

Către  
Agenția Medicamentului  
și Dispozitivelor Medicale

## NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat  
al dispozitivelor medicale

nr. 2 din 13.10.2023

Solicitantul Oxivit Med SRL, cu sediul mun.Chisinau, MD-2020, Stradela Studentilor, 6b, tel./fax: +37368781333, e-mail oxivit.medical@gmail.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter

Se anexează următoarele acte:

Declarație pe proprie răspundere

CE certificate

Declarație de conformitate

Scrisoare de imputernicire

Data 13/10/2023

Semnătura \_\_\_\_\_

### **Tabelul de recepționare a notificării**

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Către Agenția Medicamentului și Dispozitive Medicale

**DECLARAȚIE PE PROPRIE RĂSPUNDERE**

Solicitant: Oxivit Med SRL, cu sediul mun.Chisinau, MD-2020, Stradela Studentilor, 6b,

declar pe proprie răspundere, cunoscând prevederile art. **352<sup>1</sup>**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter  
**Sunt autentice și corespund realității.**

*Numele, prenumele și funcția*

Kojevnikov Dmitrii, director

*Semnătura* \_\_\_\_\_

*Data* 13/10/2023

# Medtronic

Medtronic META FZ-LLC

Injaz Building, 3rd floor

Dubai Knowledge Park, P.O. Box  
500638

Dubai, United Arab Emirates

www.medtronic.com

Tel : +971 4 818 2666

## TO WHOM IT MAY CONCERN

Date: 29.05.2023

We hereby certify that, pursuant to a non-exclusive distribution agreement expiring on 31 May 2024 between **Medtronic META FZ-LLC** (the "Company"), a Medtronic company organized under the laws of the United Arab Emirates having its principal place of business at 3rd Floor, Injaz Building, Dubai Knowledge Park, Dubai, United Arab Emirates, and **OXIVIT-MED, SRL**, a company having its principal place of business at Bld. Moscova 14/1., Chisinau, MD-2068, Republic of Moldova, the latter is authorized to act as the Company's distributor in Republic of Moldova for the below listed product lines:

- Cardiac Ablation Solutions;
- Cardiac Rhythm Management.
- Cardiovascular Diagnostics & Services;
- Cardiac Surgery
- Coronary & Renal Denervation
- Structural Heart & Aortic
- Peripheral & Endovenous
- Cranial & Spinal Technologies
- Neuromodulation
- Pelvic Health
- Ear, Nose & Throat
- Neurovascular
- Surgical Innovation
- Gastrointestinal
- Patient Monitoring
- Respiratory interventions
- Diabetes

This letter is valid until 31 May 2024 and can also be used with the Competent Authorities in Moldova for notification of medical devices manufactured by attached Medtronic and Covidien Legal Manufacturers, or other regulatory purposes.

Medtronic META FZ-LLC

M. N. ALANI



Name: Muzahim Al Ani  
Title: Authorized Signatory

## APPENDIX 1

### Medtronic Manufacturing Facilities/Legal Manufacturers:

1. Medtronic, Inc., 710 Medtronic Parkway, Minneapolis MN 55432, USA
2. Medtronic, Inc., 7000 Central Avenue N.E., Minneapolis MN 55432, USA
3. Medtronic, Inc., 3800 Annapolis Lane, Minneapolis MN 55447, USA
4. Medtronic, Inc., 8200 Coral Sea Street N.E., Mounds View, MN 5512, USA
5. Medtronic Europe Sàrl, Route du Molliau 31, Case Postale, CH-1131 Tolochenaz, Switzerland
6. Medtronic Bakken Research Center B.V., Endepolsdomein 5, 6229 GW Maastricht, The Netherlands
7. Medtronic CoreValve LLC, 1851 E. Deere Avenue, Santa Ana, CA 92705, USA
8. Medtronic MiniMed, 18000 Devonshire street, Northridge CA 91325-1219, USA
9. Medtronic Heart Valves Division, 1851 East Deere Avenue, Santa Ana, CA 92705, USA
10. Medtronic Heart Valves, 1941 Blair Avenue, Santa Ana CA 92705, USA
11. Medtronic Fabrication S.A.S. Zone Industrielle SUD, Route D'Anor, 59610 Fourmies, France
12. Medtronic Sofamor Danek USA, Inc., 1800 Pyramid Place, Memphis, TN 38132, USA
13. Medtronic Sofamor Danek USA, Inc., 4340 Swinnea Road, Memphis TN 38118, USA
14. Medtronic Sofamor Danek Manufacturing, 2500 Silveus Crossing, Warsaw IN 46582, USA
15. Medtronic Sofamor Danek Deggendorf GmbH, Werfstrasse 17, 94469 Deggendorf, Germany
16. Medtronic Sofamor Danek Deggendorf GmbH, Ulrichsberger Str. 17, 94469 Deggendorf, Germany
17. Medtronic Xomed, Inc. 6743 Southpoint Drive North, Jacksonville FL 32216, USA
18. Medtronic Xomed Instrumentation S.A.S., Le Pavillon, Saint Aubin Le Monial, 03160 Bourbon-L'Archambault, France
19. Medtronic Xomed, Inc., 950 Flanders Road, Mystic CT 06355, USA
20. Medtronic Xomed, Inc., 80 Davids Drive # 5, Hauppauge, NY 11788, USA
21. Medtronic Powered Surgical Solutions, 4620 North Beach Street, Forth Worth, Texas 76137, USA
22. Medtronic Navigation, Inc. (Littleton), 300 Foster Street, Littleton, MA 01460, USA
23. Medtronic Navigation, Inc., 826 Coal Creek Circle, Louisville, CO 80027, USA
24. Medtronic Navigation Israel, Ltd. Kochav Yokneam Building, P.O.Box 548, 20692 Yokneam Elit, Israel
25. Kyphon Sàrl, Pierre-à-Bót 97, 2000 Neuchâtel, Switzerland
26. AF Solutions, Medtronic Inc., 8200 Coral Sea Street, Mounds View, Minneapolis MN 55112, USA
27. Medtronic Ireland, Parkmore Business Park West Galway, Ireland
28. Medtronic Vascular, 35-37a Cherry Hill Drive, Danvers, MA 01923, USA
29. Medtronic Vascular, 3576 Unocal Place, Santa Rosa, CA 95403, USA
30. Medtronic Puerto Rico Operations Co., Juncos, Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos PR 00777, USA
31. Medtronic Puerto Rico Operations Co., Villalba, Rd 149, Km 56.3, Call Box 6001, PR 00766 Villalba, USA
32. Medtronic Puerto Rico Operations, Co., Road 909 Km. 0.4 Bo, 00792 Barrio Mariana, Humacao, Puerto Rico, USA
33. Medtronic Puerto Rico Operations, Co., Parcela #21, Catano Industrial Park, Dr. John A. Smith Street, 00792 Humacao, Puerto Rico, USA
34. Medtronic Mexico S. de R.L. de CV, Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tijuana, Baja California, Mexico
35. Medtronic Mexico EG, Carreta Internacional Guadalajara - Nogales, Empalme, Sonora, Mexico 85340
36. Medtronic Singapore Operations Pte. Ltd., 49 Changi South Avenue 2, Nasaco Tec Centre, 486056 Singapore
37. Medtronic Atrial Fibrillation Technologies (AFT), 8200 Coral Sea Street NE, Mounds View, Minneapolis MN 55112, USA
38. Medtronic Perfusion Systems, 7611 Northland Drive, Minneapolis, MN 55428, USA
39. Medtronic Perfusion Systems, 18501 East Plaza Drive, Parker CO 80134-9061, USA
40. Medtronic Cardiac Surgery Division Europe, Valkenhuizerlaan 16, 6466 ND Kerkrade, The Netherlands

41. Medtronic Neuromodulation, 800 53rd Avenue N.E., Minneapolis MN 55421, USA
42. Medtronic Neuromodulation, 7000 Central Avenue N.E. Minneapolis MN 55432, USA
43. Invatec S.p.A., 7, Via Martiri Della Libertà, 25030 Roncadelle, Brescia, ItalyInvatec S.p.A., 26-28 Via Industria, 25030 Torbole-Casaglia, Brescia, Italy
44. Medtronic Ardian LLC, 1380 Shorebird Way, Mountain View, CA 94043, USA
45. Medtronic Neurosurgery, 125 Cremona Drive, Goleta, CA 93117, USA
46. Medtronic Advanced Energy, LLC, 180 International Drive, Portsmouth NH 03801, USA
47. Vitatron Holding B.V. Endepolsdomein 5, 6229 GW Maastricht, The Netherlands
48. HeartWare, Inc.14400 NW 60th Avenue, Miami Lakes, Florida 33014, USA
49. BELLCO SOCIETÀ, Unipersonale A r.l., Via Camurana 1, 41037 Mirandola (MO), IT - Italy
50. Medtronic CryoCath LP., 9000 Autoroute Transcanadienne, Pointe Claire, Quebec H9R 5Z8, Canada
51. Cardiolinsight Technologies Inc., 11000 Cedar Ave, Suite 210, Cleveland, OH 44106
52. Medtronic Vascular Inc., 271 Gibraltar Drive, Sunnyvale, CA 94089
53. Teleflex Medical, Annacotty Business Park, Annacotty, Co. Limerick, Ireland
54. TYRX Inc., 1 Deer Park Dr. Suite G Monmouth Junction, NJ 08852
55. HeartWare Inc., 500 Old Connecticut Path Framingham, MA 01701
56. Medtronic Sofamor Danek Inc., Airport Logistics Center, Building "A", 4340 Swinnea Road, Memphis, TN 38118, USA
57. Medtronic Monitoring Inc., 1410 Energy Park Dr. Saint Paul, MN 55108
58. Medtronic Vascular, 3850 Brickway Blvd, Santa Rosa, CA 95403 USA
59. Osteotech, Inc., 201 Industrial Way, Eatontown, New Jersey, 07724, USA
60. Medtronic Spine LLC, 1860 Barber Ln, Milpitas, CA 95035
61. Changzhou Kanghui Medical Inovation Co., Ltd., No. 11, North Chanjiang Road, Xinbei District, Changzhou 213022, P.R. China

#### List of EC Representatives:

1. Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands
2. Medtronic Ireland, Parkmore Business Park West, Galway, Irelandkang
3. Invatec S.p.A., 7, Via Martiri Della Libertà, 25030 Roncadelle, Brescia, Italy

#### List of Medtronic Distribution Centers:

1. Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands
2. Medtronic, Inc. Mounds View Distribution, 2292 Wooddale Dr, Ramsey, 55112 Mounds View, USA
3. Medtronic, Inc. Grand Rapids Distribution, 2925 Walkent Ct NW, Walker, MI 49544, USA
4. Medtronic, Inc. Blood Management Business, 18501 East Plaza Drive, Parker CO 80134-9061, USA
5. Medtronic, Inc. Western Distribution Center, 2385 Railroad Street, Corona, CA 92880, USA
6. Medtronic Xomed, Inc. Jacksonville Distribution, 6743 Southpoint Drive North, Jacksonville, FL 32216, USA
7. Xomed MicroFrance Distribution, Le Pavillon, Saint Aubin Le Monial, 03160 Bourbon-L'Archambault, France
8. Medtronic Sofamor Danek, Inc., Airport Logistics Center, Building "B", 4340 Swinnea Road, Memphis, TN 38118, USA
9. Medtronic Powered Surgical Solutions, 4620 North Beach Street, Forth Worth, Texas 76137, USA
10. Medtronic Leipzig Distribution 3PL, Dingolfinger Strasse 19, 04349 Leipzig, Germany
11. Puerto Rico Distribution Center, Santander Tower, B-7 Tabonuco Street, Suite 1501, Guaynabo PR 00968-3028, USA
12. Medtronic, Inc. New York Distribution Center East, Exel 3PL, 699 Kapkowski Road, Suite 300, Elizabeth NJ 07201-2122, USA
13. International Shipping Associate, UPS-SCS / Medtronic, 1860 Outerloop Road, Louisville, KY 40219, USA
14. Medtronic Navigation, Inc., 826 Coal Creek Circle, Louisville, CO 80027, USA
15. Medtronic Neurosurgery, 125 Cremona Drive, Goleta, CA 93117, USA
16. Swedesboro, NJ Distribution Center, 1130 Commerce Boulevard, Swedesboro NJ 08085
17. Guaynabo Distribution Center Sector La Muda Rd #1, Km 21.1, Guaynabo PR 00971, USA

18. MDT Logistics LLC DC East, 1130 Commerce Blvd Ste 100, Swedesboro, NJ 08085-1765 USA

## Covidien Manufacturing Facilities/Legal Manufacturers, EC Representatives and Distribution Centers.

### Covidien llc (USA)

- 15 Hampshire Street, Mansfield, MA 02048 USA
- 5439 State Route 40 Argyle, NY 12809 USA
- 1430 Marvin Griffin Road Augusta, GA 30906 USA
- 815 Tek Drive Crystal Lake, IL 60039 USA
- 525 North Emerald Road Greenwood, SC 29646 USA
- 1448 Blue Ridge Boulevard Seneca, SC 29672 USA
- 1313 West Grant Boulevard Wabasha, MN 55981USA
- Two Ludlow Park Drive Chicopee, MA 01022 USA
- 400 Maple Street Commerce, TX 75428 USA
- 2010 East International Speedway Boulevard Deland, FL 32724 USA
- 1222 Sherwood Road Norfolk, NE 68701USA
- 150 Glover Avenue, Norwalk, CT 06856 USA
  
- 60 Middletown Ave, North Haven, CT 06473 USA
- Building 911-67, Sabanetas Industrial Park, Ponce, Puerto Rico 00731
- At 101a Fist Avenue, Waltham, MA 02451, USA
- 5920 Longbow Dr., Boulder, CO 80301, USA
- 15 Crosby Drive, Bedford, MA 10730, USA
- 6135 Gunbarrel Ave., Boulder, CO 80301, USA
- 675 McDonnell Blvd., Saint Louis, MO 63134, USA
- formerly Barrx Medical Inc., 540 Oakmead Parkway Sunnyvale, CA 94085, USA

### Covidien llc (Canada)

- Ludlow Technical products Canada Ltd., 215 Herbert Street Gananoque, Ontario K7G 2Y7 Canada
- 

### Covidien llc (Mexico)

- 37 Boulevard Insurgentes, Libramiento a la P, La Mesa Tijuana, B.C., Mexico
- Calle 9 Sur No. 125 Ciudad Industrial Tijuana, Mexico CP 22500
- Boulevard Insurgentes 19030 Libramiento, 22225 Tijuana, B.C., Mexico
- Avenue Henequen No. 1181, Parque Industrial Salvarcar, 32573 Ciudad Juarez, Chihuahua, Mexico

### Covidien llc (Dominican Republic)

- Zona Franca de San Isidro, Carretera San Isidro Km 17 Santo Domingo, Dominican Republic

### Covidien llc (Europe)

- Wilson Way Pool Industrial Estate Redruth, Cornwall TR15 3QN United Kingdom Unit 1, Astley Lane Industrial Estate Swillington Leeds West Yorkshire LS26 8XT, United Kingdom
- IDA Business and Tehcnology Park, Srah Industrial Estate Tullamore, Co. Offaly, Republic of Ireland
- Cornamaddy Athlone, Co. Westmeath, Ireland
- Michael Collins Road Mervue, Co. Galway, Ireland
- Via G. Bove, 2/4/6/8 Mirandola (MO) Italy 41037
- Quedlinburger Strasse 39A Halberstadt, D-38820 Germany

### Covidien llc (Thailand )

117 Moo 2, Petchkasem Rd. Klongmai Sampran, Nakornpathom, 73110, Thailand

**Covidien Ilc (Japan )**

SBS Hills 1, 4-10-2 Yoga Setagaya-ku Tokyo 158-8615, Japan

**Covidien Ilc Newton (Beacon)**

2000 Commonwealth Avenue, 1st Floor, Newton, MA 0246, USA

**Covidien AG**

Victor Von Bruns-Strasse 19, 8212 Neuhausen am Rheinfall, Switzerland

**Covidien Logistics BVBA**

Weg naar Zwartberg 239, 3660 Opglabbeek, Belgium

**Covidien Ireland Commercial Limited**

3<sup>rd</sup> Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1

**Covidien Medical Products (Shanghai) Manufacturing LLC**

Bldg. 10, No. 789 Puxing Rd. Shanghai, P.R. China

**Covidien (China) Medical Devices Technology Co., Ltd.**

Floor 6, Building 3, #2388 Chenhang Road, 201114 Shanghai, P.R. China

**Covidien Deutschland Manufacturing GmbH**

Gewerbepark 1, 93333 Neustadt and der Donau, Germany

**Covidien Manufacturing Solutions SA**

Edificio B20 Calle #2 Zona Franca Coyol Alajuela, Costa Rica

**Covidien, formerly known as Valleylab, A Division of Tyco Healthcare Group LP**

5920 Longbow Drive Boulder, CO 80301 USA

**Covidien, formerly Kendall-Gammatron Co. Ltd.**

117 Moo 2, Petchkasem Rd. Klongmai Sampran, Nakornpathom, 73110, Thailand

**Covidien, formerly MMJ S.A. de C.V.**

Avenue Henequen No. 1181, Parque Industrial Salvarcar, 32573 Ciudad Juarez, Chihuahua, Mexico

**EV3 Inc.**

4600 Nathan Lane North Plymouth, MN 55442 USA

**Micro Therapeutics Inc. d/b/a ev3 Neurovascular**

9775 Toledo Way, Irvine, CA 92618 USA

**superDimension Inc.**

161 Cheshire Lane, Suite 100, Plymouth, Minnesota 55441, USA

**Sofradim Production**

116 Avenue du Formans, 01600 Trévoux, France

**VNUS Medical Technologies, Inc.**

5799 Fontanoso Way, San Jose CA 95138, USA

**Given Imaging, Inc.**

15 Hampshire Street, Mansfield MA 02048, USA

## Given Imaging, ltd

2 Hacarmel St. New Industrial Park POB 258 Yoqneam, Ha Zafon 20692 Israel

## Given Imaging (Los Angeles) LLC

Los Angeles 5860 Uplander Way Culver City, CA 90230 USA

## Given Imaging Vietnam Co. Ltd.

Suite 6A, 6th floor, Standard Factory Buliding, 14th Street, Tan Thuan EPZ, Tan Thuan Dong Ward, District 7, Ho Chi Minh City, Vietnam

## Wem Equipamentos Eletrônicos Ltda.

Rua. Marechal Mascarenhas de Morais 550, Parque Industrial Lagoinha, Ribeirão Preto, São Paulo - CEP 14095-120, Brazil

## List of OEM - Original Equipment Manufacturers and Sub-Contracting Facilities:

### MindFrame, Inc.

12 Goodyear, Suite 125, Irvine, CA 92618, USA

### Buffalo Filter, LLC

5900 Genesee St., Lancaster, NY 14086, USA

### SCHÖLLY FIBEROPTIC GmbH

Robert-Bosch-Strasse 1-3, 79211 Denzlingen, Germany

### W.O.M. World Of Medicine GmbH

Salzufer 8, 10587 Berlin, Germany

### Liebel-Flarsheim Company Llc

2111 East Galbraith Road, Cincinnati, OH 45237 USA

### Mediquip SDN. BHD.

- Padang Lati, Mukim Paya, P.O. Box 25, 01700 Kangar, Perlis, Malaysia
- Batu 5, Padang Lati, Jln. Santan, Kangar, 02450 Kangar, Perlis, Malaysia

### Mallinckrodt Développement France S.A.S.

10 Allee Pelletier Doisy, 54601 Villers-Lès-Nancy, France

### Mallinckrodt DAR S.R.L.

Via G. Bove, 2/4/6/8, Mirandola MO 41037, Italy

### Mallinckrodt Medical

Cornamaddy Athlone, Co. Westmeath, Ireland

### SOMANETICS CORP.

1653 East Maple Road, Troy, MI 48083-4208, USA

### Aspect Medical Systems

1 Upland Road, Norwood MA 02062, USA

### POLYSUTURE

Av.Gabriel Ramos da Silva, 1245 Pq.Industrial II, São Sebastião. Paraíso, Minas Gerais, Cep: 37950-000 Brasil





**EU MDR Declaration of Conformity**  
**Sprinter Legend™ Rapid Exchange Balloon**  
**Dilatation Catheter**

D00414108

Revision A

Page 1 of 8

Form

Medtronic

## EU MDR Declaration of Conformity (DoC)

<b>Manufacturer:</b>	Medtronic, Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
<b>Manufacturer SRN:</b>	US-MF-000019977
<b>Authorized Representative:</b>	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
<b>Authorized Representative SRN:</b>	NL-AR-000006050
<b>Notified Body:</b>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands Notified Body number: 2797
<b>Conformity Assessment Certificate(s):</b>	Annex IX Ch II certificate number: MDR 731947 Annex IX Ch I & III certificate number: MDR 719088
<b>Conformity Assessment Procedure:</b>	Annex IX
<b>Risk Class:</b>	Class III
<b>Classification Rule:</b>	Annex VIII, Chapter 3, Rule 6
<b>Intended Purpose:</b>	The balloon catheter expands the stenotic portion of a coronary artery or bypass graft stenosis during PTCA. Balloon catheter models that are 2.25 to 4.00 mm in diameter are also indicated for post-delivery expansion of balloon-expandable stents.

**EU MDR Declaration of Conformity**  
**Sprinter Legend™ Rapid Exchange Balloon**  
**Dilatation Catheter**

D00414108

Revision A

Page 2 of 8

Form

Medtronic

**Statement:**

We, Medtronic, Inc, hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Other Union Legislation(s):

Union Legislation	Applicable Declaration of Conformity Document Number
Not Applicable	Not applicable

**EU MDR Declaration of Conformity**  
**Sprinter Legend™ Rapid Exchange Balloon**  
**Dilatation Catheter**

D00414108

Revision A

Page 3 of 8



**Place:** Medtronic Ireland  
**Name:** Sharon Fahy  
**Title:** Senior Regulatory Affairs Director

**Signature:** 

**Date:** 15 April 2022

**EU MDR Declaration of Conformity**  
**Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter**

D00414108

Revision A

Page 4 of 8

Form

Medtronic

**Products Covered**

Product Name	Medtronic Product Identifier	Basic UDI-DI
	CFN	
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL12506X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL12510X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL12512X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL12515X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL12520X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL15006X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL15010X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL15012X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL15015X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL15020X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL20006X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL20010X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL20012X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL20015X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL20020X	0763000B00008207U

# EU MDR Declaration of Conformity

## Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter

Form

D00414108

Revision A

Page 5 of 8



Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL20025X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL20030X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL22506X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL22510X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL22512X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL22515X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL22520X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL22525X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL25006X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL25010X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL25012X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL25015X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL25020X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL25025X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL25030X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL27506X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL27512X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL27515X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL27520X	0763000B00008207U

**EU MDR Declaration of Conformity**  
**Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter**

Form

D00414108

Revision A

Page 6 of 8



Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL27525X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL30006X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL30010X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL30012X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL30015X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL30020X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL30025X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL30030X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL32512X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL32515X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL32520X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL35006X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL35010X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL35012X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL35015X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL35020X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL35025X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL35030X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL37512X	0763000B00008207U

**EU MDR Declaration of Conformity**  
**Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter**

D00414108

Revision A

Page 7 of 8

Form

Medtronic

Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL37515X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL37520X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL40006X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL40010X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL40012X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL40015X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL40020X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL40025X	0763000B00008207U
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	SPL40030X	0763000B00008207U



**EU MDR Declaration of Conformity**  
**Sprinter Legend™ Rapid Exchange Balloon**  
**Dilatation Catheter**

D00414108

Revision A

Page 8 of 8

Form

Medtronic

## Common Specification(s)

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title
Not applicable		

## Revision History

Revision	Date Effective	Description of Change
A	Refer to Agile Map	Initial release of document for Sprinter Legend Rapid Exchange Balloon Dilatation Catheter

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 719088 R000

**Manufacturer:** Medtronic, Inc.

**Address:**

710 Medtronic Parkway  
Minneapolis  
MN  
55432  
USA

**Single Registration Number:** US-MF-000019977

**EU Authorised Representative:** Medtronic B.V.

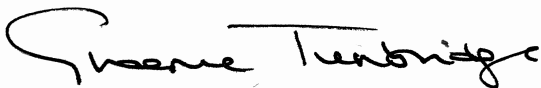
**Address:**

Earl Bakkenstraat 10  
6422 PJ Heerlen  
The Netherlands

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2021-12-09**

Date: **2022-05-30**

Expiry Date: **2026-12-08**

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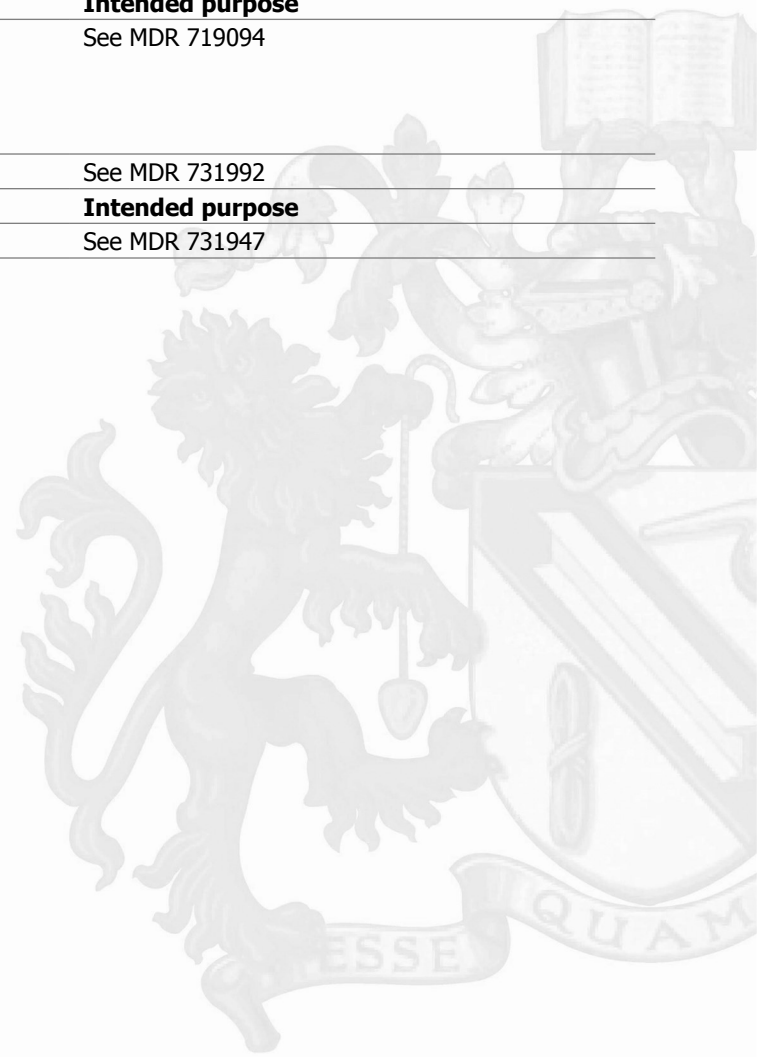
# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 719088 R000

### Device Schedule: Class III and Class IIb devices

<b>Class III, Implantable</b>	<b>Intended purpose</b>
Resolute Onyx Zotarolimus-Eluting Coronary Stent System	See MDR 719094
Onyx TruCor Zotarolimus-Eluting Coronary Stent System	
Onyx Frontier Zotarolimus-Eluting Coronary Stent System	
Onyx TruStar Zotarolimus-Eluting Coronary Stent System	
Resolute Integrity Zotarolimus-Eluting Coronary Stent System	See MDR 731992
<b>Class III</b>	<b>Intended purpose</b>
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	See MDR 731947



First Issued: **2021-12-09**

Date: **2022-05-30**

Expiry Date: **2026-12-08**

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# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 719088 R000

### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference Number	Action
2021-12-09	3084891	Issued.
2022-03-15	3625861	Amended – Change of subcontractor activity (Medtronic Ireland – Add design). Supplemented – Addition of Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter.
2022-04-08	3657388	Supplemented – Addition of Resolute Integrity Zotarolimus-Eluting Coronary Stent System. Amended – Addition of Medtronic Mexico EG as a subcontractor for manufacturing. Editorial correction to legal manufacturer’s address to change Minnesota to MN.
Current	3694380	Supplemented – Addition of Onyx Frontier & Onyx TruStar Zotarolimus-Eluting Coronary Stent Systems into device schedule

First Issued: **2021-12-09**

Date: **2022-05-30**

Expiry Date: **2026-12-08**

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# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

### MDR 719088 R000

Date: 2022-05-30

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Medtronic Ireland Parkmore Business Park West Galway Ireland	<b>Design Manufacture</b>
Medtronic Mexico EG Carret. Int. Km. 1969 Guad-Nogales Km. 2 85340 Empalme Sonora Mexico	<b>Manufacture</b>
Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California Mexico	<b>Manufacture</b>
Medtronic Vascular 3576 Unocal Place Santa Rosa California 95403 USA	<b>Design</b>
ScinoPharm Taiwan, Ltd. No. 1 Nan-Ke 8th Road Shan-Hua Tainan County 74141 Taiwan (R.O.C)	<b>Crucial Supplier</b>

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# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

### MDR 719088 R000

Date: 2022-05-30

Critical Subcontractor/Crucial Supplier	Service(s) supplied
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Synergy Health Ireland Ltd IDA Business & Technology Park Tullamore Co. Offaly Ireland	ETO Sterilization
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# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 731947 R000

**Manufacturer:** Medtronic, Inc.

**Address:**

710 Medtronic Parkway  
Minneapolis  
MN 55432  
USA

**Single Registration Number:** US-MF-000019977

**EU Authorised Representative:** Medtronic B.V.

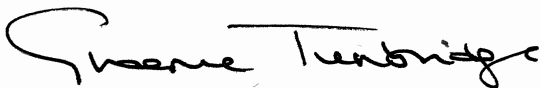
**Address:**

Earl Bakkenstraat 10  
6422 PJ Heerlen  
The Netherlands

**Scope:** See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-03-15**

Date: **2022-03-15**

Expiry Date: **2027-03-14**

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# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 731947 R000

### Device Schedule:

**Device Name:** Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter

### Intended Purpose as per the Instructions for Use:

The balloon catheter expands the stenotic portion of a coronary artery or bypass graft stenosis during PTCA. Balloon catheter models that are 2.25 to 4.00 mm in diameter are also indicated for post-delivery expansion of balloon-expandable stents.

**Risk Classification:** Class III

**Basic UDI-DI:** 0763000B00008207U

Model	Type (Code as per (EU) 2017/2185)
SPL12506X	MDN 1203
SPL12510X	MDN 1203
SPL12512X	MDN 1203
SPL12515X	MDN 1203
SPL12520X	MDN 1203
SPL15006X	MDN 1203
SPL15010X	MDN 1203
SPL15012X	MDN 1203
SPL15015X	MDN 1203
SPL15020X	MDN 1203
SPL20006X	MDN 1203
SPL20010X	MDN 1203
SPL20012X	MDN 1203
SPL20015X	MDN 1203
SPL20020X	MDN 1203
SPL20025X	MDN 1203

First Issued: **2022-03-15**

Date: **2022-03-15**

Expiry Date: **2027-03-14**

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# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 731947 R000

Model	Type (Code as per (EU) 2017/2185)
SPL20030X	MDN 1203
SPL22506X	MDN 1203
SPL22510X	MDN 1203
SPL22512X	MDN 1203
SPL22515X	MDN 1203
SPL22520X	MDN 1203
SPL22525X	MDN 1203
SPL25006X	MDN 1203
SPL25010X	MDN 1203
SPL25012X	MDN 1203
SPL25015X	MDN 1203
SPL25020X	MDN 1203
SPL25025X	MDN 1203
SPL25030X	MDN 1203
SPL27506X	MDN 1203
SPL27512X	MDN 1203
SPL27515X	MDN 1203
SPL27520X	MDN 1203
SPL27525X	MDN 1203
SPL30006X	MDN 1203
SPL30010X	MDN 1203
SPL30012X	MDN 1203
SPL30015X	MDN 1203
SPL30020X	MDN 1203

First Issued: **2022-03-15**

Date: **2022-03-15**

Expiry Date: **2027-03-14**

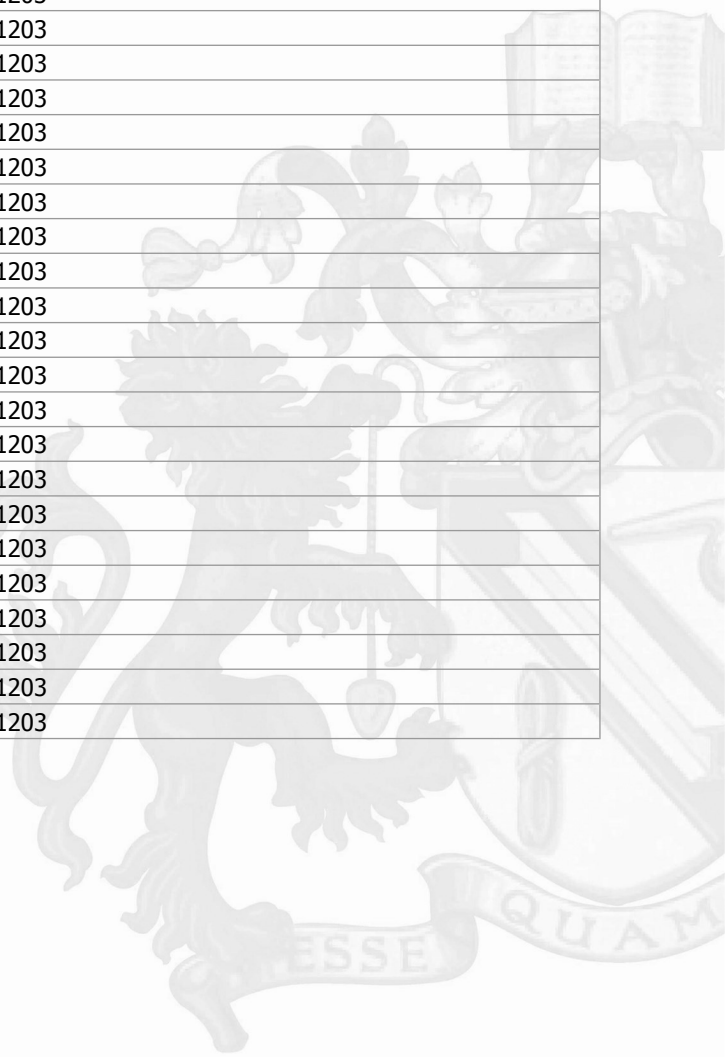
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# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 731947 R000

Model	Type (Code as per (EU) 2017/2185)
SPL30025X	MDN 1203
SPL30030X	MDN 1203
SPL32512X	MDN 1203
SPL32515X	MDN 1203
SPL32520X	MDN 1203
SPL35006X	MDN 1203
SPL35010X	MDN 1203
SPL35012X	MDN 1203
SPL35015X	MDN 1203
SPL35020X	MDN 1203
SPL35025X	MDN 1203
SPL35030X	MDN 1203
SPL37512X	MDN 1203
SPL37515X	MDN 1203
SPL37520X	MDN 1203
SPL40006X	MDN 1203
SPL40010X	MDN 1203
SPL40012X	MDN 1203
SPL40015X	MDN 1203
SPL40020X	MDN 1203
SPL40025X	MDN 1203
SPL40030X	MDN 1203



First Issued: **2022-03-15**

Date: **2022-03-15**

Expiry Date: **2027-03-14**

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# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 731947 R000

### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference Number	Action
Current	3253288	Issued



First Issued: **2022-03-15**

Date: **2022-03-15**

Expiry Date: **2027-03-14**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.