

Către
Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 5 din 29.09.2023

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

- Epicardial CapSure Leads

Se anexează următoarele acte:

Declarație pe proprie răspundere

CE certificate

Declarație de conformitate

Scrisoare de imputernicire

Data 29/09/2023

Semnătura _____

Tabelul de recepționare a notificării

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

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

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

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

declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- Epicardial CapSure Leads
Sunt autentice și corespund realității.

Numele, prenumele și funcția

Kojevnikov Dmitrii, director

Semnătura _____

Data 29/09/2023

TO WHOM IT MAY CONCERN

Date: 29.05.2023

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

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

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

Medtronic META FZ-LLC

M. N. ALANI



Name: Muzahim Al Ani

Title: Authorized Signatory

APPENDIX 1

Medtronic Manufacturing Facilities/Legal Manufacturers:

1. Medtronic, Inc., 710 Medtronic Parkway, Minneapolis MN 55432, USA
2. Medtronic, Inc., 7000 Central Avenue N.E., Minneapolis MN 55432, USA
3. Medtronic, Inc., 3800 Annapolis Lane, Minneapolis MN 55447, USA
4. Medtronic, Inc., 8200 Coral Sea Street N.E., Mounds View, MN 5512, USA
5. Medtronic Europe Sàrl, Route du Molliau 31, Case Postale, CH-1131 Tolochenaz, Switzerland
6. Medtronic Bakken Research Center B.V., Endepolsdomein 5, 6229 GW Maastricht, The Netherlands
7. Medtronic CoreValve LLC, 1851 E. Deere Avenue, Santa Ana, CA 92705, USA
8. Medtronic MiniMed, 18000 Devonshire street, Northridge CA 91325-1219, USA
9. Medtronic Heart Valves Division, 1851 East Deere Avenue, Santa Ana, CA 92705, USA
10. Medtronic Heart Valves, 1941 Blair Avenue, Santa Ana CA 92705, USA
11. Medtronic Fabrication S.A.S. Zone Industrielle SUD, Route D'Anor, 59610 Fourmies, France
12. Medtronic Sofamor Danek USA, Inc., 1800 Pyramid Place, Memphis, TN 38132, USA
13. Medtronic Sofamor Danek USA, Inc., 4340 Swinnea Road, Memphis TN 38118, USA
14. Medtronic Sofamor Danek Manufacturing, 2500 Silveus Crossing, Warsaw IN 46582, USA
15. Medtronic Sofamor Danek Deggendorf GmbH, Werfstrasse 17, 94469 Deggendorf, Germany
16. Medtronic Sofamor Danek Deggendorf GmbH, Ulrichsberger Str. 17, 94469 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-Bôt 97, 2000 Neuchâtel, Switzerland
26. AF Solutions, Medtronic Inc., 8200 Coral Sea Street, Mounds View, Minneapolis MN 55112, USA
27. Medtronic Ireland, Parkmore Business Park West Galway, Ireland
28. Medtronic Vascular, 35-37a Cherry Hill Drive, Danvers, MA 01923, USA
29. Medtronic Vascular, 3576 Unocal Place, Santa Rosa, CA 95403, USA
30. Medtronic Puerto Rico Operations Co., Juncos, Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos PR 00777, USA
31. Medtronic Puerto Rico Operations Co., Villalba, Rd 149, Km 56.3, Call Box 6001, PR 00766 Villalba, USA
32. Medtronic Puerto Rico Operations, Co., Road 909 Km. 0.4 Bo, 00792 Barrio Mariana, Humacao, Puerto Rico, USA
33. Medtronic Puerto Rico Operations, Co., Parcela #21, Catano Industrial Park, Dr. John A. Smith Street, 00792 Humacao, Puerto Rico, USA
34. Medtronic Mexico S. de R.L. de CV, Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tijuana, Baja California, Mexico
35. Medtronic Mexico EG, Carreta Internacional Guadalajara – Nogales, Empalme, Sonora, Mexico 85340
36. Medtronic Singapore Operations Pte. Ltd., 49 Changi South Avenue 2, Nasaco Tec Centre, 486056 Singapore
37. Medtronic Atrial Fibrillation Technologies (AFT), 8200 Coral Sea Street NE, Mounds View, Minneapolis MN 55112, USA
38. Medtronic Perfusion Systems, 7611 Northland Drive, Minneapolis, MN 55428, USA
39. Medtronic Perfusion Systems, 18501 East Plaza Drive, Parker CO 80134-9061, USA
40. Medtronic Cardiac Surgery Division Europe, Valkenhuizerlaan 16, 6466 ND Kerkrade, The Netherlands

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

List of EC Representatives:

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

List of Medtronic Distribution Centers:

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

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

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

Covidien llc (USA)

- 15 Hampshire Street, Mansfield, MA 02048 USA
- 5439 State Route 40 Argyle, NY 12809 USA
- 1430 Marvin Griffin Road Augusta, GA 30906 USA
- 815 Tek Drive Crystal Lake, IL 60039 USA
- 525 North Emerald Road Greenwood, SC 29646 USA
- 1448 Blue Ridge Boulevard Seneca, SC 29672 USA
- 1313 West Grant Boulevard Wabasha, MN 55981USA
- Two Ludlow Park Drive Chicopee, MA 01022 USA
- 400 Maple Street Commerce, TX 75428 USA
- 2010 East International Speedway Boulevard Deland, FL 32724 USA
- 1222 Sherwood Road Norfolk, NE 68701USA
- 150 Glover Avenue, Norwalk, CT 06856 USA

- 60 Middletown Ave, North Haven, CT 06473 USA
- Building 911-67, Sabanetas Industrial Park, Ponce, Puerto Rico 00731
- At 101a Fist Avenue, Waltham, MA 02451, USA
- 5920 Longbow Dr., Boulder, CO 80301, USA
- 15 Crosby Drive, Bedford, MA 10730, USA
- 6135 Gunbarrel Ave., Boulder, CO 80301, USA
- 675 McDonnell Blvd., Saint Louis, MO 63134, USA
- formerly Barrx Medical Inc., 540 Oakmead Parkway Sunnyvale, CA 94085, USA

Covidien llc (Canada)

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

Covidien llc (Mexico)

- 37 Boulevard Insurgentes, Libramiento a la P, La Mesa Tijuana, B.C., Mexico
- Calle 9 Sur No. 125 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

Covidien Ilc (Japan)

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

Covidien Ilc Newton (Beacon)

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

Covidien AG

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

Covidien Logistics BVBA

Weg naar Zwartberg 239, 3660 Opplabbeek, 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 Chenhong Road, 201114 Shanghai, P.R. China

Covidien Deutschland Manufacturing GmbH

Gewerbepark 1, 93333 Neustadt and der Donau, Germany

Covidien Manufacturing Solutions SA

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

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

5920 Longbow Drive Boulder, CO 80301 USA

Covidien, formerly Kendall-Gammatron Co. Ltd.

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

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

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

EV3 Inc.

4600 Nathan Lane North Plymouth, MN 55442 USA

Micro Therapeutics Inc. d/b/a ev3 Neurovascular

9775 Toledo Way, Irvine, CA 92618 USA

superDimension Inc.

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

Sofradim Production

116 Avenue du Formans, 01600 Trévoux, France

VNUS Medical Technologies, Inc.

5799 Fontanoso Way, San Jose CA 95138, USA

Given Imaging, Inc.

15 Hampshire Street, Mansfield MA 02048, USA

Given Imaging, Ltd

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

Given Imaging (Los Angeles) LLC

Los Angeles 5860 Uplander Way Culver City, CA 90230 USA

Given Imaging Vietnam Co. Ltd.

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

Wem Equipamentos Eletrônicos Ltda.

Rua. Marechal Mascarenhas de Moraes 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 Sebastiao. 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: DEKRA
Meander 1051, 6825 MJ Arnhem
P.O. Box 5185, 6802 ED
Arnhem, The Netherlands

Identification Number: 0344

Conformity Assessment Certificate(s): 2250280CE01 (Quality)
2250280TD09 (Product)

Conformity Assessment Procedure: Annex IX

Risk Class: Class III

Classification Rule: Rule 8 and Rule 14

Intended Purpose: The Models 4965 and 4968 epicardial leads are intended to monitor and regulate the patient's atrial or ventricular heart rate by delivery of pacing therapies for the treatment of bradyarrhythmia.

EU MDR Declaration of Conformity

D00450411

Revision B

Page 2 of 3

Form

Medtronic

Statement:

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

Other Union Legislation(s):

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

Place: Mounds View, MN

Name: Luke Ranta

Title: Engineering Manager, Heart Failure & Tachy Post Market Quality

Signature: *Refer to electronic signature*

Date: *Refer to electronic signature*

Products Covered

Product Name	Medtronic Product Identifier		Conformity Assessment Certificates	Basic UDI-DI	Optional: Additional nomenclature identifier (e.g., GMDN)
	Model # (with variants-if applicable)				
Epicardial CapSure Leads	4965	4965-15; 4965-25; 4965-35; 4965-50.	2250280CE01 (Quality) 2250280TD09 (Product)	0763000B000075488	CND: J019001
Epicardial CapSure Leads	4968	4968-25; 4968-35; 4968-60.			

Common Specification(s)

Not Applicable.

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title

Document Approval Report

Medtronic

Report Generated By: Catinas, Diana

Report Create Date/Time: 2022-10-28 09:36 GMT

Change Number:	RCH00297064
Change Originator:	Berly, Rafael

Document/Part Information

Number:	Lifecycle Phase:	Description:	Revision:	Effective Date/Time of Revision:	Type Category:	Document Owner:
D00450411	Released	EU MDR Declaration of Conformity - EPI Models 4965 and 4968 Leads	B RCH00297064	2022-10-27 17:53 GMT	Regulatory Declaration of Conformity Europe - Medical Device Regulation	Ranta, Luke

Approvals

Approver Name:	Approver Job Function:	Action:	Approval Date/Time:	Signoff:	Workflow Status:
Berly, Rafael	Regulatory	Approved	2022-10-27 15:30 GMT	Berly, Rafael	Approve Change
Ranta, Luke	Document Owner	Approved	2022-10-27 14:47 GMT	Ranta, Luke	Approve Change
Ranta, Luke	Quality Management	Approved	2022-10-27 14:47 GMT	Ranta, Luke	Approve Change

D00450411

Number: 2250280TD09

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

Manufacturer:

Medtronic Inc.
710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America
SRN ID.: US-MF-000019977

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 EU- Regulation which apply to them:

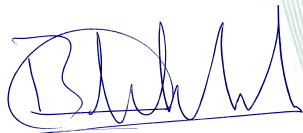
0344

Supplement to certificate: 2007841CN

Authorized Representative: Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Principal Certification Manager

First Issued: **24 August 2022**

Date: **24 August 2022**

Expiry date: **1 August 2027**

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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 www.dekra.nl Company registration 09085396

Number: 2250280TD09

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

This certificate covers the following device(s) / groups of device(s):

Class III	
Basic-UDI-DI: 0763000B000075488 CapSure™ EPI Lead Model 4965 (class III) CapSure™ EPI Lead Model 4968 (class III) (J019001, Permanent Cardiac Electrocateters)	<i>Intended Purpose:</i> Lead Models 4965 and 4968 are designed for pacing therapies when used as part of an implantable pacemaker system. The leads are intended for use on the atrium or ventricle to monitor and regulate the patient's heart rate by delivery of pacing therapies for the treatment of bradyarrhythmias.

First Issued: **24 August 2022**

Date: **24 August 2022**

Expiry date: **1 August 2027**

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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 www.dekra.nl Company registration 09085396

Number: 2250280TD09

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	24-08-2022	2007841CN111	First issue

First Issued: **24 August 2022**

Date: **24 August 2022**

Expiry date: **1 August 2027**

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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 www.dekra.nl Company registration 09085396

Number: 2250280CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Medtronic Inc.

710 Medtronic Parkway

MN 55432 Minneapolis

United States Of America

SRN ID.: US-MF-000019977

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 EU- Regulation which apply to them:

0344

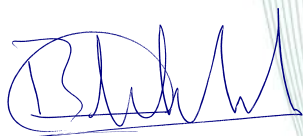
Supplement to certificate: 2007841CN

**Additional certificate: 2250280TD01/ 2250280TD02/2250280TD03/2250280TD04/2250280TD05/
2250280TD06/2250280TD07/2250280TD08/2250280TD09/2250280TD10/2250280TD11/2250280TD12/
2250280TD13/2250280TD14/2250280TD15/2250280TD16/2250280TD17**

Authorized Representative: Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M.A. McKenzie
Principal Certification Manager

First Issued: **15 December 2021**

Date: **16 June 2023**

Expiry date: **1 December 2026**

© Integral publication of this certificate and adjoining reports is allowed

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 www.dekra.nl Company registration 09085396

Number: 2250280CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

This certificate covers the following device(s) / groups of device(s):

Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools (MDN1203, class Is)

Sterilization method: gamma irradiation

Group of Devices:

Model 6248VAL adjustable valve
Model 6230UNI Universal II splitter
Model 6232ADJ Adjustable splitter

Class III

Device Name: 6719 - DF-1 Pin Plug Kit

Device Name: 6937 TRANSVENE™

Device Name: Model 6996SQ

Group of Devices:

Epsilon EV™ EAZ101
Epsilon EV™ EAZ201

Group of Devices:

Attesta MRI SureScan™
Sphera MRI SureScan™

Attesta™ and Sphera™ Programmer SW Application (external), SW043, For Programmers 2090 and 29901

Group of Devices:

CapSure Sense MRI SureScan
CapSureFix Novus
CapSureFix Novus MRI SureScan

Group of Devices:

Sprint Quattro Secure S
Sprint Quattro Secure S MRI SureScan
Sprint Quattro
Sprint Quattro MRI SureScan
Sprint Quattro Secure
Sprint Quattro Secure MRI SureScan

Device Name: Attain Stability™ Quad MRI SureScan™

Device Name: CapSure™ EPI Lead

Device Name: HV Splitter/Adaptor Kit (model 5019)

Device Name: Micra™ Introducer

Device Name: Stylet Kit 6093

Device Name: Rotation Tool Kit, Model 6056

Device Name: Wrench Kit, Model 5873W

Group of Devices:

First Issued: 15 December 2021

Date: 16 June 2023

Expiry date: 1 December 2026

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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
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Number: 2250280CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Class III

CapSure® VDD-2 Leads

Device Name: Myocardial Screw-In 5071 Pacing Lead

Device Name: SelectSecure (model 3830)

Device Name: SelectSecure MRI SureScan (model 3830)

Device Name: Lead Introducer Kits

Conditions for or limitations to the validity of this certificate:

- For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	15-12-2021	2007841CN107	First Issue
1	21-03-2022	2007841CN108	Revised
2	08-04-2022	2007841CN109	Revised
3	19-07-2022	2007841CN110	Revised
4	29-07-2022	2007841CN111	Revised
5	24-08-2022	2007841CN112	Revised
6	25-11-2022	2007841CN113	Revised
7	02-02-2023	2007841CN113	Revised
8	27-02-2023	2007841CN113	Revised
9	27-05-2023	2007841CN115	Revised
10	12-06-2023	2007841CN116	Revised
11	16-06-2023	2007841CN117	Revised

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