

Către
Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 13 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:

- Screw-In Lead

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:

- Screw-In Lead

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 an 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

	Document Title: EC Declaration of Conformity Certificate: Screw-In Lead 5071 DoC-5071	Document Number: BL0003687
EC DECLARATION OF CONFORMITY	Screw-In Lead, Model 5071	

Revision/History description	Revision level	Impl. Date
Leads for implantable IPGs and their auxiliary components Screw-In leads, 4057M, 4058M, 4067, 4068, 4557M, 4558M, 4568, 5069, 5071	—	18-Aug-2001
Update of Standards	A	23-Jan-2002
Update to reflect correct issue dates of standards	B	23-Aug-2002
Update to implement new EC Rep Address, editorial changes, new CE mark certificate number	C	13-Feb-2003
This Declaration of Conformity supersedes DOC 272-02. Update to implement new documentation number, add editorial changes, new CE Mark certificate and remove models 4057M, 4058M, 4067, 4068, 4557M, 4558M, 4568 and 5069	6.0	20-Nov-2007
Updated to support AIMD Directive 90/385/EEC: Amendment 2007 and New Template, Corrected Issue date.	7.0	07-Apr-2010
Updated to latest standards. Corrected Issue date. Updated to new template.	8.0	22-Feb-2012
Updated to the new EC Quality System Certificate number.	9.0	26-Mar-2012
Updated to add new design certificate number and quality system certificate number due to CE Renewal; update to latest revision of DoC template	10.0	19-Nov-2012
Updated EN ISO 14971 to reflect latest version	11.0	05-Jul-2013
Updated approver to Stacey Pivovar Updated Standards EN ISO 11135, EN ISO 11607-1 Updated to title of EN 980, EN 1041, EN ISO 10993-1, EN ISO 10993-7 and revision year of ISO 5841-3 Deleted footnote to Standard EN 45502-2-1 Updated footnotes to Standards EN ISO 14971, EN ISO 10993-1, EN 62366 to "Full Compliance"	12.0	06-Oct-2016
Updated to latest revision of DoC template. Updated GMDN Code and Description from 36241 (Defibrillator/pacemaker lead) to 35039 (Epicardial pacing lead) as the code 36241 is obsolete. Updated to reflect new EC certificate number. New certificate (I5 17 07 39709 01130) replaces certificate (I5 12 07 39709 826) and becomes effective November 21, 2017. Updated to reflect new EC Quality System certificate number. New certificate (I2 17 11 39709 01117) replaces certificate I2 12 11 39709 844 and becomes effective November 21, 2017. As such, validity date updated to reflect November 21, 2017.	13.0	30-Oct-2017
Updated to reflect 62366-1:2015	14.0	03-Apr-2018
Updated to reflect Validity Date	15.0	12-Apr-2018
Updated to reflect new EC certificate number. New certificate (2007841TE25) replaces certificate (I5 17 07 39709 01130) and becomes effective April 30, 2018. As such, validity date updated to reflect April 30, 2018.	16.0	20-Apr-2018
Updated to reflect BL0016607 Rev 13.0 ERM standards changes: 1. From EN 980:2008 to EN ISO 15223-1:2016 2. From EN 1041:2008 to EN 1041:2008/A1:2013 3. From EN 45502-1:1997 to EN 45502-1:2015	17.0	20-Dec-2018
Updated from EN ISO 10993-1:2009/AC:2010 to ISO 10993-1:2018	18.0	27-Aug-2019
Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020	19.0	20-Feb-2020
Added Amendment 1:2019 to EN ISO 11135:2014 Updated to match Agile MAP revision numbering convention Added referral to change record for signatures and approval date	AA	12-Oct-2020
Updated EC Quality System Certificate number	AB	18-May-2021

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Updated EN ISO 14971 from 2012 to 2019 Updated EN ISO 10993-7 from 2008/AC:2009 to 2008 + Amd1:2019 Updated ISO 10993-1:2018 to EN ISO 10993-1:2020 Added standards ISO 14708-1 and ISO 14708-2	AC	07-Sep-2021
Replace EN 1041:2008 + A1:2013 with EN ISO 20417:2021 Updated EN ISO 15223-1 from 2016 to 2021 Updated EN ISO 14971 from 2019 to 2019+A11:2021 Updated Engineering Manager to Luke Ranta Updated Document template to latest revision AB	AD	16-Mar-2023
This revision is to update the AIMD Declaration of Conformity to include requirements of amended Regulation (EU) 2023/607. Updated implementation date of last revision. Updated Variants information to include only correct variants. Updated Validity DoC From Date with statement of reference to change record.	AE	Upon Approval

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EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned:	Screw-In Lead
Model number:	5071
Variants:	Lead is available in 25cm, 35cm, and 53cm lengths.
GMDN Code and Description	35039, Epicardial pacing lead
Classification, rule	AIMD
Conformity Assessment Route:	Annex 3 with Annex 5
EC Certificate number:	2007841TE25
EC Quality System Certificate:	I2 039709 1117
Name & Address of Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Identification Number Notified Body:	0123
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:
We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 90/385/EEC¹ which apply to them. In addition, Medtronic declares compliance to Article 120 of the Regulation (EU) 2017/745 and the Regulation (EU) 2023/607, amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards to the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive and the evidence of compliance to the conditions presented under Article 1 Paragraph 3c of the amended Regulation (EU) 2023/607. This declaration applies to all devices specified above distributed from the signature date through the amended Regulation extension date of 31 December 2027. The validity of the certificates listed on this DoC are valid through 31 December 2027..

Validity DoC from date: Refer to change record	Place: Minneapolis	Date: Refer to document approval date in the change record
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Name: Luke Ranta Title: Engineering Manager	Signature: Refer to change record for electronic signature Available upon request: Non-electronic Date and Signature
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¹ Including amendments issued in the years following

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN 45502-1	2015	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
ISO 14708-1	2014	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN 45502-2-1	2003	Active Implantable Medical Devices – Part 2-1: Particular Requirements for Active Implantable Medical Devices Intended to Treat Bradyarrhythmia (cardiac pacemakers)
ISO 14708-2	2019	Implants for surgery - Active Implantable Medical Devices – Part 2: Particular Requirements for Active Implantable Medical Devices Intended to Treat Bradyarrhythmia (includes cardiac pacemakers) – Second edition
EN ISO 14971	2019 +A11:2021	Medical devices – Application of risk management to medical devices
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 15223-1	2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
EN ISO 20417	2021	Medical devices – Information to be supplied by the manufacturer
EN ISO 11135	2014 + A1:2019	Sterilization of healthcare products- Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN 556-1	2001/AC:2006	Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices
EN ISO 10993-1	2020	Biological Evaluation Of Medical Devices – Part 1: Evaluation And Testing within a Risk Management Process
ISO 10993-7	2008 + Amd1:2019	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals
ISO 5841-3	2013	Implants for Surgery – Cardiac Pacemakers – Part 3: Low Profile Connectors (IS-1) for Implantable Pacemakers
EN 62366-1	2015	Medical devices – Part 1: Application of usability engineering to medical devices

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Document Approval Report

Medtronic

Report Generated By: Lungu, Mihaela Luminita

Report Create Date/Time: 2023-05-11 11:32 GMT

Change Number:	RCH00332920
Change Originator:	Levi, Joshua

Document/Part Information

Number:	Lifecycle Phase:	Description:	Revision:	Effective Date/Time of Revision:	Type Category:	Document Owner:
BL0003687	Released	EC Declaration of Conformity Certificate: Screw-In Lead 5071 DoC-5071	AE RCH00332920	2023-03-21 21:24 GMT	Regulatory Declaration of Conformity Europe - Active Implantable Medical Devices Directive	Ranta, Luke

Approvals

Approver Name:	Approver Job Function:	Action:	Approval Date/Time:	Signoff:	Workflow Status:
Ranta, Luke	Document Owner	Approved	2023-03-21 20:15 GMT	Ranta, Luke	Approve Change
Ranta, Luke	Quality Management	Approved	2023-03-21 20:15 GMT	Ranta, Luke	Approve Change
Lapadat, Gillian	Regulatory	Approved	2023-03-21 20:41 GMT	Lapadat, Gillian	Approve Change

BL0003687



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03



Product Service

EC Certificate

Production Quality Assurance System

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 5

(Other devices than custom made or intended for clinical investigation)

No. I2 039709 1117 Rev. 01

Manufacturer:

Medtronic, Inc.

710 Medtronic Parkway

Minneapolis, MN 55432

USA

Product:

Implantable Leads for AIMDs

**Accessories for Implantable Leads for
AIMDs**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with AIMDD Annex 5. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 3 certificate is mandatory. 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:I2 039709 1117 Rev. 01

Report no.:

713194256

Valid from:

2021-04-23

Valid until:

2024-05-26

Date,

2021-03-31

Christoph Dicks

Head of Certification/Notified Body

EC TYPE-EXAMINATION CERTIFICATE

Number: 2007841TE25

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 3
(Other devices than custom made or intended for clinical investigation)

Manufacturer:

Medtronic Inc.
710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America

For the product / product category

Leads for Brady IPGs and their auxiliary components

Documents, that form the basis of this certificate:

Certification Notice 2007841CN, initially dated 1 January 2001
Addendum, initially dated 30 April 2018

DEKRA hereby declares that the type of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 3 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 3 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.

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: 20 November 2022
Issued for the first time: 30 April 2018

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
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: 2007841TE25

1/2

EC TYPE-EXAMINATION ACTIVE IMPLANTABLE MEDICAL DEVICES

Leads for Brady IPGs and their auxiliary components

Issued to:

Medtronic Inc.
710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America

This certificate covers the following product(s):

Leads for Brady IPGs:

CapSure® Z Novus Lead models 5054,5554
CapSureFix® Lead model 5568
CapSure® SP Novus Lead models 4092, 4592, 5092,5592, 5594
CapSureFix® Novus Lead model 5076
CapSure® Sense Lead models 4074,4574
CapSure® VDD-2 Lead models 5038, 5038 L, 5038 S
CapSure® Epi models 4965, 4968

Auxiliary components

Epicardial Lead Implant Tool model 10626
Lead End Cap Kit model 5867-3M
Lead Anchoring Sleeve model 5867-2
Rotation Tool Kit model 6056
Medical Adhesive model 080118
Service Kit model 5873C
Wrench Kit model 5873W
Stylet Kit models 6048,6052,6054,6057,6082,6091,6094
Stylet Kit (downsized knob) models 6254,6282,6293
Pin-Plug Kit models 6725

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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ADDENDUM

Belonging to certificate: 2007841TE25

2/2

EC TYPE-EXAMINATION ACTIVE IMPLANTABLE MEDICAL DEVICES

Leads for Brady IPGs and their auxiliary components

Issued to:

Medtronic Inc.
710 Medtronic Parkway
MN 55432 Minneapolis
United States Of America

Percutaneous Lead Introducer models:

6207-S1, 6207-S5, 6207-D1
6208-S1, 6208-S5, 6208-D1
6209-S1, 6209-S5, 6209-D1
6210-S1, 6210-S5, 6210-D1
6211-S1, 6211-S5, 6211-D1
6212-S1, 6212-S5
6214-S1, 6214-S5

Solo-Trak® -KR Percutaneous Lead Introducer models:

6207BTK-1, 6207BTK-5, 6207BTK-01, 6207BTKL-1
6208BTK-1, 6208BTK-5, 6208BTK-01, 6208BTKL-1
6209BTK-1, 6209BTK-5, 6209BTK-01, 6209BTKL-1
6210BTK-1, 6210BTK-5, 6210BTK-01, 6210BTKL-1
6211 BTK-1, 6211BTK-5, 6211BTK-01
6212BTK-1, 6212BTK-5
6214BTK-1, 6214BTK-5

Sutureless unipolar myocardial screw-in model 5071

Initial date: 30 April 2018

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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