Anexă

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr.1 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 şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System
- Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System
- Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System
- Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System

Se anexează următoarele acte:
Declaraţie pe proprie răspundere
CE certificate
Declaratie de conformitate
Scrisoare de imputernicire

Digitally signed by Kojevnikov Dmitrii
Date: 2023.10.13 17:12:34 EEST
Reason: MoldSign Signature
Location: Moldova

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	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

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

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

- Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System
- Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System
- Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System
- Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____

Kojevnikov Dmitrii, director

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. AL-ANI

_____

Name: Muzahim Al Ani
Title: Authorized Signatory

Medtronic

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 See 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 Degendorf, 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 C0 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. CardioInsight 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 C0 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, Libriamento a la P, La Mesa Tijuana, B.C., Mexico
- Calle 9 Sur No. 125 Cuidad 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

Medtronic

Covidien llc (Japan)
SBS Hills 1, 4-10-2 Yoga Setagaya-ku Tokyo 158-8615, Japan

Covidien llc 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
3rd 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

Medtronic

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 Sebestio. Paraíso, Minas Gerais, Cep: 37950-000 Brasil

EU MDR Declaration of Conformity (DoC)

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
Manufacturer SRN:	US-MF-000019977
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Authorized Representative SRN:	NL-AR-000006050
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands Notified Body number: 2797
Conformity Assessment Certificate(s):	Annex IX Ch II certificate number: MDR 719094 Annex IX Ch I & III certificate number: MDR 719088
Conformity Assessment Procedure:	Annex IX
Risk Class:	Class III
Classification Rule:	Annex VIII, Chapter 3, Rule 8 and Rule 14.

Intended Purpose:

Resolute Onyx™	The Resolute Onyx™ stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.
Onyx TruCor™	The Onyx TruCor™ stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.
Onyx Frontier™	The stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.
Onyx TruStar™	The stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

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

Place:	Medtronic Ireland
Name:	Sharon Fahy
Title:	Senior Regulatory Affairs Director
Signature:	Sharon Fahy
Date:	12 July 2022

Products Covered

Product Name	Medtronic Product Identifier	Basic UDI-DI
	CFN	
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX20008X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX20012X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX20015X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX20018X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX20022X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX20026X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX20030X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22508X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22512X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22515X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22518X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22522X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22526X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22530X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22534X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22538X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25008X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25012X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25015X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25018X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25022X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25026X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25030X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25034X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25038X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27508X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27512X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27515X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27518X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27522X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27526X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27530X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27534X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27538X	0763000B00000156T

Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30008X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30012X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30015X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30018X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30022X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30026X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30030X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30034X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30038X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35008X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35012X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35015X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35018X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35022X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35026X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35030X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35034X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35038X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40008X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40012X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40015X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40018X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40022X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40026X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40030X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40034X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40038X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX45012X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX45015X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX45018X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX45022X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX45026X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX45030X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX50012X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX50015X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX50018X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX50022X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX50026X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX50030X	0763000B00000156T

Product Name	Medtronic Product Identifier	Basic UDI-DI
	CFN	
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22508X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22512X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22515X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22518X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22522X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22526X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22530X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22534X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22538X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25008X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25012X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25015X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25018X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25022X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25026X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25030X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25034X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25038X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR27508X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR27512X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR27515X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR27518X	0763000B00000156T
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Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR27534X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR27538X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30008X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30012X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30015X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30018X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30022X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30026X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30030X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30034X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30038X	0763000B00000156T

Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35008X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35012X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35015X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35018X	0763000B00000156T
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Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35026X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35030X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35034X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35038X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40008X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40012X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40015X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40018X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40022X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40026X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40030X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40034X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40038X	0763000B00000156T

Product Name	Medtronic Product Identifier	Basic UDI-DI
	CFN	
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG20008X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG20012X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG20015X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG20018X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG20022X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG20026X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG20030X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22508X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22512X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22515X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22518X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22522X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22526X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22530X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22534X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22538X	0763000B00006588B

Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG25008X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG25012X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG25015X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG25018X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG25022X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG25026X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG25030X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG25034X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG25038X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG27508X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG27512X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG27515X	0763000B00006588B
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Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG27534X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG27538X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG30008X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG30012X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG30015X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG30018X	0763000B00006588B
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Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG30026X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG30030X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG30034X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG30038X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG35008X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG35012X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG35015X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG35018X	0763000B00006588B
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Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG35026X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG35030X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG35034X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG35038X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40008X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40012X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40015X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40018X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40022X	0763000B00006588B

Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40026X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40030X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40034X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40038X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG45012X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG45015X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG45018X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG45022X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG45026X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG45030X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG50012X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG50015X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG50018X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG50022X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG50026X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG50030X	0763000B00006588B

Product Name	Medtronic Product Identifier	Basic UDI-DI
	CFN	
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR20008X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR20012X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR20015X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR20018X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR20022X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR20026X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR20030X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR22508X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR22512X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR22515X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR22518X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR22522X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR22526X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR22530X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR22534X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR22538X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR25008X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR25012X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR25015X	0763000B00006588B

Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR25018X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR25022X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR25026X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR25030X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR25034X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR25038X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR27508X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR27512X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR27515X	0763000B00006588B
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Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR27538X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR30008X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR30012X	0763000B00006588B
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Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR35008X	0763000B00006588B
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Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR35015X	0763000B00006588B
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Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR35030X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR35034X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR35038X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR40008X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR40012X	0763000B00006588B
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Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR40018X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR40022X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR40026X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR40030X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR40034X	0763000B00006588B

Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR40038X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR45012X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR45015X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR45018X	0763000B00006588B
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Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR50015X	0763000B00006588B
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Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR50022X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR50026X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR50030X	0763000B00006588B

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 Resolute Onyx™
B	Refer to Agile MAP	Addition of Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System information. Addition of product names to document header. Extension of Resolute Onyx™ & Onyx TruCor™ Zotarolimus-Eluting Coronary Stent Systems shelf life from 2 to 3 years.
C	Refer to Agile Map	Addition of Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System and Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System information.

Revision	Date Effective	Description of Change
		Addition of product names to document header. Addition of trademark symbol (™) in product names throughout.

EU Technical Documentation Assessment Certificate

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

MDR 719094 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: **2021-12-09** Date: **2022-05-30** Expiry Date: **2026-12-08**

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EU Technical Documentation Assessment Certificate

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

MDR 719094 R000

Device Schedule:

Device Name: Resolute Onyx Zotarolimus-Eluting Coronary Stent System

Intended Purpose as per the Instructions for Use:
The Resolute Onyx stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable

Basic UDI-DI: 0763000B00000156T

Type: (Code as per (EU) 2017/2185): MDN 1101

Models:

Stent Diameter [mm]	Stent Length [mm]					
	8	12	15	18	22	26
2.00	RONYX20008X	RONYX20012X	RONYX20015X	RONYX20018X	RONYX20022X	RONYX20026X
2.25	RONYX22508X	RONYX22512X	RONYX22515X	RONYX22518X	RONYX22522X	RONYX22526X
2.50	RONYX25008X	RONYX25012X	RONYX25015X	RONYX25018X	RONYX25022X	RONYX25026X
2.75	RONYX27508X	RONYX27512X	RONYX27515X	RONYX27518X	RONYX27522X	RONYX27526X
3.00	RONYX30008X	RONYX30012X	RONYX30015X	RONYX30018X	RONYX30022X	RONYX30026X
3.50	RONYX35008X	RONYX35012X	RONYX35015X	RONYX35018X	RONYX35022X	RONYX35026X
4.00	RONYX40008X	RONYX40012X	RONYX40015X	RONYX40018X	RONYX40022X	RONYX40026X
4.50	--	RONYX45012X	RONYX45015X	RONYX45018X	RONYX45022X	RONYX45026X
5.00	--	RONYX50012X	RONYX50015X	RONYX50018X	RONYX50022X	RONYX50026X

First Issued: **2021-12-09** Date: **2022-05-30** Expiry Date: **2026-12-08**

EU Technical Documentation Assessment Certificate

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

MDR 719094 R000

Device Schedule (con't):

Device Name: Resolute Onyx Zotarolimus-Eluting Coronary Stent System

Intended Purpose as per the Instructions for Use:
The Resolute Onyx stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable

Basic UDI-DI: 0763000B00000156T

Type: (Code as per (EU) 2017/2185): MDN 1101

Models:

Stent Diameter [mm]	Stent Length [mm]		
	30	34	38
2.00	RONYX20030X	--	--
2.25	RONYX22530X	RONYX22534X	RONYX22538X
2.50	RONYX25030X	RONYX25034X	RONYX25038X
2.75	RONYX27530X	RONYX27534X	RONYX27538X
3.00	RONYX30030X	RONYX30034X	RONYX30038X
3.50	RONYX35030X	RONYX35034X	RONYX35038X
4.00	RONYX40030X	RONYX40034X	RONYX40038X
4.50	RONYX45030X	--	--
5.00	RONYX50030X	--	--

First Issued: **2021-12-09** Date: **2022-05-30** Expiry Date: **2026-12-08**

EU Technical Documentation Assessment Certificate

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

MDR 719094 R000

Device Schedule (con't):

Device Name: Onyx TruCor Zotarolimus-Eluting Coronary Stent System

Intended Purpose as per the Instructions for Use:
The Onyx TruCor stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable

Basic UDI-DI: 0763000B00000156T

Type: (Code as per (EU) 2017/2185): MDN 1101

Models:

Stent Diameter [mm]	Stent Length [mm]					
	8	12	15	18	22	26
2.25	TRCR22508X	TRCR22512X	TRCR22515X	TRCR22518X	TRCR22522X	TRCR22526X
2.50	TRCR25008X	TRCR25012X	TRCR25015X	TRCR25018X	TRCR25022X	TRCR25026X
2.75	TRCR27508X	TRCR27512X	TRCR27515X	TRCR27518X	TRCR27522X	TRCR27526X
3.00	TRCR30008X	TRCR30012X	TRCR30015X	TRCR30018X	TRCR30022X	TRCR30026X
3.50	TRCR35008X	TRCR35012X	TRCR35015X	TRCR35018X	TRCR35022X	TRCR35026X
4.00	TRCR40008X	TRCR40012X	TRCR40015X	TRCR40018X	TRCR40022X	TRCR40026X

First Issued: **2021-12-09** Date: **2022-05-30** Expiry Date: **2026-12-08**

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EU Technical Documentation Assessment Certificate

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

MDR 719094 R000

Device Schedule (con't):

Device Name: Onyx TruCor Zotarolimus-Eluting Coronary Stent System

Intended Purpose as per the Instructions for Use:
The Onyx TruCor stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable

Basic UDI-DI: 0763000B00000156T

Type: (Code as per (EU) 2017/2185): MDN 1101

Models:

Stent Diameter [mm]	Stent Length [mm]		
	30	**34**	**38**
2.25	TRCR22530X	TRCR22534X	TRCR22538X
2.50	TRCR25030X	TRCR25034X	TRCR25038X
2.75	TRCR27530X	TRCR27534X	TRCR27538X
3.00	TRCR30030X	TRCR30034X	TRCR30038X
3.50	TRCR35030X	TRCR35034X	TRCR35038X
4.00	TRCR40030X	TRCR40034X	TRCR40038X

First Issued: **2021-12-09** Date: **2022-05-30** Expiry Date: **2026-12-08**

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EU Technical Documentation Assessment Certificate

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

MDR 719094 R000

Device Schedule (con't):

Device Name: Onyx Frontier Zotarolimus-Eluting Coronary Stent System

Intended Purpose as per the Instructions for Use:
The stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable

Basic UDI-DI: 0763000B00006588B

Type: (Code as per (EU) 2017/2185): MDN 1101

Models:

Stent Diameter [mm]	Stent Length [mm]					
	8	12	15	18	22	26
2.00	ONYXNG20008X	ONYXNG20012X	ONYXNG20015X	ONYXNG20018X	ONYXNG20022X	ONYXNG20026X
2.25	ONYXNG22508X	ONYXNG22512X	ONYXNG22515X	ONYXNG22518X	ONYXNG22522X	ONYXNG22526X
2.50	ONYXNG25008X	ONYXNG25012X	ONYXNG25015X	ONYXNG25018X	ONYXNG25022X	ONYXNG25026X
2.75	ONYXNG27508X	ONYXNG27512X	ONYXNG27515X	ONYXNG27518X	ONYXNG27522X	ONYXNG27526X
3.00	ONYXNG30008X	ONYXNG30012X	ONYXNG30015X	ONYXNG30018X	ONYXNG30022X	ONYXNG30026X
3.50	ONYXNG35008X	ONYXNG35012X	ONYXNG35015X	ONYXNG35018X	ONYXNG35022X	ONYXNG35026X
4.00	ONYXNG40008X	ONYXNG40012X	ONYXNG40015X	ONYXNG40018X	ONYXNG40022X	ONYXNG40026X
4.50	--	ONYXNG45012X	ONYXNG45015X	ONYXNG45018X	ONYXNG45022X	ONYXNG45026X
5.00	--	ONYXNG50012X	ONYXNG50015X	ONYXNG50018X	ONYXNG50022X	ONYXNG50026X

First Issued: **2021-12-09** Date: **2022-05-30** Expiry Date: **2026-12-08**

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EU Technical Documentation Assessment Certificate

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

MDR 719094 R000

Device Schedule (con't):

Device Name: Onyx Frontier Zotarolimus-Eluting Coronary Stent System

Intended Purpose as per the Instructions for Use:
The stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable

Basic UDI-DI: 0763000B00006588B

Type: (Code as per (EU) 2017/2185): MDN 1101

Models:

Stent Diameter [mm]	Stent Length [mm]		
	30	34	38
2.00	ONYXNG20030X	--	--
2.25	ONYXNG22530X	ONYXNG22534X	ONYXNG22538X
2.50	ONYXNG25030X	ONYXNG25034X	ONYXNG25038X
2.75	ONYXNG27530X	ONYXNG27534X	ONYXNG27538X
3.00	ONYXNG30030X	ONYXNG30034X	ONYXNG30038X
3.50	ONYXNG35030X	ONYXNG35034X	ONYXNG35038X
4.00	ONYXNG40030X	ONYXNG40034X	ONYXNG40038X
4.50	ONYXNG45030X	--	--
5.00	ONYXNG50030X	--	--

First Issued: **2021-12-09** Date: **2022-05-30** Expiry Date: **2026-12-08**

EU Technical Documentation Assessment Certificate

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

MDR 719094 R000

Device Schedule (con't):

Device Name: Onyx TruStar Zotarolimus-Eluting Coronary Stent System

Intended Purpose as per the Instructions for Use:
The stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable

Basic UDI-DI: 0763000B00006588B

Type: (Code as per (EU) 2017/2185): MDN 1101

Models:

Stent Diameter [mm]	Stent Length [mm]					
	8	12	15	18	22	26
2.00	TSTAR20008X	TSTAR20012X	TSTAR20015X	TSTAR20018X	TSTAR20022X	TSTAR20026X
2.25	TSTAR22508X	TSTAR22512X	TSTAR22515X	TSTAR22518X	TSTAR22522X	TSTAR22526X
2.50	TSTAR25008X	TSTAR25012X	TSTAR25015X	TSTAR25018X	TSTAR25022X	TSTAR25026X
2.75	TSTAR27508X	TSTAR27512X	TSTAR27515X	TSTAR27518X	TSTAR27522X	TSTAR27526X
3.00	TSTAR30008X	TSTAR30012X	TSTAR30015X	TSTAR30018X	TSTAR30022X	TSTAR30026X
3.50	TSTAR35008X	TSTAR35012X	TSTAR35015X	TSTAR35018X	TSTAR35022X	TSTAR35026X
4.00	TSTAR40008X	TSTAR40012X	TSTAR40015X	TSTAR40018X	TSTAR40022X	TSTAR40026X
4.50	--	TSTAR45012X	TSTAR45015X	TSTAR45018X	TSTAR45022X	TSTAR45026X
5.00	--	TSTAR50012X	TSTAR50015X	TSTAR50018X	TSTAR50022X	TSTAR50026X

First Issued: **2021-12-09** Date: **2022-05-30** Expiry Date: **2026-12-08**

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EU Technical Documentation Assessment Certificate

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

MDR 719094 R000

Device Schedule (con't):

Device Name: Onyx TruStar Zotarolimus-Eluting Coronary Stent System

Intended Purpose as per the Instructions for Use:
The stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

Risk Classification: Class III Implantable

Basic UDI-DI: 0763000B00006588B

Type: (Code as per (EU) 2017/2185): MDN 1101

Models:

Stent Diameter [mm]	Stent Length [mm]		
	30	34	38
2.00	TSTAR20030X	--	--
2.25	TSTAR22530X	TSTAR22534X	TSTAR22538X
2.50	TSTAR25030X	TSTAR25034X	TSTAR25038X
2.75	TSTAR27530X	TSTAR27534X	TSTAR27538X
3.00	TSTAR30030X	TSTAR30034X	TSTAR30038X
3.50	TSTAR35030X	TSTAR35034X	TSTAR35038X
4.00	TSTAR40030X	TSTAR40034X	TSTAR40038X
4.50	TSTAR45030X	--	--
5.00	TSTAR50030X	--	--

First Issued: **2021-12-09** Date: **2022-05-30** Expiry Date: **2026-12-08**

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EU Technical Documentation Assessment Certificate

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

MDR 719094 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	3084913	Issued
2022-03-11	3636646	Amended – Correction to the certificate device table to include model RONYX27530X, RONYX40012X, TRCR27512X, TRCR27515X and TRCR27518X. Addition of SRN.
Current	3603011 3635821	Amended – Extension of Resolute Onyx & Onyx TruCor Zotarolimus-Eluting Coronary Stent Systems shelf life from two (2) years to three (3) years Amended – Administrative update of Legal Manufacture address from 'Minnesota' to 'MN'; removal of associated, certificate history revision statement. Device Schedule format update Supplemented – Addition of Onyx Frontier & Onyx TruStar Zotarolimus-Eluting Coronary Stent Systems into device schedule; shelf life of (3) three years

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

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

Class III, Implantable	**Intended purpose**
Resolute Onyx Zotarolimus-Eluting Coronary Stent System Onyx TruCor Zotarolimus-Eluting Coronary Stent System Onyx Frontier Zotarolimus-Eluting Coronary Stent System Onyx TruStar Zotarolimus-Eluting Coronary Stent System	See MDR 719094
Resolute Integrity Zotarolimus-Eluting Coronary Stent System	See MDR 731992
Class III	**Intended purpose**
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	**Design** **Manufacture**
Medtronic Mexico EG Carret. Int. Km. 1969 Guad-Nogales Km. 2 85340 Empalme Sonora Mexico	**Manufacture**
Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California Mexico	**Manufacture**
Medtronic Vascular 3576 Unocal Place Santa Rosa California 95403 USA	**Design**
ScinoPharm Taiwan, Ltd. No. 1 Nan-Ke 8th Road Shan-Hua Tainan County 74141 Taiwan (R.O.C)	**Crucial Supplier**

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By Royal Charter

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
Synergy Health Ireland Ltd IDA Business & Technology Park Tullamore Co. Offaly Ireland	**ETO Sterilization**

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