Anexă

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 7 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:

- IN.PACT Admiral (Paclitaxel-Coated PTA Balloon Catheter)

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 17:13:16 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:

- IN.PACT Admiral (Paclitaxel-Coated PTA Balloon Catheter)

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 Netherland B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam Netherlands Notified Body Number: 2797
Conformity Assessment Certificate(s):	EU Technical Documentation Assessment Certificate (MDR 731886 R000) EU Quality Management System Certificate (MDR 731827 R000)
Conformity Assessment Procedure:	Conformity Assessment based on a Quality Management System (EU Regulation 2017/745, Annex IX, Chapter I and III) and on Assessment of Technical Documentation (EU Regulation 2017/745 Annex IX, Chapter II)
Risk Class:	Class III
Classification Rule:	The IN.PACT Admiral DCB is a Class III medical device in accordance with Annex VIII, Rule 14 of EU Regulation 2017/745.

Intended Purpose:

The intended purpose of the IN.PACT Admiral DCB is to restore lumen patency and blood flow to peripheral arteries, previously stented peripheral arteries with in-stent restenosis, and native arteriovenous dialysis fistulae and to reduce the proliferative response associated with restenosis.

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):

Not applicable

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

Place: Santa Rosa, CA

Name: Áine Smalley

Title: Vice President, PVH Regulatory Affairs

Signature: Áine Smalley

Date: April 11th 2022

Products Covered

Balloon Diameter (mm)	Balloon Length (mm)	Model Number	Basic UDI-DI	Optional: Additional nomenclature identifier (e.g. GMDN)
4.0	40	SBI 040 040 04P	0763000B00000436Y	62551
	60	SBI 040 060 04P	0763000B00000436Y	62551
	80	SBI 040 080 04P	0763000B00000436Y	62551
	120	SBI 040 120 04P	0763000B00000436Y	62551
	150	SBI 040 150 04P	0763000B00000436Y	62551
	40	SBI 040 040 08P	0763000B00000436Y	62551
	60	SBI 040 060 08P	0763000B00000436Y	62551
	80	SBI 040 080 08P	0763000B00000436Y	62551
	120	SBI 040 120 08P	0763000B00000436Y	62551
	150	SBI 040 150 08P	0763000B00000436Y	62551
	200	SBI 040 200 08P	0763000B00000436Y	62551
	250	SBI 040 250 08P	0763000B00000436Y	62551
	40	SBI 040 040 13P	0763000B00000436Y	62551
	60	SBI 040 060 13P	0763000B00000436Y	62551
	80	SBI 040 080 13P	0763000B00000436Y	62551
	120	SBI 040 120 13P	0763000B00000436Y	62551
	150	SBI 040 150 13P	0763000B00000436Y	62551
	200	SBI 040 200 13P	0763000B00000436Y	62551
	250	SBI 040 250 13P	0763000B00000436Y	62551
5.0	40	SBI 050 040 04P	0763000B00000436Y	62551
	60	SBI 050 060 04P	0763000B00000436Y	62551
	80	SBI 050 080 04P	0763000B00000436Y	62551
	120	SBI 050 120 04P	0763000B00000436Y	62551
	150	SBI 050 150 04P	0763000B00000436Y	62551
	40	SBI 050 040 08P	0763000B00000436Y	62551
	60	SBI 050 060 08P	0763000B00000436Y	62551
	80	SBI 050 080 08P	0763000B00000436Y	62551
	120	SBI 050 120 08P	0763000B00000436Y	62551
	150	SBI 050 150 08P	0763000B00000436Y	62551
	200	SBI 050 200 08P	0763000B00000436Y	62551
	250	SBI 050 250 08P	0763000B00000436Y	62551
	40	SBI 050 040 13P	0763000B00000436Y	62551
	60	SBI 050 060 13P	0763000B00000436Y	62551
	80	SBI 050 080 13P	0763000B00000436Y	62551
	120	SBI 050 120 13P	0763000B00000436Y	62551
	150	SBI 050 150 13P	0763000B00000436Y	62551
	200	SBI 050 200 13p	0763000B00000436Y	62551
	250	SBI 050 250 13P	0763000B00000436Y	62551
6.0	40	SBI 060 040 04P	0763000B00000436Y	62551

Balloon Diameter (mm)	Balloon Length (mm)	Model Number	Basic UDI-DI	Optional: Additional nomenclature identifier (e.g. GMDN)
	60	SBI 060 060 04P	0763000B00000436Y	62551
	80	SBI 060 080 04P	0763000B00000436Y	62551
	120	SBI 060 120 04P	0763000B00000436Y	62551
	150	SBI 060 150 04P	0763000B00000436Y	62551
	40	SBI 060 040 08P	0763000B00000436Y	62551
	60	SBI 060 060 08P	0763000B00000436Y	62551
	80	SBI 060 080 08P	0763000B00000436Y	62551
	120	SBI 060 120 08P	0763000B00000436Y	62551
	150	SBI 060 150 08P	0763000B00000436Y	62551
	200	SBI 060 200 08P	0763000B00000436Y	62551
	250	SBI 060 250 08P	0763000B00000436Y	62551
	40	SBI 060 040 13P	0763000B00000436Y	62551
	60	SBI 060 060 13P	0763000B00000436Y	62551
	80	SBI 060 080 13P	0763000B00000436Y	62551
	120	SBI 060 120 13P	0763000B00000436Y	62551
	150	SBI 060 150 13P	0763000B00000436Y	62551
	200	SBI 060 200 13P	0763000B00000436Y	62551
	250	SBI 060 250 13P	0763000B00000436Y	62551
7.0	40	SBI 070 040 04P	0763000B00000436Y	62551
	60	SBI 070 060 04P	0763000B00000436Y	62551
	80	SBI 070 080 04P	0763000B00000436Y	62551
	40	SBI 070 040 08P	0763000B00000436Y	62551
	60	SBI 070 060 08P	0763000B00000436Y	62551
	80	SBI 070 080 08P	0763000B00000436Y	62551
	40	SBI 070 040 13P	0763000B00000436Y	62551
	60	SBI 070 060 13P	0763000B00000436Y	62551
	80	SBI 070 080 13P	0763000B00000436Y	62551
8.0	40	SBI 080 040 04P	0763000B00000436Y	62551
	60	SBI 080 060 04P	0763000B00000436Y	62551
	80	SBI 080 080 04P	0763000B00000436Y	62551
	40	SBI 080 040 08P	0763000B00000436Y	62551
	60	SBI 080 060 08P	0763000B00000436Y	62551
	80	SBI 080 080 08P	0763000B00000436Y	62551
	40	SBI 080 040 13P	0763000B00000436Y	62551
	60	SBI 080 060 13P	0763000B00000436Y	62551
	80	SBI 080 080 13P	0763000B00000436Y	62551
9.0	40	SBI 090 040 04P	0763000B00000436Y	62551
	60	SBI 090 060 04P	0763000B00000436Y	62551
	80	SBI 090 080 04P	0763000B00000436Y	62551
	40	SBI 090 040 08P	0763000B00000436Y	62551
	60	SBI 090 060 08P	0763000B00000436Y	62551
	80	SBI 090 080 08P	0763000B00000436Y	62551

Balloon Diameter (mm)	Balloon Length (mm)	Model Number	Basic UDI-DI	Optional: Additional nomenclature identifier (e.g. GMDN)
	40	SBI 090 040 13P	0763000B00000436Y	62551
	60	SBI 090 060 13P	0763000B00000436Y	62551
	80	SBI 090 080 13P	0763000B00000436Y	62551
10.0	40	SBI 100 040 04P	0763000B00000436Y	62551
	40	SBI 100 040 08P	0763000B00000436Y	62551
	40	SBI 100 040 13P	0763000B00000436Y	62551
12.0	40	SBI 120 040 04P	0763000B00000436Y	62551
	40	SBI 120 040 08P	0763000B00000436Y	62551
	40	SBI 120 040 13P	0763000B00000436Y	62551

Common Specification(s)

Not applicable.

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title
Not applicable	Not applicable	Not Applicable

By Royal Charter

EU Quality Management System Certificate

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

MDR 731827 R000

Manufacturer: Medtronic, Inc.

Address:
710 Medtronic Parkway
Minneapolis
Minnesota
55432
USA

Single Registration Number: Not Available

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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-08-26** Date: **2021-08-26** Expiry Date: **2026-08-25**

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EU Quality Management System Certificate

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

MDR 731827 R000

Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
IN.PACT Admiral Paclitaxel-coated PTA Balloon Catheter	See MDR 731886

First Issued: **2021-08-26** Date: **2021-08-26** Expiry Date: **2026-08-25**

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EU Quality Management System Certificate

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

MDR 731827 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	3252786	Issued

First Issued: **2021-08-26** Date: **2021-08-26** Expiry Date: **2026-08-25**

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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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

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 731827 R000

Date: **2021-08-26**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Indena S.p.A. Viale Ortles, 12 Milano (MI) 20139 Italy	**Crucial Supplier**
Invatec S.p.A. Via Martiri della Libertà 7 25030 Roncadelle (BS) Italy	**Manufacture**
Medistri SA Rte de L'Industrie 96 1564 Domdidier Switzerland	**ETO Sterilization**
Medtronic Ireland Parkmore Business Park West Galway Ireland	**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**

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By Royal Charter

EU Technical Documentation Assessment Certificate

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

MDR 731886 R000

Manufacturer: Medtronic, Inc.

Address:
710 Medtronic Parkway
Minneapolis
Minnesota
55432
USA

Single Registration Number: Not Available

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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-08-26** Date: **2021-08-26** Expiry Date: **2026-08-25**

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EU Technical Documentation Assessment Certificate

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

MDR 731886 R000

Device Name: IN.PACT Admiral Paclitaxel-coated PTA Balloon Catheter

Intended Purpose as per the Instructions for Use:

The intended purpose of the IN.PACT Admiral DCB is to restore lumen patency and blood flow to peripheral arteries, previously stented peripheral arteries with in-stent restenosis, and native arteriovenous dialysis fistulae and to reduce the proliferative response associated with restenosis.

The IN.PACT Admiral DCB is indicated for percutaneous transluminal angioplasty (PTA) in patients with denovo, restenotic, or in-stent restenotic lesions with lengths up to 360 mm in superficial femoral or popliteal arteries.

The IN.PACT Admiral DCB with balloon lengths ≤ 150 mm is also indicated for patients with obstructive lesions of native arteriovenous dialysis fistulae.

Risk Classification: Class III

Basic UDI-DI: 0763000B00000436Y

Model	**Type** (Codes as per (EU) 2017/2185)	**Balloon Diameter (mm)**	**Balloon Length (mm)**	**Balloon Catheter Usable Length (cm)**
SBI 040 040 04P	MDN 1203	4.0	40	40
SBI 040 060 04P		4.0	60	40
SBI 040 080 04P		4.0	80	40
SBI 040 120 04P		4.0	120	40
SBI 040 150 04P		4.0	150	40
SBI 050 040 04P		5.0	40	40
SBI 050 060 04P		5.0	60	40
SBI 050 080 04P		5.0	80	40
SBI 050 120 04P		5.0	120	40
SBI 050 150 04P		5.0	150	40

First Issued: **2021-08-26** Date: **2021-08-26** Expiry Date: **2026-08-25**

EU Technical Documentation Assessment Certificate

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

MDR 731886 R000

Model	Type (Codes as per (EU) 2017/2185)	Balloon Diameter (mm)	Balloon Length (mm)	Balloon Catheter Usable Length (cm)
SBI 060 040 04P	MDN 1203	6.0	40	40
SBI 060 060 04P		6.0	60	40
SBI 060 080 04P		6.0	80	40
SBI 060 120 04P		6.0	120	40
SBI 060 150 04P		6.0	150	40
SBI 070 040 04P		7.0	40	40
SBI 070 060 04P		7.0	60	40
SBI 070 080 04P		7.0	80	40
SBI 080 040 04P		8.0	40	40
SBI 080 060 04P		8.0	60	40
SBI 080 080 04P		8.0	80	40
SBI 090 040 04P		9.0	40	40
SBI 090 060 04P		9.0	60	40
SBI 090 080 04P		9.0	80	40
SBI 100 040 04P		10.0	40	40
SBI 120 040 04P		12.0	40	40
SBI 040 040 08P		4.0	40	80
SBI 040 060 08P		4.0	60	80
SBI 040 080 08P		4.0	80	80
SBI 040 120 08P		4.0	120	80
SBI 040 150 08P		4.0	150	80
SBI 040 200 08P		4.0	200	80
SBI 040 250 08P		4.0	250	80
SBI 050 040 08P		5.0	40	80
SBI 050 060 08P		5.0	60	80
SBI 050 080 08P		5.0	80	80
SBI 050 120 08P		5.0	120	80

First Issued: **2021-08-26** Date: **2021-08-26** Expiry Date: **2026-08-25**

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EU Technical Documentation Assessment Certificate

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

MDR 731886 R000

Model	Type (Codes as per (EU) 2017/2185)	Balloon Diameter (mm)	Balloon Length (mm)	Balloon Catheter Usable Length (cm)
SBI 050 150 08P	MDN 1203	5.0	150	80
SBI 050 200 08P		5.0	200	80
SBI 050 250 08P		5.0	250	80
SBI 060 040 08P		6.0	40	80
SBI 060 060 08P		6.0	60	80
SBI 060 080 08P		6.0	80	80
SBI 060 120 08P		6.0	120	80
SBI 060 150 08P		6.0	150	80
SBI 060 200 08P		6.0	200	80
SBI 060 250 08P		6.0	250	80
SBI 070 040 08P		7.0	40	80
SBI 070 060 08P		7.0	60	80
SBI 070 080 08P		7.0	80	80
SBI 080 040 08P		8.0	40	80
SBI 080 060 08P		8.0	60	80
SBI 080 080 08P		8.0	80	80
SBI 090 040 08P		9.0	40	80
SBI 090 060 08P		9.0	60	80
SBI 090 080 08P		9.0	80	80
SBI 100 040 08P		10.0	40	80
SBI 120 040 08P		12.0	40	80
SBI 040 040 13P		4.0	40	130
SBI 040 060 13P		4.0	60	130
SBI 040 080 13P		4.0	80	130
SBI 040 120 13P		4.0	120	130
SBI 040 150 13P		4.0	150	130
SBI 040 200 13P		4.0	200	130

First Issued: **2021-08-26** Date: **2021-08-26** Expiry Date: **2026-08-25**

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EU Technical Documentation Assessment Certificate

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

MDR 731886 R000

Model	Type (Codes as per (EU) 2017/2185)	Balloon Diameter (mm)	Balloon Length (mm)	Balloon Catheter Usable Length (cm)
SBI 040 250 13P	MDN 1203	4.0	250	130
SBI 050 040 13P		5.0	40	130
SBI 050 060 13P		5.0	60	130
SBI 050 080 13P		5.0	80	130
SBI 050 120 13P		5.0	120	130
SBI 050 150 13P		5.0	150	130
SBI 050 200 13P		5.0	200	130
SBI 050 250 13P		5.0	250	130
SBI 060 040 13P		6.0	40	130
SBI 060 060 13P		6.0	60	130
SBI 060 080 13P		6.0	80	130
SBI 060 120 13P		6.0	120	130
SBI 060 150 13P		6.0	150	130
SBI 060 200 13P		6.0	200	130
SBI 060 250 13P		6.0	250	130
SBI 070 040 13P		7.0	40	130
SBI 070 060 13P		7.0	60	130
SBI 070 080 13P		7.0	80	130
SBI 080 040 13P		8.0	40	130
SBI 080 060 13P		8.0	60	130
SBI 080 080 13P		8.0	80	130
SBI 090 040 13P		9.0	40	130
SBI 090 060 13P		9.0	60	130
SBI 090 080 13P		9.0	80	130
SBI 100 040 13P		10.0	40	130
SBI 120 040 13P		12.0	40	130

First Issued: **2021-08-26** Date: **2021-08-26** Expiry Date: **2026-08-25**

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EU Technical Documentation Assessment Certificate

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

MDR 731886 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	3253069	Issued

First Issued: **2021-08-26** Date: **2021-08-26** Expiry Date: **2026-08-25**

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