Anexă

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr.2 din 13.07.2023

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:

- Cryo Accessories

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

Data 13/07/2023 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:

- Cryo Accessories

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____

Kojevnikov Dmitrii, director

Data _13/07/2023__

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

Medtronic

DECLARATION OF CONFORMITY
European Medical Device Directive 93/42/EEC

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Manufacturer:
Medtronic Inc.
710 Medtronic Parkway
Minneapolis, MN 55432 USA
Tel. +1 763-514-4000

Authorized Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel: 31-45-566-8000

Device Name(s)/ Model Number(s)/Class:

Device Name	Model Number	Classification / Rule
Catheter Connecting Cable	2ACHC	Class Is / Rule 1

Conformity Assessment Route: Medical Devices Directive (93/42/EEC) Annex II without II.4, Full Quality Assurance System

Certificate(s) number(s): EC Full Quality Assurance: G1S 039709 1306 Rev. 00

Notified Body (or Quality System Registrar):
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany

Notified Body Number: 0123

Standards Applied: Harmonized Standards per Essential Requirements Checklist

Statement
We, the manufacturer, hereby declare that the above-mentioned products comply with the European Medical Device Directive 93/42/EEC, including amendments issued. All supporting documentation is retained under the premises of the manufacturer.

Approval

Place: Minneapolis, MN, USA

Date of Declaration validity: ***Refer to Effectivity Date in the electronic documentation system***

Name & Title: ***Refer to electronic signature***

Signature & Date: ***Refer to electronic signature***

Non-electronic signature and date available upon request

Andrei Manole
Sr. Manager – Quality

Date: 06-Oct-2020

Medtronic

DECLARATION OF CONFORMITY
European Medical Device Directive 93/42/EEC

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Manufacturer:
Medtronic CryoCath LP
9000 Autoroute Transcanadienne
Pointe-Claire, Quebec, H9R 5Z8
Canada

Authorized Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel: 31-45-566-8000

Device Name(s)/ Model Number(s)/Class:

Device Name	Model Number	Classification / Rule
Coaxial Umbilical Cable	203CX, 203CXC	Class I sterile / Rule 1
Electrical Umbilical Cable	2035U, 2035UC	Class I sterile / Rule 1
Manual Retraction Kit	20MRK	Class I sterile / Rule 1

Conformity Assessment Route: Medical Devices Directive (93/42/EEC) Annex II without II.4, Full Quality Assurance System

Certificate(s) number: EC Full Quality Assurance: G1S 074486 0028 Rev. 00

Notified Body:
TUV SUD Product Service GmbH
Ridlerstrasse 65
80339 Munich
Germany

Notified Body Number: 0123

Standards Applied: Harmonized Standards per Essential Requirements Matrix

Statement
We, the manufacturer, hereby declare that the above-mentioned products comply with the European Medical Device Directive 93/42/EEC, including amendments issued. All supporting documentation is retained under the premises of the manufacturer.

Approval

Place: Pointe-Claire, QC, Canada

Date of Declaration validity: ***Refer to Effectivity Date in the electronic documentation system***

Name & Title: ***Refer to electronic signature***

Signature & Date: ***Refer to electronic signature***

Non-electronic signature and date available upon request

Andrei Manole
Sr. Manager – Quality
Date: 08-JUL-2020

Digitally signed by Kojevnikov Dmitrii
Date: 2023.07.13 11:30:21 EEST
Reason: MoldSign Signature
Location: Moldova

Scanned with CamScanner

EU MDR Declaration of Conformity (DoC)

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis MN 55432 USA

Product	Manufacturing facilities
Coaxial umbilical	**Medtronic Mexico** Medtronic Mexico S. De R.L.De C.V. Av. Paseo Cucapah 10510 El Lago Tijuana Baja California, Mexico C.P. 22210
Electrical umbilical	**CEA Medical Manufacturing Inc. d.b.a Nissha Medical Technologies** Zona Franca Industrial San Pedro De Macoris, DO 21000 Dominican Republic

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:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich, Germany
Notified Body number: 0123

Conformity Assessment Certificate(s): Full Quality Assurance - G11 039709 1402

Conformity Assessment Procedure: Annex IX, Chapter 1
Risk Class: Class 1 -Sterile

Classification Rule: Rule 1

Intended Purpose:

Device Name	Intended Purpose
Coaxial umbilical	The coaxial umbilical is used to deliver the nitrous oxide (N_2O) gas from the CryoConsole to the catheter and to transport refrigerant vapors from the catheter back to the CryoConsole, which is vented into the hospital scavenging system.
Electrical umbilical	The Electrical Umbilical is used to make the electrical connection from the CryoConsole to the catheter (via the auto connection box).

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
ROHS 3 Directive 2015/863 on restriction of the use of certain hazardous substances in electrical and electronic equipment (ROHS Directive)	D00275956

Place: Minneapolis

Name:

Title: Post Market Quality Director

Signature:

DocuSigned by:
greg haider
Signer Name: greg haider
Signing Reason: I approve this document
Signing Time: 06 September 2022 | 08:42 PDT
B45F58EE829A4D5C93C89B1C1C698041

Date:

Products Covered

Product Name	Medtronic Product Identifier CFN	Basic UDI-DI	Optional: Additional nomenclature identifier (e.g. EMDN, **GMDN)**
Coaxial umbilical	203CX & 203CXC	0763000B00003357G	56300
Electrical umbilical	2035U &2035UC	0763000B00003367J	47250

Common Specification(s)

Not applicable

The following common specifications were used to demonstrate conformity:

Revision History

Revision	Date Effective	Description of Change
A	July 2022	Initial release of the document
B	September 2022	Release signed version in MAP Agile

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:	Not applicable
Conformity Assessment Certificate(s):	Not applicable
Conformity Assessment Procedure:	Not applicable for Class I (non-measuring, non-sterile, reusable) products, only DoC in accordance with Annex IV
Risk Class:	Class 1 – non-sterile
Classification Rule:	Rule 1

Intended Purpose:

Device Name	Intended Purpose
Auto Connection Box	Depending on catheter type, the auto connection box provides a noise free intracardiac electrogram (Freezor catheters family) or an electrical signal feedthrough (Arctic Front Advance catheters family).
ECG Cable	The ECG cable connects the auto connection box to the hospital's ECG monitor and EP recording system, thereby allowing intracardiac monitoring/recording via catheter electrodes. This feature is only available with Freezor catheters family.
Foot Switch	Depending on catheter type, the foot switch provides hands free control (start and/or stop) of the injection (Freezor catheters family) or inflation (Arctic Front Advance catheters family) functions. Also allows user to 'stop current action' similarly to the physical button on the CryoConsole's front panel.
Nitrous Oxide (N_2O) Refrigerant Tank	The nitrous oxide refrigerant tank supplies pressurized liquid nitrous oxide (N_2O) to the CryoConsole.
Power Cords	The power cord is used to connect the CryoConsole to the electrical system and supplies electricity to the CryoConsole and is available in multiple configurations to meet local electrical requirements.
Scavenging Hoses	The scavenging hose transports returning refrigerant from the CryoConsole into the hospital's scavenging system.
Adapters	The adapters connect the scavenging hose to the hospital's scavenging system, in case when the scavenging hose connector is not compatible with the hospital wall receptacle.
Wrench, 1 1/8"	The wrench is used to loosen or tighten the nut that secures the refrigerant tank to the supply tubing.

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
RoHS 3 Directive 2015/863 on restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive)	D00275956

Place: Minneapolis, MN

Name: ***Andrei Manole***

Title: ***Sr. Manager - Quality***

Signature:

DocuSigned by:
Andrei Manole
Signer Name: Andrei Manole
Signing Reason: I approve this document
Signing Time: 09 March 2022 | 09:37 PST
D8C658C698AC4201940F95A84C112D2D

Date:

Products Covered

Product Name	Medtronic Product Identifier	Basic UDI-DI
	CFN	
Auto Connection box	2037A	0763000B00000597F
ECG cable	2035W	0763000B00000136P
Footswitch	104FS	0763000B00000146R
Refrigerant tank	103NE	0763000B00000606Y
Power cord	1038E, 1038U; 1038Y, 1038SW, 1038D	0763000B000006172
Scavenging hoses	1035E, 1035EW, 1035F, 1035FW, 1035G	0763000B000006274
Scavenging hose Adapters	1036L, 1036M, 1036N	0763000B000006274
Wrench	1036W	0763000B00001136U

Common Specification(s)

Not applicable

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 039709 1402 Rev. 00

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

SRN Manufacturer: US-MF-000019977

Authorized Representative:

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G11 039709 1402 Rev. 00

Report No.: 72172299

Valid from: 2022-05-30
Valid until: 2027-05-29

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-05-30

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 039709 1402 Rev. 00

Classification:	I
Device Group:	C0280 - ARRYTHMOLOGY DEVICES - ACCESSORIES NOT INCLUDED IN OTHER CLASSES
The validity of this certificate depends on conditions and/or is limited to the following:	-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in class I in sterile conditions, sterilized systems or procedure packs)

No. G1S 074486 0028 Rev. 00

Manufacturer: **Medtronic CryoCath LP**
9000 Autoroute Transcanadienne
Pointe-Claire QC H9R 5Z8
CANADA

Product Category(ies): **Sterile Electrical Umbilicals, Manual Retraction Kit, Sterile CoAxial Umbilicals.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 72152811

Valid from: 2020-05-05
Valid until: 2024-05-26

Date, 2020-05-05

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in class I in sterile conditions, sterilized systems or procedure packs)

No. G1S 039709 1306 Rev. 00

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product Category(ies):

Catheter Connecting Cable and RF Catheter Adapter Cable Model 4825

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 72152792

Valid from: 2020-05-25
Valid until: 2024-05-26

Date, 2020-05-25

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Anexă

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 1 din 13.07.2023

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:

- Cryoablation Consoles

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

Data 13/07/2023 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:

- Cryoablation Consoles

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____

Kojevnikov Dmitrii, director

Data _13/07/2023__

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

Medtronic

DECLARATION OF CONFORMITY
European Medical Device Directive 93/42/EEC

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Manufacturer:	Medtronic CryoCath LP 9000 Autoroute Transcanadienne Pointe-Claire, Quebec, H9R 5Z8 Canada
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands Tel: 31-45-566-8000

Device Name(s)/ Model Number(s)/Class:

Device Name	Model Number	Classification / Rule
CryoConsole	106E2	Class IIb / Rule 9

Conformity Assessment Route:	Medical Devices Directive (93/42/EEC) Annex II without II.4, Full Quality Assurance System
Certificate(s) number:	EC Full Quality Assurance: G1 074486 0027 Rev. 00
Notified Body:	TUV SUD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Notified Body Number:	0123
Standards Applied:	Harmonized Standards per Essential Requirements Matrix

Statement
We, the manufacturer, hereby declare that the above-mentioned products comply with the European Medical Device Directive 93/42/EEC, including amendments issued. All supporting documentation is retained under the premises of the manufacturer.

Approval

Place:	Pointe-Claire, QC, Canada
Date of Declaration validity:	***Refer to Effectivity Date in the electronic documentation system***
Name & Title:	***Refer to electronic signature***
Signature & Date:	***Refer to electronic signature***

Non-electronic signature and date available upon request

Andrei Manole
Sr Manager - Quality

04-Nov-2020

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 074486 0027 Rev. 00

Manufacturer:

Medtronic CryoCath LP
9000 Autoroute Transcanadienne
Pointe-Claire QC H9R 5Z8
CANADA

Product Category(ies):

Class IIb Products

Cryoablation Consoles (Universal Gen V, CCT. 2 Gen IV, CCT.2 Gen III)

Class III Products

Freezor® Cardiac Cryoablation Catheters

Freezor® Xtra Cardiac Cryoablation Catheters

Freezor® MAX Cardiac Cryoablation Catheters

Arctic Front Advance Catheters and Arctic Front Advance Pro Catheters

FlexCath Advance™ and FlexCath Select™ Steerable Sheaths and Dilators

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72152793

Valid from: 2020-05-05
Valid until: 2024-05-26

Date, 2020-05-05

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Anexă

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 3 din 13.07.2023

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:

- Electrophysiology Catheters

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

Data 13/07/2023 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:

- Electrophysiology Catheters

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____

Kojevnikov Dmitrii, director

Data _13/07/2023__

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:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich, Germany Notified Body number: 0123
Conformity Assessment Certificate(s):	Design Examination Certification: G70 0397091384 Quality Management Certification: G12 039709 1406
Conformity Assessment Procedure:	Annex IX chapter II
Risk Class:	Class III
Classification Rule:	Rule 7
Intended Purpose:	The *intended purpose* of the Achieve/Achieve Advance mapping catheter is to collect intracardiac electrograms from multiple electrodes for evaluation on an electrophysiology (EP) recording system and to use for cardiac stimulation during electrophysiology studies. The mapping catheter is compatible for use with, and may be used to support and position, all catheters in the Medtronic Arctic Front family of cardiac cryoablation catheters.

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
RoHS 3 Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment	D00275956

Place:	Minneapolis, MN
Name:	Refer to electronic signature
Title:	Refer to electronic signature
Signature:	***Refer to electronic signature***
Date:	***Refer to electronic signature***

Andrei Manole
Quality Management
18 May 2022

Products Covered

Product Name	Medtronic Product Identifier	Basic UDI-DI
	CFN	
Achieve™	990063-015, 990063-020	0763000B000040072
Achieve Advance™	2ACH15, 2ACH20, 2ACH25	

Common Specification(s)

Not Applicable

Revision History

Revision	Date Effective	Description of Change
A	TBD	Initial release of document

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:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich, Germany Notified Body Number: 0123
Conformity Assessment Certificate(s):	Technical Documentation Assessment Certificate: **G70 039709 1379** Quality Management System Certificate: **G12 039709 1406**
Conformity Assessment Procedure:	Annex IX
Risk Class:	Class III
Classification Rule:	Rule 7
Intended Purpose:	The intended purpose of the Arctic Front family of cardiac cryoablation catheters is to ablate cardiac tissue in the left atrium.

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
RoHS 3 Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment	D00275956

Place: ***Refer to electronic signature***

Name: ***Refer to electronic signature***

Title: ***Refer to electronic signature***

Signature: ***Refer to electronic signature***

Date: ***Refer to electronic signature***

Andrei Manole
Quality Management
18 May 2022

Products Covered

Product Name	Medtronic Product Identifier CFN	Basic UDI-DI
Arctic Front Advance™	2AF233, 2AF283	0763000B00000256W
Arctic Front Advance Pro™	AFAPRO23, AFAPRO28	

Common Specification(s)

Not Applicable

Revision History

Revision	Date Effective	Description of Change
A	TBD	Initial release of document

DECLARATION OF CONFORMITY
European Medical Device Directive 93/42/EEC

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Manufacturer:
Medtronic Inc.
710 Medtronic Parkway
Minneapolis, MN 55432 USA
Tel. +1 763-514-4000

Authorized Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel: 31-45-566-8000

Device Name(s)/ Model Number(s)/Class/Rule:

Device Name	Model Number	Classification/Rule
Brockenbrough Curved Needle	EP003997S	Class III, Rule 6
	EP003994S	

Conformity Assessment Route: Medical Devices Directive (93/42/EEC) Annex II (4)

CE Certificate(s) number(s): EC Design Examination: G7 039709 0983 Rev. 01
EC Full Quality Assurance System: G1 039709 1144 Rev. 02

Notified Body (or Quality System Registrar): TUV SUD Product Service GmbH
Ridlerstrasse 65
80339 Munich
Germany

Notified Body Number: 0123

Standards Applied: Harmonized Standards per Essential Requirements Checklist

Statement
We, the manufacturer, hereby declare that the above-mentioned products comply with the European Medical Device Directive 93/42/EEC, including amendments issued. All supporting documentation is retained under the premises of the manufacturer.

Approval

Place: Minneapolis, MN, USA

Date of Declaration validity: ***Refer to Effectivity Date in the electronic documentation system***

Name & Title: ***Refer to electronic signature***

Signature & Date: ***Refer to electronic signature***

Andrew Harings
Reliability Engineering Manager
April 16, 2020

Non-electronic signature and date available upon request

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:	TÜV SÜD Product Service GmbH Certification Body Ridlerstraße 65 80339 München Germany Notified Body Identification Number: 0123
Conformity Assessment Certificate(s):	Technical Documentation Assessment Certificate: G70 039709 1389 Quality Management System Certificate: G12 039709 1406
Conformity Assessment Procedure:	Annex IX
Risk Class:	Class III
Classification Rule:	Rule 7
Intended Purpose:	The intended purpose of FlexCath Advance™ steerable sheath is to provide percutaneous introduction into the vasculature and chambers of the heart, and to facilitate positioning of compatible devices.

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 relevant Union Legislation(s): None

Place: Minneapolis, MN

Name: Eric Nygaard

Title: Sr Post Market Reliability Engineering Manager

Signature:

DocuSigned by:
Eric Nygaard
Signer Name: Eric Nygaard
Signing Reason: I approve this document
Signing Time: 29 September 2022 | 09:54 PDT
30DE2E6CC52C44699840443E239193DC

Date:

Products Covered

Product Name	Medtronic Product Identifier	Basic UDI-DI
	CFN	
FlexCath Advance™	4FC12	0763000B00004317D

Common Specification(s)

The following common specifications were used to demonstrate conformity:

Not applicable

Revision History

Revision	Date Effective	Description of Change
A	12May2022	Initial release of document
B	TBD	Update to conformity assessment route reference. Inclusion of signatory name and title. Application or revision D of template D00009859.

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:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich, Germany Notified Body Number: 0123
Conformity Assessment Certificate(s):	Technical Documentation Assessment Certificate: G70 039709 1385 Quality Management System Certificate: G12 039709 1406
Conformity Assessment Procedure:	Annex IX
Risk Class:	Class III
Classification Rule:	Rule 7
Intended Purpose:	The intended purpose of the Freezor family of cardiac cryoablation catheters is to ablate arrhythmogenic sites in the heart by applying cryoenergy to cardiac tissue for the treatment of cardiac arrhythmias. The Freezor and Freezor Xtra catheters also has the ability to perform cryomapping (confirmation of the ablation site). In addition, the Freezor family catheters can collect intracardiac electrograms rom multiple electrodes for evaluation on an electrophysiology (EP) recording system and to use for cardiac stimulation during electrophysiology studies.

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
RoHS 3 Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment	D00275956

Place: ***Refer to electronic signature***

Name: ***Refer to electronic signature***

Title: ***Refer to electronic signature***

Signature: ***Refer to electronic signature***

Date: ***Refer to electronic signature***

Andrei Manole
Quality Management
18 May 2022

Products Covered

Product Name	Medtronic Product Identifier CFN	Basic UDI-DI
Freezor™	207F1, 207F3, 207F5	07963000B000038783
Freezor Xtra™	217F1, 217F3, 217F5	
Freezor MAX™	209F3, 209F5	

Common Specification(s)

Not Applicable

Revision History

Revision	Date Effective	Description of Change
A	TBD	Initial release of document

Oscor Inc.
EC Declaration of Conformity

Manufacturer Name and: **Business Address:**	Oscor Inc. 3816 DeSoto Blvd Palm Harbor, FL. 34683 U.S.A
European Authorized Representative and Business Address:	Oscor Europe GmbH Fritz-Vomfelde-Strasse 6 40547 Düsseldorf, Germany
Distributor Name and Business Address:	Medtronic, Inc 710 Medtronic Parkway Minneapolis, MN 55432
Medical Device(s):	ARRIVE - See List in Appendix I
GMDN Code and Term:	17846 Intravascular Guiding Sheath, Single Use
Classification per MDD 93/42/EEC:	Class III Rule 6
MDD Conformity Assessment Route:	Annex II (4)

We hereby declare that the distributed CE marked products conform to the product(s) covered by the "CE Marking of Conformity Certificate", reference number **3811236CE02**, first issued on **December 16, 2014**, and EC Design-Examination Certificate **3811236DE05**, EN ISO 13485:2016 certificate # 3321100 first issued on February 26, 2019 and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, in accordance with Annex II of the "EC-Directive" the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices.

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive. The conformity of the full quality assurance system set out in Annex II, is described in the said CE Marking of Conformity Certificate, issued and delivered by DEKRA Certification B.V.

This Declaration of Conformity covers all products belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site(s) under the responsibility of Oscor Inc., 3816 DeSoto Boulevard, Palm Harbor, FL 34683, U.S.A.

Site name	Address
Oscor Inc.	3816 DeSoto Boulevard, Palm Harbor, FL 34683, U.S.A.
Oscor Inc.	4875 Palm Harbor Boulevard, Palm Harbor, FL 34683, U.S.A.
Oscor Inc.	4614 Pet Lane, Lutz, FL 33559
Oscor Caribe	Zona Franca Las Americas Nave I-2, Santo Domingo, Dominican Republic

This declaration is issued under the sole responsibility of Oscor Inc.

Place of Issuance: Palm Harbor, Florida

Signature & Date of Issuance:

Doug Myers
VP QA & RA

Date

Appendix I

Product Name:	**ARRIVE**
Branded for:	**Medtronic**
Date of First CE Mark:	**July 30, 2010**

ARRIVE Transseptal T Series – Electrophisiology	
Medtronic Model Number	**Description**
Straight	
990061	10F S61cm D66cm with 71cm needle
990079	10F S61cm D84cm with 71cm needle
55 - Curve	
990061-055	10F S61cm D66cm with 71cm needle
990079-055	10F S61cm D84cm with 71cm needle
70 - Curve	
990061-070	10F S61cm D66cm with 71cm needle
990079-070	10F S61cm D84cm with 71cm needle
90 - Curve	
990061-090	10F S61cm D66cm with 71cm needle
990079-090	10F S61cm D84cm with 71cm needle
120 - Curve	
990061-120	10F S61cm D66cm with 71cm needle
990079-120	10F S61cm D84cm with 71cm needle

Revision History

Revision	Revision Change	Date of Revision
Rev. 00	Initial	December 22, 2015
Rev. 01	Moved Conformity Assessment Route to a new line under classification. Added Revision History to document. Added GMDN Code.	February 19, 2016
Rev.02	Changed signature to current RA Manager.	March 23, 2017
Rev. 03	Changed last name of current RA Manager Update to EN ISO 13485:2016	April 8, 2019
Rev. 04	Update the approval signature from RA Manager Aletta Torres to VP of QA/RA Doug Myers. Update DOC template, include device description	February 01, 2020
Rev. 05	Update site address section, remove from the table the 1053 Progress Court Palm Harbor site and include the 4614 Pet Lane Unit 109 Lutz site address.	February 06, 2020

EC DESIGN-EXAMINATION CERTIFICATE

Number: 3811236DE05

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

Oscor Incorporated

3816 DeSoto Blvd
Palm Harbor FL 34683
United States Of America

For the product

Delivery Sheaths: Adelante Breezeway and Arrive.

Documents, that form the basis of this certificate:

Certification Notice 3811236CN, initially dated 7 December 2013
Addendum, initially dated 16 December 2014

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 27 May 2024
Issued for the first time: 16 December 2014
Reissued: 08 January 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 3811236DE05

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Delivery Sheaths: Adelante Breezeway and Arrive.

Issued to:

Oscor Incorporated
3816 DeSoto Blvd
Palm Harbor FL 34683
United States Of America

This certificate covers the following product(s):

Product Designation: Transeptal T series Electrophysiology:				
Sheath Inner Diameter	Usable Sheath Length	Usable Dialator Length	Compatible Transseptal Needle	Sheath Tip Curve
8 F	61 cm	66 cm	71 cm	Straight
8 F	79 cm	84 cm	89 cm	
*10 F	61 cm	66 cm	71 cm	
*10 F	79 cm	84 cm	89 cm	
8 F	61 cm	66 cm	71 cm	55°
8 F	79 cm	84 cm	89 cm	
*10 F	61 cm	66 cm	71 cm	
*10 F	79 cm	84 cm	89 cm	
8 F	61 cm	66 cm	71 cm	70°
8 F	79 cm	84 cm	89 cm	
*10 F	61 cm	66 cm	71 cm	

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

ADDENDUM

Belonging to certificate: 3811236DE05

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Delivery Sheaths: Adelante Breezeway and Arrive.

Issued to:

Oscor Incorporated
3816 DeSoto Blvd
Palm Harbor FL 34683
United States Of America

Product Designation: Transeptal T series Electrophysiology:

Sheath Inner Diameter	Usable Sheath Length	Usable Dialator Length	Compatible Transseptal Needle	Sheath Tip Curve
*10 F	79 cm	84 cm	89 cm	70°
8 F	61 cm	66 cm	71 cm	90°
8 F	79 cm	84 cm	89 cm	
*10 F	61 cm	66 cm	71 cm	
*10 F	79 cm	84 cm	89 cm	
8 F	61 cm	66 cm	71 cm	120°
8 F	79 cm	84 cm	89 cm	
*10 F	61 cm	66 cm	71 cm	
*10 F	79 cm	84 cm	89 cm	

*Corresponds to 10F models available in the Arrive Delivery Sheath

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 3811236DE05

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Delivery Sheaths: Adelante Breezeway and Arrive.

Issued to:

Oscor Incorporated
3816 DeSoto Blvd
Palm Harbor FL 34683
United States Of America

Product Designation: I series Interventional			
Sheath Inner Diameter	Usable Sheath Length	Usable Dilator Length	Sheath Tip Curve
6 F	45 cm	50 cm	Straight
6 F	55 cm	60 cm	
6 F	70 cm	75 cm	
6 F	90 cm	95 cm	
7 F	45 cm	50 cm	
7 F	55 cm	60 cm	
7 F	70 cm	75 cm	
7 F	90 cm	95 cm	
8 F	45 cm	50 cm	
8 F	55 cm	60 cm	
8 F	70 cm	75 cm	
8 F	90 cm	95 cm	
6 F	45 cm	50 cm	MP
6 F	55 cm	60 cm	
6 F	70 cm	75 cm	
6 F	90 cm	95 cm	

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B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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ADDENDUM

Belonging to certificate: 3811236DE05

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Delivery Sheaths: Adelante Breezeway and Arrive.

Issued to:

Oscor Incorporated
3816 DeSoto Blvd
Palm Harbor FL 34683
United States Of America

Product Designation: I series Interventional			
Sheath Inner Diameter	Usable Sheath Length	Usable Dilator Length	Sheath Tip Curve
7 F	45 cm	50 cm	MP
7 F	55 cm	60 cm	
7 F	70 cm	75 cm	
7 F	90 cm	95 cm	
8 F	45 cm	50 cm	
8 F	55 cm	60 cm	
8 F	70 cm	75 cm	
8 F	90 cm	95 cm	
6 F	45 cm	50 cm	RDC
6 F	55 cm	60 cm	
7 F	45 cm	50 cm	
7 F	55 cm	60 cm	
8 F	45 cm	50 cm	
8 F	55 cm	60 cm	
6 F	45 cm	50 cm	TD
6 F	55 cm	60 cm	
7 F	45 cm	50 cm	
7 F	55 cm	60 cm	
8 F	45 cm	50 cm	

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B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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Belonging to certificate: 3811236DE05

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Delivery Sheaths: Adelante Breezeway and Arrive.

Issued to:

Oscor Incorporated
3816 DeSoto Blvd
Palm Harbor FL 34683
United States Of America

Product Designation: I series Interventional			
Sheath Inner Diameter	Usable Sheath Length	Usable Dilator Length	Sheath Tip Curve
8 F	55 cm	60 cm	TD
6 F	45 cm	50 cm	LIMA
6 F	55 cm	60 cm	
7 F	45 cm	50 cm	
7 F	55 cm	60 cm	
8 F	45 cm	50 cm	
8 F	55 cm	60 cm	
6 F	40 cm	45 cm	ISF 180° Straight
7 F	40 cm	45 cm	
8 F	40 cm	45 cm	
6 F	40 cm	45 cm	ISF 180° Curve
7 F	40 cm	45 cm	
8 F	40 cm	45 cm	

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Managing Director

J.A. van Vugt
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EC DESIGN-EXAMINATION
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Delivery Sheaths: Adelante Breezeway and Arrive.

Issued to:

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3816 DeSoto Blvd
Palm Harbor FL 34683
United States Of America

Breezeway Renal			
Sheath Inner Diameter	Usable Sheath Length	Usable Dilator Length	Sheath Tip Curve
6 F	45 cm	50 cm	RDC
6 F	55 cm	60 cm	
7 F	45 cm	50 cm	
7 F	55 cm	60 cm	
8 F	45 cm	50 cm	
8 F	55 cm	60 cm	
6 F	45 cm	50 cm	LIMA
6 F	55 cm	60 cm	
7 F	45 cm	50 cm	
7 F	55 cm	60 cm	
8 F	45 cm	50 cm	
8 F	55 cm	60 cm	
6 F	45 cm	50 cm	MP
6 F	55 cm	60 cm	
7 F	45 cm	50 cm	
7 F	55 cm	60 cm	
8 F	45 cm	50 cm	
8 F	55 cm	60 cm	
6 F	45 cm	50 cm	TD
6 F	55 cm	60 cm	
7 F	45 cm	50 cm	

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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EC DESIGN-EXAMINATION
MEDICAL DEVICES

Delivery Sheaths: Adelante Breezeway and Arrive.

Issued to:

Oscor Incorporated
3816 DeSoto Blvd
Palm Harbor FL 34683
United States Of America

Breezeway Renal			
Sheath Inner Diameter	Usable Sheath Length	Usable Dilator Length	Sheath Tip Curve
7 F	55 cm	60 cm	TD
8 F	45 cm	50 cm	
8 F	55 cm	60 cm	

Initial date: 16 December 2014
Revised date: 21 December 2015

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable Class IIb Devices and Class III Devices)

No. G12 039709 1406 Rev. 00

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

SRN Manufacturer: US-MF-000019977

Authorized Representative:

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G12 039709 1406 Rev. 00

Report No.: 72172299

Valid from: 2022-03-28
Valid until: 2027-03-27

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-03-28

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable Class IIb Devices and Class III Devices)

No. G12 039709 1406 Rev. 00

Classification:	III
Device Group:	C0502 - CARDIOVASCULAR INTRODUCER SHEATHS, VALVED
Intended Purpose:	The intended purpose of FlexCathAdvance Steerable Sheath is to provide percutaneous introduction into the vasculature and chambers of the heart, and to facilitate positioning of compatible devices.
Classification:	III
Device Group:	C02010499 - ARRHYTHMOLOGY MULTIPOLAR LEADS - OTHER
Intended Purpose:	To collect intracardiac electrograms from multiple electrodes for evaluation on an electrophysiology (EP) recording system and to use for cardiac stimulation during electrophysiology studies. The mapping catheter is compatible for use with, and may be used to support and position, all catheters in the Medtronic Arctic Front family of cardiac cryoablation catheters.
Classification:	III
Device Group:	C020302 - ARRHYTHMOGENIC FOCI CRYOENERGY ABLATION LEADS
Intended Purpose:	The intended purpose of the Freezor family cardiac cryoablation catheters is to ablate arrhythmogenic sites in the heart by applying cryoenergy to cardiac tissue for the treatment of cardiac arrhythmias. In addition, the Freezor family catheters can detect electrical signals from multiple electrodes for evaluation on an electrophysiology (EP) recording system and to use for cardiac stimulation during electrophysiology studies.
Classification:	III
Device Group:	C020302 - ARRHYTHMOGENIC FOCI CRYOENERGY ABLATION LEADS
Intended Purpose:	The intended purpose of the Arctic Front family of cardiac cryoablation catheters is to ablate cardiac tissue in the left atrium.
The validity of this certificate depends on conditions and/or is limited to the following:	-

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Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable Class IIb Devices and Class III Devices)

No. G12 039709 1406 Rev. 00

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

SRN Manufacturer: US-MF-000019977

Authorized Representative:

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G12 039709 1406 Rev. 00

Report No.: 72172299

Valid from: 2022-03-28
Valid until: 2027-03-27

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-03-28

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable Class IIb Devices and Class III Devices)

No. G12 039709 1406 Rev. 00

Classification:	III
Device Group:	C0502 - CARDIOVASCULAR INTRODUCER SHEATHS, VALVED
Intended Purpose:	The intended purpose of FlexCathAdvance Steerable Sheath is to provide percutaneous introduction into the vasculature and chambers of the heart, and to facilitate positioning of compatible devices.
Classification:	III
Device Group:	C02010499 - ARRHYTHMOLOGY MULTIPOLAR LEADS - OTHER
Intended Purpose:	To collect intracardiac electrograms from multiple electrodes for evaluation on an electrophysiology (EP) recording system and to use for cardiac stimulation during electrophysiology studies. The mapping catheter is compatible for use with, and may be used to support and position, all catheters in the Medtronic Arctic Front family of cardiac cryoablation catheters.
Classification:	III
Device Group:	C020302 - ARRHYTHMOGENIC FOCI CRYOENERGY ABLATION LEADS
Intended Purpose:	The intended purpose of the Freezor family cardiac cryoablation catheters is to ablate arrhythmogenic sites in the heart by applying cryoenergy to cardiac tissue for the treatment of cardiac arrhythmias. In addition, the Freezor family catheters can detect electrical signals from multiple electrodes for evaluation on an electrophysiology (EP) recording system and to use for cardiac stimulation during electrophysiology studies.
Classification:	III
Device Group:	C020302 - ARRHYTHMOGENIC FOCI CRYOENERGY ABLATION LEADS
Intended Purpose:	The intended purpose of the Arctic Front family of cardiac cryoablation catheters is to ablate cardiac tissue in the left atrium.
The validity of this certificate depends on conditions and/or is limited to the following:	-

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www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1385 Rev. 00

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

SRN Manufacturer: US-MF-000019977

Authorized Representative:

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 039709 1385 Rev. 00

Report No.: 713203024

Valid from: 2022-03-23
Valid until: 2027-03-22

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-03-23

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1385 Rev. 00

Classification:	III
Device Group:	C020302 - ARRHYTHMOGENIC FOCI CRYOENERGY ABLATION LEADS
Basic UDI-DI:	0763000B000038783
Intended Purpose:	The intended purpose of the Freezor family cardiac cryoablation catheters is to ablate arrhythmogenic sites in the heart by applying cryoenergy to cardiac tissue for the treatment of cardiac arrhythmias. In addition, the Freezor family catheters can detect electrical signals from multiple electrodes for evaluation on an electrophysiology (EP) recording system and to use for cardiac stimulation during electrophysiology studies.
Device(s):	Freezor Article/Model Numbers - 207F1 - 207F3 - 207F5 Freezor MAX Article/Model Numbers - 209F3 - 209F5 Freezor Xtra Article/Model Numbers - 217F1 - 217F3 - 217F5
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039709 1144 Rev. 02

Manufacturer: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product Category(ies): **External pacemakers, diagnostic and ablation catheter, transseptal needles**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713159141

Valid from: 2020-03-03
Valid until: 2024-05-26

Date, 2020-02-28

Christoph Dicks
Head of Certification/Notified Body

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 039709 0983 Rev. 01

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis MN 55432
USA

Product:

Medical Cannula for single use
Brockenbrough Transseptal Needle

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713157058

Valid from: 2020-01-01
Valid until: 2024-05-26

Date, 2019-12-18

Christoph Dicks
Head of Certification/Notified Body

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 039709 0983 Rev. 01

Facility(ies):

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Medtronic Mexico S.de R.L.de CV
Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tijuana, Baja California, MEXICO

Model(s):

Brockenbrough Curved Needle Adult, Model No. EP003994S

Brockenbrough Curved Needle Pediatric, Model No. EP003997S

Parameters:

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BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1384 Rev. 00

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

SRN Manufacturer: US-MF-000019977

Authorized Representative:

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 039709 1384 Rev. 00

Report No.: 713203021

Valid from: 2022-02-23
Valid until: 2027-02-22

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-02-23

Erin M Suek
NOTARY PUBLIC
MINNESOTA
My Commission Expires Jan. 31, 2025

Erin M Suek 8/25/22

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TÜV SÜD Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1384 Rev. 00

Classification:	III
Device Group:	C02010499 - ARRHYTHMOLOGY MULTIPOLAR LEADS - OTHER
Basic UDI-DI:	0763000B000040072
Intended Purpose:	To collect intracardiac electrograms from multiple electrodes for evaluation on an electrophysiology (EP) recording system and to use for cardiac stimulation during electrophysiology studies. The mapping catheter is compatible for use with, and may be used to support and position, all catheters in the Medtronic Arctic Front family of cardiac cryoablation catheters.
Device(s):	Achieve Article/Model Numbers - 990063-015 - 990063-020 Achieve Advance Article/Model Numbers - 2ACH15 - 2ACH20 - 2ACH25
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1389 Rev. 00

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

SRN Manufacturer: US-MF-000019977

Authorized Representative:

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

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Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 039709 1389 Rev. 00

Report No.: 713215011

Valid from: 2022-02-14
Valid until: 2027-02-13

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-02-14

Erin M Suek
NOTARY PUBLIC
MINNESOTA
My Commission Expires Jan. 31, 2025

Erin M Suek 8/25/22

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EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1389 Rev. 00

Classification:	III
Device Group:	C0502 - CARDIOVASCULAR INTRODUCER SHEATHS, VALVED
Basic UDI-DI:	0763000B00004317D
Intended Purpose:	The intended purpose of FlexCath Advance steerable sheath is to provide percutaneous introduction into the vasculature and chambers of the heart, and to facilitate positioning of compatible devices.
Device(s):	FlexCath Advance - 4FC12
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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EC CERTIFICATE

Number: 3811236CE02

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III and Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

Oscor Incorporated

3816 DeSoto Blvd
Palm Harbor, FL 34683
United States Of America

For the product category(ies)

Medical Devices for the area of cardiological application

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 3811236CN, initially dated 7 December 2013
Addendum, initially dated 16 December 2014

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection, that covers the aspects of manufacture concerned with securing and maintaining sterile conditions, for the above mentioned product category in accordance to the provisions of Annex II Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory.
The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 27 May 2024
Issued for the first time: 16 December 2014
Revised: 12 May 2019
Reissued: 31 January 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van VugtJ.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 3811236CE02

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Medical Devices for the area of cardiological application

Issued to:

Oscor Incorporated
3816 DeSoto Blvd
Palm Harbor, FL 34683
United States Of America

This certificate covers the following product(s):

Transseptal Guidewires (Class III)
Steerable guiding sheath (Class III)
Delivery sheaths (Class III)
Introducer sets
- Peelaway Introducer Sets (Class III)
- Non Peelaway Introducer Kits (Class IIa)
- Adelante Magnum (Class III)

Extension Cables (Class IIa)
Plugs (Class Is)

Initial date: 16 December 2014
Revision date: 31 January 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

DEKRA Certification B.V. is Notified Body with ID no 0344

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Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1379 Rev. 00

Manufacturer:	**Medtronic, Inc.** 710 Medtronic Parkway Minneapolis, MN 55432 USA
SRN Manufacturer:	US-MF-000019977
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

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For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 039709 1379 Rev. 00

Report No.:	713190982
Valid from:	2022-02-14
Valid until:	2027-02-13

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-02-14

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Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1379 Rev. 00

Classification:	III
Device Group:	C020302 - ARRHYTHMOGENIC FOCI CRYOENERGY ABLATION LEADS
Basic UDI-DI:	0763000B00000256W
Intended Purpose:	To ablate cardiac tissue in the left atrium
Device(s):	Arctic Front Advance Article/Model Numbers - 2AF233 - 2AF283 Arctic Front Advance Pro Article/Model Numbers - AFAPRO23 - AFAPRO28
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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