Anexă

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

# NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

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

- Attain Ability Plus Lead

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

Digitally signed by Kojevnikov Dmitrii
Date: 2023.09.27 15:23:04 EEST
Reason: MoldSign Signature
Location: Moldova

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 | |

*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:

- Attain Ability Plus Lead

**Sunt autentice și corespund realității.**

*Numele, prenumele şi funcţia* *Semnătura* _____

Kojevnikov Dmitrii, director

*Data _29/09/2023__*

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

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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 | Document Title: DoC-4296 | Document Number: BL0021461 |
|---|---|---|
| **EC DECLARATION OF CONFORMITY** | Attain Ability Plus Lead, Model 4296 | |

| Revision/History description | Revision level | Impl. Date |
|---|---|---|
| Initial Release Attain Ability Plus, Model 4296 | 1.0 in Regulatory documentum, version 2.0 in TDS EFS | 28-Jan-2010 |
| Update to comply with new AIMD form | 3.0 in TDS EFS | 24-Sep-2010 |
| Updated for CE Mark Renewal | 4.0 | 29-Jun-2011 |
| Update to reflect new Quality System Certificate number. Update to standards table. | 5.0 | 25-Apr-2012 |
| Updated to add new quality system certificate number due to quality system cert renewal; update to latest revision of DoC template | 6.0 | 19-Nov-2012 |
| Update ISO 14971:2012 | 7.0 | 22-May-2013 |
| New Revision to obtain signature due to recent renewal by DEKRA. No certificate number changed during renewal, thus no update to EC Certificate number. GMDN Description updated from “Pacing lead, implantable, endocardial” to “Endocardial pacing lead”. New version of certificate 2007841TE17 becomes effective January 1, 2016. | 8.0 | 05 October 2015 |
| Update document title to show lead models.<br>Update compliance reference notes, Attachment 1, for EN ISO 10993-1, EN ISO 14971, and EN 62366 for clarity.<br>Update EN 1041 to show the A1:2013 standard update<br>Update ISO 5841-3: 2000/AC:2003 to 5841-3:2013 | 9.0 | 29 April 2016 |
| Update standard from EN ISO 11135-1:2007 to EN ISO 11135:2014 and from EN ISO 11607-1:2009 to EN ISO 11607-1:2009+A1:2014 | 10.0 | 07-Oct-2016 |
| Updated to latest revision of DoC template.<br>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.<br>Updated GMDN Code and Description from 35223 (Endocardial pacing lead) to 60190 (Coronary venous pacing lead). | 11.0 | 17-Oct-2017 |
| Correction to GMDN Code number from 60190 to 60910. | 12.0 | 18-Octt-2017 |
| Updated EN 62366:2008 to EN 62366-1:2015 | 13.0 | 11-Apr-2018 |
| Updated to reflect MDT30106734 rev 4.0 Standards Changes:<br>1. From EN 980:2008 to EN ISO 15223-1:2016<br>2. From EN 1041:2008 + A1: 2013 to EN 1041:2008/A1:2013<br>3. From EN 45502-1:1997 to EN 45502-1:2015 | 14.0 | 26-Jun-2018 |
| Updated approver to Jeff Chaput<br>Updated from EN ISO 10993-1:2009/AC:2010 to ISO 10993-1:2018 | 15.0 | 03-Dec-2019 |
| Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020 | 16.0 | 20-Feb-2020 |
| Added Amendment 1:2019 to EN ISO 11135:2014, updated title<br>Updated to match Agile MAP revision numbering convention<br>Added referral to change record for signatures and approval date | A | 12-Oct-2020 |
| Updated EC Quality System Certificate number | B | 18-May-2021 |
| Updated EN ISO 14971 revision from 2012 to 2019<br>Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019<br>Added standards ISO 14708-1 and ISO 14708-2<br>Updated ISO 10993-1:2018 to EN ISO 10993-1:2020 | C | 07-Sep-2021 |
| Replace EN 1041:2008 + A1:2013 with EN ISO 20417:2021<br>Updated EN ISO 15223-1 from 2016 to 2021 | D | 16-Mar-2023 |

| | | |
|---|---|---|
| Updated EN ISO 14971 from 2019 to 2019+A11:2021<br>Updated Engineering Manager to Luke Ranta<br>Updated Document template to latest revision AB | | |
| This revision is to update the AIMD Declaration of Conformity to include requirements of amended Regulation (EU) 2023/607.<br><br>Updated implementation date of last revision. | E | 28-Apr-2023 |
| Document revision E was inadvertently updated in error. Language related to the MDR extension is being removed to correct the error.<br><br>Updated implementation date of last revision. | F | Upon Approval |

Medtronic

# EC Declaration of Conformity

| | |
|---|---|
| Manufacturer: | Medtronic Inc.<br>710 Medtronic Parkway<br>Minneapolis MN 55432 USA |
| EC Representative: | Medtronic B.V.<br>Earl Bakkenstraat 10<br>6422 PJ Heerlen<br>The Netherlands |
| Description of device concerned:<br>Model number:<br>Variants: | Attain Ability Plus Lead<br>4296<br>4296-78, 4296-88 |
| GMDN Code and Description | 60910, Coronary venous pacing lead |
| Classification, rule | AIMD |
| Conformity Assessment Route: | Annex 3 with Annex 5 |
| EC Certificate number: | 2007841TE17 |
| EC Quality System Certificate: | I2 039709 1117 |
| Name & Address of Notified Body: | TÜV SÜD Product Service GmbH<br>Ridlerstrasse 65<br>80339 Munich<br>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/EEC[1] which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Validity DoC from date: ***Refer to document approval date in the change record*** Place: Minneapolis Date: ***Refer to document approval date in the change record***

Name: Luke Ranta
Title: Engineering Manager

Signature: ***Refer to change record for electronic signature***
*Available upon request: Non-electronic Date and Signature*

[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 | Active Implantable Medical Devices - Part 1: General Requirements for Safety, Marking and 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 – Second edition |
| EN ISO 14971 | 2019 +A11:2021 | Medical devices – Application of risk management to medical devices |
| 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 | 2019 | Sterilization of health care products – Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices |
| EN 556-1: 2001/AC:2006 | 2006 | Sterilization of medical devices - Requirements for medical devices to be labeled “Sterile”- Part 1: Requirements for terminally sterilized medical devices |
| EN ISO 11607-1 | 2020 | Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems |
| 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: Tests for Ethylene Oxide Sterilization Residuals |
| ISO 5841-3 | 2013 | Cardiac Pacemakers – Pacemaker leads - Connector Assembly (IS-1) for Implantable Pacemakers – Part 1: Safety and Design Requirements |
| EN 62366-1 | 2015 | Medical devices – Application of usability engineering to medical devices |

# Document
# Approval Report

Medtronic

**Report Generated By:** Lungu, Mihaela Luminita

**Report Create Date/Time:** 2023-09-26 08:37 GMT

| | |
|---|---|
| **Change Number:** | RCH00348106 |
| **Change Originator:** | Pierce, Nathan |

## Document/Part Information

| Number: | Lifecycle Phase: | Description: | Revision: | Effective Date/Time of Revision: | Type\|Category: | Document Owner: |
|---|---|---|---|---|---|---|
| BL0021461 | Released | DoC-4296 | F<br>RCH00348106 | 2023-05-15 14:00 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 | 2023-05-15 13:55 GMT | Ranta, Luke | Approve Change |
| Ranta, Luke | Quality Management | Approved | 2023-05-15 13:55 GMT | Ranta, Luke | Approve Change |
| Rivera, Kristen | Regulatory | Approved | 2023-05-11 21:35 GMT | Rivera, Kristen | Approve Change |

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
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


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

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

# EC TYPE-EXAMINATION CERTIFICATE

Number: 2007841TE17

**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 NE**
**Minneapolis MN 55432**
**United States Of America**

For the product / product category

**Left Ventricular Lead**

Documents, that form the basis of this certificate:

**Certification Notice 2007841CN, initially dated 1 January 2001**
**Addendum, initially dated 18 December 2009**

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: 1 January 2024
Issued for the first time: 18 December 2009
Reissued: 1 January 2019

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager



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: 2007841TE17 

# EC TYPE-EXAMINATION
## ACTIVE IMPLANTABLE MEDICAL DEVICES

Left Ventricular Lead

Issued to:

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

This certificate covers the following product(s):

Attain Ability™ Plus 4296
Attain Ability™ Plus MRI SureScan™ 4296

The products are designed in the facility:

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

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

Initial date: 18 December 2009

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager



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