H74938969310	6F RunWay FL5 ST
H74938969380	6F RunWay MP1
H74938969390	6F RunWay MP2
H74938969400	6F RunWay BR1 80cm
H74938969410	6F RunWay HS
H749389694420	6F RunWay FR3
H749389694460	6F RunWay IM 90cm
H749389694480	6F RunWay RC4 SC
H74938969460	6F RunWay RC3.5 SC
H749389694700	6F RunWay Radial ST
H74938969470	6F RunWay FR3.5 SH (SIDE HOLES)
H749389694720	6F RunWay Radial
H749389694730	6F RunWay Radial SH (SIDE HOLES)
H74938969480	6F RunWay FR4 SH (SIDE HOLES)
H749389694960	6F RunWay ART3
H749389694970	6F RunWay ART3 SH (SIDE HOLES)
H749389694980	6F RunWay ART3.5
H749389694990	6F RunWay ART3.5 SH (SIDE HOLES)
H749389695000	6F RunWay ART4
H749389695010	6F RunWay ART4 SH (SIDE HOLES)
H749389695020	6F RunWay ART4.5
H749389695140	6F RunWay FR4.5
H74938969520	6F RunWay FL3.5 SH (SIDE HOLES)
H74938969530	6F RunWay FL4 SH (SIDE HOLES)
H749389695360	6F RunWay ML3
H749389695370	6F RunWay ML3.5
H749389695380	6F RunWay ML4
H749389695390	6F RunWay ML4.5
H749389695730	6F RunWay CLS3
H749389695740	6F RunWay CLS3.5
H749389695750	6F RunWay CLS4
H749389695760	6F RunWay CLS4.5
H749389695770	6F RunWay CLS3.75
H749389695780	6F RunWay CLS3.5 SH (SIDE HOLES)
H749389695790	6F RunWay CLS4 SH (SIDE HOLES)
H749389695800	6F RunWay CLS3.75 SH (SIDE HOLES)
H749389695830	6F RunWay KIMNY
H749389695840	6F RunWay KIMNY mini
H749389695910	6F RunWay KIMNY SH (SIDE HOLES)
H749389695920	6F RunWay KIMNY mini SH (SIDE HOLE
H749389696090	6F RunWay WRP
H749389696100	6F RunWay WRP SH (SIDE HOLES)
H749389696110	6F RunWay KL3H
H749389696120	6F RunWay KL4H
H749389696130	6F RunWay KL5H
H749389696140	6F RunWay KL3H SH (SIDE HOLES)
H749389696150	6F RunWay KL4H SH (SIDE HOLES)
H749389696160	6F RunWay KL5H SH (SIDE HOLES)
H749389696320	6F RunWay Mann IM 90cm
H749389696380	6F RunWay IMC 90cm
H749389696480	6F RunWay KR3H
H749389696490	6F RunWay KR4H
H749389696500	6F RunWay KR5H
H749389696510	6F RunWay KR3H SH (SIDE HOLES)

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Certificate No. 12854-9-2024-3

Certificate to Foreign Government - Name of Product(s) Attachment Page 3 of 4

H749389696520	6F RunWay KR4H SH (SIDE HOLES)
H749389696530	6F RunWay KR5H SH (SIDE HOLES)
H749389696540	6F RunWay KR3S
H749389696550	6F RunWay KR4S
H749389696560	6F RunWay KR5S
H749389696570	6F RunWay KR3S SH (SIDE HOLES)
H749389696580	6F RunWay KR4S SH (SIDE HOLES)
H749389696590	6F RunWay KR5S SH (SIDE HOLES)
H749389696600	6F RunWay JL3
H74938969660	6F RunWay AR1 SH (SIDE HOLES)
H749389696610	6F RunWay JL3.5
H749389696620	6F RunWay JL4
H749389696630	6F RunWay JL4.5
H749389696640	6F RunWay JL5
H749389696650	6F RunWay JL6
H749389696670	6F RunWay JL3.5 SH (SIDE HOLES)
H749389696680	6F RunWay JL4 SH (SIDE HOLES)
H74938969670	6F RunWay AR2 SH (SIDE HOLES)
H749389696730	6F RunWay JL3.5 ST
H749389696740	6F RunWay JL4 ST
H749389696750	6F RunWay JL4.5 ST
H749389696760	6F RunWay JL5 ST
H74938969680	6F RunWay AL1 SH (SIDE HOLES)
H749389696840	6F RunWay JR3
H749389696850	6F RunWay JR3.5
H749389696860	6F RunWay JR4
H749389696870	6F RunWay JR4.5
H749389696880	6F RunWay JR5
H749389696890	6F RunWay JR6
H74938969690	6F RunWay AL2 SH (SIDE HOLES)
H749389696910	6F RunWay JR3.5 SH (SIDE HOLES)
H749389696920	6F RunWay JR4 SH (SIDE HOLES)
H749389696970	6F RunWay JR3.5 ST
H749389696980	6F RunWay JR4 ST
H74938969710	6F RunWay VL3
H749389697130	6F RunWay LeftBU3
H749389697140	6F RunWay LeftBU3.5
H749389697150	6F RunWay LeftBU3.75
H749389697160	6F RunWay LeftBU4
H749389697170	6F RunWay LeftBU4.5
H749389697180	6F RunWay LeftBU5
H749389697190	6F RunWay LeftBU3 SH (SIDE HOLES)
H749389697200	6F RunWay LeftBU3.5 SH (SIDE HOLES
H74938969720	6F RunWay VL3.5
H749389697210	6F RunWay LeftBU3.75 SH (SIDE HOLE
H749389697220	6F RunWay LeftBU4 SH (SIDE HOLES)
H749389697230	6F RunWay LeftBU4.5 SH (SIDE HOLES
H749389697240	6F RunWay LeftBU5 SH (SIDE HOLES)
H74938969730	6F RunWay VL4
H74938969740	6F RunWay VL4.5
H74938969750	6F RunWay VL5
H74938969780	6F RunWay VL3.5 SH (SIDE HOLES)
H74938969790	6F RunWay VL4 SH (SIDE HOLES)
H74938969850	6F RunWay AL1.5
H74938969910	6F RunWay FR3.5 ST
H74938969920	6F RunWay FR4 ST
H749389691240	6F RunWay AL.75 SH (SIDE HOLES)
H749389691910	6F RunWay AL.75 90cm

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U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
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Certificate No. 12854-9-2024-3

Certificate to Foreign Government - Name of Product(s) Attachment Page 4 of 4

H749389693510	6F RunWay CLS3 SH (SIDE HOLES)
H749389693760	6F RunWay AL1 90cm
H749389697290	6F RunWay LeftBU3.25
H749389697300	6F RunWay LeftBU4.25
H749389697310	6F RunWay LeftBU4.75
H749389697350	6F RunWay RBL3.5
H749389697360	6F RunWay RBL4
H749389697370	6F RunWay RBL4.5
H749389697380	6F RunWay RBR3
H749389697390	6F RunWay RBR3.5
H749389697400	6F RunWay RBR4
H749389697410	6F RunWay TIG3
H749389697420	6F RunWay TIG3.5
H749389697430	6F RunWay TIG4
H749389697440	6F RunWay TIG4.5
H749389697450	6F RunWay TIG5
H749389697500	6F RunWay LeftBU3.25 SH (SIDE HOLES)
H749389697510	6F RunWay LeftBU4.25 SH (SIDE HOLES)
H749389697520	6F RunWay LeftBU4.75 SH (SIDE HOLES)
H749389697560	6F RunWay RBL3.5 SH (SIDE HOLES)
H749389697570	6F RunWay RBL4 SH (SIDE HOLES)
H749389697580	6F RunWay RBL4.5 SH (SIDE HOLES)
H749389697590	6F RunWay RBR3 SH (SIDE HOLES)
H749389697600	6F RunWay RBR3.5 SH (SIDE HOLES)
H749389697610	6F RunWay RBR4 SH (SIDE HOLES)
H749389697620	6F RunWay TIG3 SH (SIDE HOLES)
H749389697630	6F RunWay TIG3.5 SH (SIDE HOLES)
H749389697640	6F RunWay TIG4 SH (SIDE HOLES)
H749389697650	6F RunWay TIG4.5 SH (SIDE HOLES)
H749389697660	6F RunWay TIG5 SH (SIDE HOLES)
H74938969770	6F RunWay VL3 SH (SIDE HOLES)
H749389699530	6F RunWay MP1 125cm
H749389699560	6F RunWay JR4 125cm

----------END OF PRODUCT LIST----------

JACK FACK

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QUIRNO CODAS THOMPSON LLANO
Traductor Público Matriculado
Gómez de Castro 238
Tel.: 600 865 – Fax 612 314
Asunción - Paraguay

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APOSTILLA

(Convención de La Haye del 5 de octubre de 1961)

1. País:Estados Unidos de América

Este documento público

2. ha sido firmado por: Director, DRP2: División de Apoyo a Establecimientos.

3. actuando en calidad de: Notario Público, Estado de Minnesota

4. lleva el sello/timbre de: Departamento de Salud y Servicios Humanos de EE. UU.

Certificado

5. en: St. Paul, Minnesota

6. el: el treinta de setiembre de 2025

7. por: Notario Público, Estado de Minnesota

8. Nº: 250855866

9. Sello de lacre:

10 Firma:

Veda Matthews

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los 21 días del mes de enero del 2025.

QUIRNO CODAS THOMPSON LL.
Traductor Publico
Matrícula Nº 670

2026-07-22 10:05:56.224342-03

QUIRNO CODAS THOMPSON LLANO
Traductor Público Matriculado
Gómez de Castro 238
Tel.: 600 865 – Fax 612 314
Asunción - Paraguay

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Certificado N° 12854-9-2024-3

CERTIFICADO A GOBIERNOS EXTRANJEROS

A fin de permitir la importación de productos de los Estados Unidos en países extranjeros, la Administración de Comidas y Drogas de los EE.UU. (FDA) certifica la siguiente información relacionada con los productos a ser exportados listados abajo:

Nombre de los Productos	**Nombre del Fabricante/Distribuidor, Dirección**
Ver Lista Adjunta	Ver Lista Adjunta
(Cuatro Páginas)	(Una Página)

Los productos descritos arriba (y los sitios de fabricación/distribución que los producen/distribuyen) están sujetos a la jurisdicción de la FDA bajo el Acta Federal de Comidas, Drogas y Cosméticos.

Está certificado que los productos mencionados arriba pueden ser comercializados, y legalmente exportados de los Estados Unidos de América en este momento. Las plantas de fabricación en las que los productos son fabricados están sujetas a inspecciones periódicas.

Atentamente,

CDR Cesar A. Perez, PhD, Director
DRP2: División de Apoyo al Establecimiento
Oficina de Programas Regulatorios
Oficina de Evaluación de Productos y Calidad
Centro de Dispositivos y Salud Radiológica
Administración de Comidas y Drogas de los EE.UU., DHHS

Este certificado es válido desde el 12 de septiembre de 2024 hasta el 11 de septiembre de 2026.

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los 21 días del mes de enero del 2025

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Traductor Público
Matrícula Nº 670

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Traductor Público Matriculado
Gómez de Castro 238
Tel.: 600 865 – Fax 612 314
Asunción - Paraguay

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Certificado N° 12854-9-2024-3
Certificado a Gobiernos Extranjeros - Adjunto Nombre del Fabricante/Distribuidor

Nombre del Dueño Operador
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA EE. UU 01752

Nombre del Fabricante
Fabricación por contrato
AvailMed S.A.De C.V.
C.Industrial Lt.001 Mz.105
No. 20905 Int.A. Col. Cd. Industrial
Tijuana, Baja California
MEXICO C.P. 22444

Nombre del Distribuidor
Boston Scientific Corp., Marina Bay Cust. Fullfilment Center
500 Commander Shea Boulevard
QUINCY, MA USA 02171

---FIN DE LA LISTA DE FABRICANTES/DISTRIBUIDORES---

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital de Paraguay, a los 21 días del mes de enero del 2025

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Traductor Publico
Matrícula Nº 670

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Traductor Público Matriculado
Gómez de Castro 238
Tel.: 600 865 – Fax 612 314
Asunción - Paraguay

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Certificado N° 12854-9-2024-3

Certificado para gobierno extranjero - Nombre del producto(s) Anexo Página 1 de 4

Nombre del Dueño Operador
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA EE. UU.01752

Nombre del Fabricante
Fabricación por contrato
AvailMed S.A.De C.V.
C.Industrial Lt.001 Mz.105
No. 20905 Int.A. Col. Cd. Industrial
Tijuana, Baja California
MEXICO C.P. 22444

Nombre del Distribuidor
Boston Scientific Corp., Marina Bay Cust. Fullfilment Center
500 Commander Shea Boulevard
QUINCY, MA USA 02171

Nombre del Producto
Catéteres guía RunWay™

UPN:	Description:
H74938969010	6F RunWay FR3.5
H74938969020	6F RunWay FR4
H74938969030	6F RunWay FR5
H74938969040	6F RunWay FR6
H74938969050	6F RunWay FL3
H74938969060	6F RunWay FL3.5
H74938969070	6F RunWay FL4
H74938969080	6F RunWay FL4.5
H74938969090	6F RunWay FL5
H74938969100	6F RunWay FL6
H749389691220	6F RunWay IM 85cm
H749389691230	6F RunWay IM 110cm
H749389691260	6F RunWay RCB SH (SIDE HOLES)
H749389691270	6F RunWay LCB SH (SIDE HOLES)
H749389691290	6F RunWay IM SH (SIDE HOLES)
H749389691380	6F RunWay MP1 SH (SIDE HOLES)
H749389691410	6F RunWay HS SH (SIDE HOLES)
H74938969170	6F RunWay AR1
H74938969180	6F RunWay AR2
H74938969190	6F RunWay AL1
H74938969200	6F RunWay AL2

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los 21 días del mes de enero del 2025

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Matrícula Nº 670

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Traductor Público Matriculado
Gómez de Castro 238
Tel.: 600 865 – Fax 612 314
Asunción - Paraguay

H74938969210 6F RunWay AL3
H74938969220 6F RunWay AL.75
H74938969240 6F RunWay RCB
H74938969250 6F RunWay LCB
H74938969260 6F RunWay IM
H749389692720 6F RunWay FCL3.5
H749389692730 6F RunWay FCL4
H749389692790 6F RunWay FCR3.5
H749389692800 6F RunWay FCR4
H74938969280 6F RunWay FL3.5 ST
H74938969290 6F RunWay FL4 ST
H749389692930 6F RunWay Q3.5
H749389692940 6F RunWay Q4
H749389692950 6F RunWay Q4.5

Certificado N° 12854-9-2024-3

Certificado para gobierno extranjero - Nombre del producto(s) Anexo Página 2 de 4

H749389692960 6F RunWay Q5
H749389692970 6F RunWay Q3.5 SH (SIDE HOLES)
H749389692980 6F RunWay Q4 SH (SIDE HOLES)
H74938969300 6F RunWay FL4.5 ST
H74938969310 6F RunWay FL5 ST
H74938969380 6F RunWay MP1
H74938969390 6F RunWay MP2
H74938969400 6F RunWay BR1 80cm
H74938969410 6F RunWay HS
H749389694420 6F RunWay FR3
H749389694460 6F RunWay IM 90cm
H749389694480 6F RunWay RC4 SC
H74938969460 6F RunWay RC3.5 SC
H749389694700 6F RunWay Radial ST
H74938969470 6F RunWay FR3.5 SH (SIDE HOLES)
H749389694720 6F RunWay Radial
H749389694730 6F RunWay Radial SH (SIDE HOLES)
H74938969480 6F RunWay FR4 SH (SIDE HOLES)
H749389694960 6F RunWay ART3
H749389694970 6F RunWay ART3 SH (SIDE HOLES)
H749389694980 6F RunWay ART3.5
H749389694990 6F RunWay ART3.5 SH (SIDE HOLES)
H749389695000 6F RunWay ART4

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital de la Paraguay, a los 21 días del mes de enero del 2025

QUIRNO CODAS THOMPSON LL.
Traductor Publico
Matrícula Nº 670

JACK FACK

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Gómez de Castro 238
Tel.: 600 865 – Fax 612 314
Asunción - Paraguay

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H749389695010 6F RunWay ART4 SH (SIDE HOLES)
H749389695020 6F RunWay ART4.5
H749389695140 6F RunWay FR4.5
H74938969520 6F RunWay FL3.5 SH (SIDE HOLES)
H74938969530 6F RunWay FL4 SH (SIDE HOLES)
H749389695360 6F RunWay ML3
H749389695370 6F RunWay ML3.5
H749389695380 6F RunWay ML4
H749389695390 6F RunWay ML4.5
H749389695730 6F RunWay CLS3
H749389695740 6F RunWay CLS3.5
H749389695750 6F RunWay CLS4
H749389695760 6F RunWay CLS4.5
H749389695770 6F RunWay CLS3.75
H749389695780 6F RunWay CLS3.5 SH (SIDE HOLES)
H749389695790 6F RunWay CLS4 SH (SIDE HOLES)
H749389695800 6F RunWay CLS3.75 SH (SIDE HOLES)
H749389695830 6F RunWay KIMNY
H749389695840 6F RunWay KIMNY mini
H749389695910 6F RunWay KIMNY SH (SIDE HOLES)
H749389695920 6F RunWay KIMNY mini SH (SIDE HOLE
H749389696090 6F RunWay WRP
H749389696100 6F RunWay WRP SH (SIDE HOLES)
H749389696110 6F RunWay KL3H
H749389696120 6F RunWay KL4H
H749389696130 6F RunWay KL5H
H749389696140 6F RunWay KL3H SH (SIDE HOLES)
H749389696150 6F RunWay KL4H SH (SIDE HOLES)
H749389696160 6F RunWay KL5H SH (SIDE HOLES)
H749389696320 6F RunWay Mann IM 90cm
H749389696380 6F RunWay IMC 90cm
H749389696480 6F RunWay KR3H
H749389696490 6F RunWay KR4H
H749389696500 6F RunWay KR5H
H749389696510 6F RunWay KR3H SH (SIDE HOLES)

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital del Paraguay, a los 21 días del mes de enero del 2025

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Matrícula Nº 670

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Certificado N° 12854-9-2024-3

Certificado para gobierno extranjero - Nombre del producto(s) Anexo Página 3 de 4

749389696520 6F RunWay KR4H SH (SIDE HOLES)
H749389696530 6F RunWay KR5H SH (SIDE HOLES)
H749389696540 6F RunWay KR3S
H749389696550 6F RunWay KR4S
H749389696560 6F RunWay KR5S
H749389696570 6F RunWay KR3S SH (SIDE HOLES)
H749389696580 6F RunWay KR4S SH (SIDE HOLES)
H749389696590 6F RunWay KR5S SH (SIDE HOLES)
H749389696600 6F RunWay JL3
H74938969660 6F RunWay AR1 SH (SIDE HOLES)
H749389696610 6F RunWay JL3.5
H749389696620 6F RunWay JL4
H749389696630 6F RunWay JL4.5
H749389696640 6F RunWay JL5
H749389696650 6F RunWay JL6
H749389696670 6F RunWay JL3.5 SH (SIDE HOLES)
H749389696680 6F RunWay JL4 SH (SIDE HOLES)
H74938969670 6F RunWay AR2 SH (SIDE HOLES)
H749389696730 6F RunWay JL3.5 ST
H749389696740 6F RunWay JL4 ST
H749389696750 6F RunWay JL4.5 ST
H749389696760 6F RunWay JL5 ST
H74938969680 6F RunWay AL1 SH (SIDE HOLES)
H749389696840 6F RunWay JR3
H749389696850 6F RunWay JR3.5
H749389696860 6F RunWay JR4
H749389696870 6F RunWay JR4.5
H749389696880 6F RunWay JR5
H749389696890 6F RunWay JR6
H74938969690 6F RunWay AL2 SH (SIDE HOLES)
H749389696910 6F RunWay JR3.5 SH (SIDE HOLES)
H749389696920 6F RunWay JR4 SH (SIDE HOLES)
H749389696970 6F RunWay JR3.5 ST
H749389696980 6F RunWay JR4 ST
H74938969710 6F RunWay VL3
H749389697130 6F RunWay LeftBU3
H749389697140 6F RunWay LeftBU3.5
H749389697150 6F RunWay LeftBU3.75

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital de Paraguay, a los 21 días del mes de enero del 2025.

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H749389697160 6F RunWay LeftBU4
H749389697170 6F RunWay LeftBU4.5
H749389697180 6F RunWay LeftBU5
H749389697190 6F RunWay LeftBU3 SH (SIDE HOLES)
H749389697200 6F RunWay LeftBU3.5 SH (SIDE HOLES
H74938969720 6F RunWay VL3.5
H749389697210 6F RunWay LeftBU3.75 SH (SIDE HOLE
H749389697220 6F RunWay LeftBU4 SH (SIDE HOLES)
H749389697230 6F RunWay LeftBU4.5 SH (SIDE HOLES
H749389697240 6F RunWay LeftBU5 SH (SIDE HOLES)
H74938969730 6F RunWay VL4
H74938969740 6F RunWay VL4.5
H74938969750 6F RunWay VL5
H74938969780 6F RunWay VL3.5 SH (SIDE HOLES)
H74938969790 6F RunWay VL4 SH (SIDE HOLES)
H74938969850 6F RunWay AL1.5
H74938969910 6F RunWay FR3.5 ST
H74938969920 6F RunWay FR4 ST
H749389691240 6F RunWay AL.75 SH (SIDE HOLES)
H749389691910 6F RunWay AL.75 90cm

Certificado N° 12854-9-2024-3
Certificado para gobierno extranjero - Nombre del producto(s) Anexo Página 3 de 4
H749389693510 6F RunWay CLS3 SH (SIDE HOLES)
H749389693760 6F RunWay AL1 90cm
H749389697290 6F RunWay LeftBU3.25
H749389697300 6F RunWay LeftBU4.25
H749389697310 6F RunWay LeftBU4.75
H749389697350 6F RunWay RBL3.5
H749389697360 6F RunWay RBL4
H749389697370 6F RunWay RBL4.5
H749389697380 6F RunWay RBR3
H749389697390 6F RunWay RBR3.5
H749389697400 6F RunWay RBR4
H749389697410 6F RunWay TIG3
H749389697420 6F RunWay TIG3.5
H749389697430 6F RunWay TIG4
H749389697440 6F RunWay TIG4.5
H749389697450 6F RunWay TIG5
H749389697500 6F RunWay LeftBU3.25 SH (SIDE HOLES)
H749389697510 6F RunWay LeftBU4.25 SH (SIDE HOLES)

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Gómez de Castro 238
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Asunción - Paraguay

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H749389697520 6F RunWay LeftBU4.75 SH (SIDE HOLES)
H749389697560 6F RunWay RBL3.5 SH (SIDE HOLES)
H749389697570 6F RunWay RBL4 SH (SIDE HOLES)
H749389697580 6F RunWay RBL4.5 SH (SIDE HOLES)
H749389697590 6F RunWay RBR3 SH (SIDE HOLES)
H749389697600 6F RunWay RBR3.5 SH (SIDE HOLES)
H749389697610 6F RunWay RBR4 SH (SIDE HOLES)
H749389697620 6F RunWay TIG3 SH (SIDE HOLES)
H749389697630 6F RunWay TIG3.5 SH (SIDE HOLES)
H749389697640 6F RunWay TIG4 SH (SIDE HOLES)
H749389697650 6F RunWay TIG4.5 SH (SIDE HOLES)
H749389697660 6F RunWay TIG5 SH (SIDE HOLES)
H74938969770 6F RunWay VL3 SH (SIDE HOLES)
H749389699530 6F RunWay MP1 125cm
H749389699560 6F RunWay JR4 125cm

--FINAL DE LA LISTA DE PRODUCTOS--

Yo, el suscrito, declaro bajo fe de juramento, que esta es una traducción fiel y correcta al español de un documento redactado en idioma inglés, que al efecto tuve a la vista y al cual me remito. Doy fe con mi firma y sello, en la ciudad de Asunción, capital de la República del Paraguay, a los 21 días del mes de enero del 2025

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ID: 445273

PLANILLA DE DATOS GARANTIZADOS

DESCRIPCIÓN DEL LOTE OFERTADO ITEM N°	LOTE N° 1 – ITEM N°1
NOMBRE DEL PRODUCTO:	CATETER BALON
FABRICANTE:	BOSTON SCIENTIFIC CORPORATION
MARCA COMERCIAL:	BOSTON SCIENTIFIC
PROCEDENCIA/S:	ESTADOS UNIDOS / MALASIA
ORIGEN:	ESTADOS UNIDOS / MALASIA
REGISTRO SANITARIO:	DM-001153-02
ESPECIFICACIONES TÉCNICAS:	CATÉTER BALÓN NO COMPLACIENTE DE 2,0mm de diámetro de 6 A 27 MM de longitud de alta presión compatible con Catéter Guía 5french y con Alambre Guía 0,014" presión nominal de 6 a 20 ATM. Perfil de entrada de 0,018" o menor con sistema de intercambio rápido y largo de 135 a 155 cm. Empaque individual, en papel grado médico y/o blíster trasparente estéril, herméticamente cerrado, la aja debe contener los siguientes datos: medidas, código de lote, fecha de fabricación, fecha de vencimiento, procedencia o fabricante legal, logotipo de la CE o FDA, folleto de instrucciones de uso, indicaciones de almacenamiento.
ESPECIFICAR: ESTÉRIL - NO ESTÉRIL	ESTÉRIL
PRESENTACIÓN DEL PRODUCTO:	UNIDAD
EMBALAJE:	CAJA
INFORMACIÓN ADICIONAL SOBRE LO OFERTADO QUE SE CONSIDERE RELEVANTE:	

FIRMA Y SELLO DEL OFERENTE

RAFAEL CÁCERES
Jack Fack S.R.L.

Observaciones:

1. Esta planilla es de llenado obligatorio en una hoja con membrete de la firma cotizante debidamente rubricada. Deberá ser presentada por cada ítem ofertado con el nombre del producto y el número de ítem correspondiente.
2. En caso de discrepancia entre: la marca comercial, el fabricante, las especificaciones técnicas, unidad de medida de la Planilla de Precios y la Planilla de Datos Garantizados, prevalecerá la planilla de precios.
3. Los productos deberán llevar la leyenda **I.P.S o USO EXCLUSIVO DEL I.P.S.**, en tinta de difícil remoción.

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PLANILLA DE DATOS GARANTIZADOS

DESCRIPCIÓN DEL LOTE OFERTADO **ITEM N°**	LOTE N° 1 – ITEM N°2
NOMBRE DEL PRODUCTO:	CATETER BALON
FABRICANTE:	BOSTON SCIENTIFIC CORPORATION
MARCA COMERCIAL:	BOSTON SCIENTIFIC
PROCEDENCIA/S:	ESTADOS UNIDOS / MALASIA
ORIGEN:	ESTADOS UNIDOS / MALASIA
REGISTRO SANITARIO:	DM-001153-02
ESPECIFICACIONES TÉCNICAS:	CATÉTER BALÓN NO COMPLACIENTE DE 2,0mm de diámetro de 6 A 27 MM de longitud de alta presión compatible con Catéter Guía 5french y con Alambre Guía 0,014" presión nominal de 6 a 20 ATM. Perfil de entrada de 0,018" o menor con sistema de intercambio rápido y largo de 135 a 155 cm. Empaque individual, en papel grado médico y/o blíster trasparente estéril, herméticamente cerrado, la aja debe contener los siguientes datos: medidas, código de lote, fecha de fabricación, fecha de vencimiento, procedencia o fabricante legal, logotipo de la CE o FDA, folleto de instrucciones de uso, indicaciones de almacenamiento.
ESPECIFICAR: ESTÉRIL - NO ESTÉRIL	ESTÉRIL
PRESENTACIÓN DEL PRODUCTO:	UNIDAD
EMBALAJE:	CAJA
INFORMACIÓN ADICIONAL SOBRE LO OFERTADO QUE SE CONSIDERE RELEVANTE	

FIRMA Y SELLO DEL OFERENTE
RAFAEL CÁCERES
Jack Fack S.R.L.

Observaciones:

1. Esta planilla es de llenado obligatorio en una hoja con membrete de la firma cotizante debidamente rubricada. Deberá ser presentada por cada ítem ofertado con el nombre del producto y el número de ítem correspondiente.
2. En caso de discrepancia entre: la marca comercial, el fabricante, las especificaciones técnicas, unidad de medida de la Planilla de Precios y la Planilla de Datos Garantizados, prevalecerá la planilla de precios.
3. Los productos deberán llevar la leyenda **I.P.S o USO EXCLUSIVO DEL I.P.S.**, en tinta de difícil remoción.

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PLANILLA DE DATOS GARANTIZADOS

DESCRIPCIÓN DEL LOTE OFERTADO **ITEM N°**	LOTE N° 1 – ITEM N°3
NOMBRE DEL PRODUCTO:	CATETER BALON
FABRICANTE:	BOSTON SCIENTIFIC CORPORATION
MARCA COMERCIAL:	BOSTON SCIENTIFIC
PROCEDENCIA/S:	ESTADOS UNIDOS / MALASIA
ORIGEN:	ESTADOS UNIDOS / MALASIA
REGISTRO SANITARIO:	DM-001153-02
ESPECIFICACIONES TÉCNICAS:	CATÉTER BALÓN NO COMPLACIENTE DE 2,0mm de diámetro de 6 A 27 MM de longitud de alta presión compatible con Catéter Guía 5french y con Alambre Guía 0,014" presión nominal de 6 a 20 ATM. Perfil de entrada de 0,018" o menor con sistema de intercambio rápido y largo de 135 a 155 cm. Empaque individual, en papel grado médico y/o blíster trasparente estéril, herméticamente cerrado, la aja debe contener los siguientes datos: medidas, código de lote, fecha de fabricación, fecha de vencimiento, procedencia o fabricante legal, logotipo de la CE o FDA, folleto de instrucciones de uso, indicaciones de almacenamiento.
ESPECIFICAR: ESTÉRIL - NO ESTÉRIL	ESTÉRIL
PRESENTACIÓN DEL PRODUCTO:	UNIDAD
EMBALAJE:	CAJA
INFORMACIÓN ADICIONAL SOBRE LO OFERTADO QUE SE CONSIDERE RELEVANTE	

FIRMA Y SELLO DEL OFERENTE

RAFAEL CÁCERES
Jack Fack S.R.L.

Observaciones:

1. Esta planilla es de llenado obligatorio en una hoja con membrete de la firma cotizante debidamente rubricada. Deberá ser presentada por cada ítem ofertado con el nombre del producto y el número de ítem correspondiente.
2. En caso de discrepancia entre: la marca comercial, el fabricante, las especificaciones técnicas, unidad de medida de la Planilla de Precios y la Planilla de Datos Garantizados, prevalecerá la planilla de precios.
3. Los productos deberán llevar la leyenda **I.P.S o USO EXCLUSIVO DEL I.P.S.**, en tinta de difícil remoción.

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PLANILLA DE DATOS GARANTIZADOS

DESCRIPCIÓN DEL LOTE OFERTADO ITEM N°	LOTE N° 1 – ITEM N°4
NOMBRE DEL PRODUCTO:	CATETER BALON
FABRICANTE:	BOSTON SCIENTIFIC CORPORATION
MARCA COMERCIAL:	BOSTON SCIENTIFIC
PROCEDENCIA/S:	ESTADOS UNIDOS / MALASIA
ORIGEN:	ESTADOS UNIDOS / MALASIA
REGISTRO SANITARIO:	DM-001153-02
ESPECIFICACIONES TÉCNICAS:	CATETER BALON SEMICOMPLACIENTE DE 2,0mm de diámetro y de 6 A 27 mm de longitud de alta presión compatible con Cateter Guía 5 french y con Alambre Guía 0,014" presión nominal de 6 a 20 ATM. Perfil de entrada de 0,018" o menor con sistema de intercambio rápido y largo de 135 a 155 cm. Empaque individual, en papel grado médico y/o blister trasparente estéril, herméticamente cerrado, la caja debe contener los siguientes datos: medidas, código de lote, fecha de fabricación, fecha de vencimiento, procedencia o fabricante legal, logotipo de la CE o FDA, folleto de instrucciones de uso, indicaciones de almacenamiento.
ESPECIFICAR: ESTÉRIL - NO ESTÉRIL	ESTÉRIL
PRESENTACIÓN DEL PRODUCTO:	UNIDAD
EMBALAJE:	CAJA
INFORMACIÓN ADICIONAL SOBRE LO OFERTADO QUE SE CONSIDERE RELEVANTE	

FIRMA Y SELLO DEL OFERENTE

RAFAEL CÁCERES
Jack Fack S.R.L.

Observaciones:

1. Esta planilla es de llenado obligatorio en una hoja con membrete de la firma cotizante debidamente rubricada. Deberá ser presentada por cada ítem ofertado con el nombre del producto y el número de ítem correspondiente.
2. En caso de discrepancia entre: la marca comercial, el fabricante, las especificaciones técnicas, unidad de medida de la Planilla de Precios y la Planilla de Datos Garantizados, prevalecerá la planilla de precios.
3. Los productos deberán llevar la leyenda **I.P.S o USO EXCLUSIVO DEL I.P.S.**, en tinta de difícil remoción.

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PLANILLA DE DATOS GARANTIZADOS

DESCRIPCIÓN DEL LOTE OFERTADO **ITEM N°**	LOTE N° 1 – ITEM N°5
NOMBRE DEL PRODUCTO:	CATETER BALON
FABRICANTE:	BOSTON SCIENTIFIC CORPORATION
MARCA COMERCIAL:	BOSTON SCIENTIFIC
PROCEDENCIA/S:	ESTADOS UNIDOS / MALASIA
ORIGEN:	ESTADOS UNIDOS / MALASIA
REGISTRO SANITARIO:	DM-001153-02
ESPECIFICACIONES TÉCNICAS:	CATETER BALON SEMICOMPLACIENTE DE 2,0mm de diámetro y de 6 A 27 mm de longitud de alta presión compatible con Catéter Guía 5 french y con Alambre Guía 0,014" presión nominal de 6 a 20 ATM. Perfil de entrada de 0,018" o menor con sistema de intercambio rápido y largo de 135 a 155 cm. Empaque individual, en papel grado médico y/o blister trasparente estéril, herméticamente cerrado, la caja debe contener los siguientes datos: medidas, código de lote, fecha de fabricación, fecha de vencimiento, procedencia o fabricante legal, logotipo de la CE o FDA, folleto de instrucciones de uso, indicaciones de almacenamiento.
ESPECIFICAR: ESTÉRIL - NO ESTÉRIL	ESTÉRIL
PRESENTACIÓN DEL PRODUCTO:	UNIDAD
EMBALAJE:	CAJA
INFORMACIÓN ADICIONAL SOBRE LO OFERTADO QUE SE CONSIDERE RELEVANTE	

FIRMA Y SELLO DEL OFERENTE

RAFAEL CÁCERES
Jack Fack S.R.L.

Observaciones:

1. Esta planilla es de llenado obligatorio en una hoja con membrete de la firma cotizante debidamente rubricada. Deberá ser presentada por cada ítem ofertado con el nombre del producto y el número de ítem correspondiente.
2. En caso de discrepancia entre: la marca comercial, el fabricante, las especificaciones técnicas, unidad de medida de la Planilla de Precios y la Planilla de Datos Garantizados, prevalecerá la planilla de precios.
3. Los productos deberán llevar la leyenda **I.P.S o USO EXCLUSIVO DEL I.P.S.**, en tinta de difícil remoción.

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ID: 445273

PLANILLA DE DATOS GARANTIZADOS

DESCRIPCIÓN DEL LOTE OFERTADO **ITEM N°**	LOTE N° 1 – ITEM N°6
NOMBRE DEL PRODUCTO:	CATETER BALON
FABRICANTE:	BOSTON SCIENTIFIC CORPORATION
MARCA COMERCIAL:	BOSTON SCIENTIFIC
PROCEDENCIA/S:	ESTADOS UNIDOS / MALASIA
ORIGEN:	ESTADOS UNIDOS / MALASIA
REGISTRO SANITARIO:	DM-001153-02
ESPECIFICACIONES TÉCNICAS:	CATETER BALON SEMICOMPLACIENTE DE 2,0mm de diámetro y de 6 A 27 mm de longitud de alta presión compatible con Catéter Guía 5 french y con Alambre Guía 0,014" presión nominal de 6 a 20 ATM. Perfil de entrada de 0,018" o menor con sistema de intercambio rápido y largo de 135 a 155 cm. Empaque individual, en papel grado médico y/o blister trasparente estéril, herméticamente cerrado, la caja debe contener los siguientes datos: medidas, código de lote, fecha de fabricación, fecha de vencimiento, procedencia o fabricante legal, logotipo de la CE o FDA, folleto de instrucciones de uso, indicaciones de almacenamiento.
ESPECIFICAR: ESTÉRIL - NO ESTÉRIL	ESTERIL
PRESENTACIÓN DEL PRODUCTO:	UNIDAD
EMBALAJE:	CAJA
INFORMACIÓN ADICIONAL SOBRE LO OFERTADO QUE SE CONSIDERE RELEVANTE	

FIRMA Y SELLO DEL OFERENTE
RAFAEL CÁCERES
Jack Fack S.R.L.

Observaciones:

1. Esta planilla es de llenado obligatorio en una hoja con membrete de la firma cotizante debidamente rubricada. Deberá ser presentada por cada ítem ofertado con el nombre del producto y el número de ítem correspondiente.
2. En caso de discrepancia entre: la marca comercial, el fabricante, las especificaciones técnicas, unidad de medida de la Planilla de Precios y la Planilla de Datos Garantizados, prevalecerá la planilla de precios.
3. Los productos deberán llevar la leyenda **I.P.S o USO EXCLUSIVO DEL I.P.S.**, en tinta de difícil remoción.

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PLANILLA DE DATOS GARANTIZADOS

DESCRIPCIÓN DEL LOTE OFERTADO	
ITEM N°	LOTE N° 1 – ITEM N°7
NOMBRE DEL PRODUCTO:	CATÉTER BALON
FABRICANTE:	BOSTON SCIENTIFIC CORPORATION
MARCA COMERCIAL:	BOSTON SCIENTIFIC
PROCEDENCIA/S:	ESTADOS UNIDOS / MALASIA
ORIGEN:	ESTADOS UNIDOS / MALASIA
REGISTRO SANITARIO:	DM-001153-02
ESPECIFICACIONES TÉCNICAS:	CATÉTER BALÓN DE 2,5MM DE DIÁMETRO x 6 A 27 MM DE LONGITUD NO COMPLACIENTE DE ALTA PRESIÓN COMPATIBLE CON CATÉTER GUÍA 5 FRENCH Y CON ALAMBRE GUÍA 0,014" PRESIÓN NOMINAL DE 6 a 20 ATM. PERFIL DE ENTRADA DE 0,018" O MENOR CON SISTEMA DE INTERCAMBIO RÁPIDO Y LARGO DE 135 A 155 CM. Envase estéril individual, en papel grado médico y/o blíster trasparente estéril, herméticamente cerrado, La caja debe contener los siguientes datos: medidas, código de lote, fecha de fabricación, fecha de vencimiento, procedencia o fabricante legal, folleto de instrucciones de uso, indicaciones de almacenamiento y certificación de países con alta vigilancia sanitaria.
ESPECIFICAR: ESTÉRIL - NO ESTÉRIL	ESTÉRIL
PRESENTACIÓN DEL PRODUCTO:	UNIDAD
EMBALAJE:	CAJA
INFORMACIÓN ADICIONAL SOBRE LO OFERTADO QUE SE CONSIDERE RELEVANTE	

FIRMA Y SELLO DEL OFERENTE

RAFAEL CÁCERES
Jack Fack S.R.L.

Observaciones:

1. Esta planilla es de llenado obligatorio en una hoja con membrete de la firma cotizante debidamente rubricada. Deberá ser presentada por cada ítem ofertado con el nombre del producto y el número de ítem correspondiente.
2. En caso de discrepancia entre: la marca comercial, el fabricante, las especificaciones técnicas, unidad de medida de la Planilla de Precios y la Planilla de Datos Garantizados, prevalecerá la planilla de precios.
3. Los productos deberán llevar la leyenda **I.P.S o USO EXCLUSIVO DEL I.P.S.**, en tinta de difícil remoción.

Reclus N° 283 e/ Guido C. Spano
y Olegario Andrade
Asunción - Paraguay
Tels.: (595-21) 612 313,- 612 314
www.jackfack.com.py

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JACK FACK S.R.L.

ID: 445273

PLANILLA DE DATOS GARANTIZADOS

DESCRIPCIÓN DEL LOTE OFERTADO **ITEM N°**	LOTE N° 1 – ITEM N° 8
NOMBRE DEL PRODUCTO:	CATETER BALON
FABRICANTE:	BOSTON SCIENTIFIC CORPORATION
MARCA COMERCIAL:	BOSTON SCIENTIFIC
PROCEDENCIA/S:	ESTADOS UNIDOS / MALASIA
ORIGEN:	ESTADOS UNIDOS / MALASIA
REGISTRO SANITARIO:	DM-001153-02
ESPECIFICACIONES TÉCNICAS:	CATÉTER BALÓN DE 2,5MM DE DIÁMETRO x 6 A 27 MM DE LONGITUD NO COMPLACIENTE DE ALTA PRESIÓN COMPATIBLE CON CATÉTER GUÍA 5 FRENCH Y CON ALAMBRE GUÍA 0,014" PRESIÓN NOMINAL DE 6 a 20 ATM. PERFIL DE ENTRADA DE 0,018" O MENOR CON SISTEMA DE INTERCAMBIO RÁPIDO Y LARGO DE 135 A 155 CM. Envase estéril individual, en papel grado médico y/o blíster trasparente estéril, herméticamente cerrado, La caja debe contener los siguientes datos: medidas, código de lote, fecha de fabricación, fecha de vencimiento, procedencia o fabricante legal, folleto de instrucciones de uso, indicaciones de almacenamiento y certificación de países con alta vigilancia sanitaria.
ESPECIFICAR: ESTÉRIL - NO ESTÉRIL	ESTÉRIL
PRESENTACIÓN DEL PRODUCTO:	UNIDAD
EMBALAJE:	CAJA
INFORMACIÓN ADICIONAL SOBRE LO OFERTADO QUE SE CONSIDERE RELEVANTE:	

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