Anexă

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 6 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:

- Implantable Cardioverter Defibrillator
- Implantable Cardioverter Defibrillator with Cardiac Resynchronization Therapy Defibrillator
- Application Software (External)

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 15:23:22 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:

- Implantable Cardioverter Defibrillator
- Implantable Cardioverter Defibrillator with Cardiac Resynchronization Therapy Defibrillator
- Application Software (External)

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

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):	G70 039709 1413 (Product) G12 039709 1393 (Quality)
Conformity Assessment Procedure:	Annex IX
Risk Class:	Class III
Classification Rule:	Refer to the Products Covered Table A below.
Intended Purpose:	Refer to the Products Covered Table B below.

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.

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

Place: Mounds View, MN

Name: Luke Ranta

Title: Sr. Engineering Manager Post-market Quality

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

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

Products Covered

Table A: Risk Class / Classification Rule

Model Number	Product Name	Basic UDI-DI	Classification	Rule	CND Code
DDBB2D1	Evera™ XT DR	0763000B00009958Y	III	8	J010502
DDBB2D4	Evera™ XT DR	0763000B00009958Y	III	8	J010502
DDBC3D1	Evera™ S DR	0763000B00009958Y	III	8	J010502
DDBC3D4	Evera™ S DR	0763000B00009958Y	III	8	J010502
DVBB2D1	Evera™ XT VR	0763000B00009958Y	III	8	J010501
DVBB2D4	Evera™ XT VR	0763000B00009958Y	III	8	J010501
DVBC3D1	Evera™ S VR	0763000B00009958Y	III	8	J010501
DVBC3D4	Evera™ S VR	0763000B00009958Y	III	8	J010501
DVAB2D1	Visia AF XT VR	0763000B00009958Y	III	8	J010501
DVAB2D4	Visia AF XT VR	0763000B00009958Y	III	8	J010501
DVAC3D1	Visia AF S VR	0763000B00009958Y	III	8	J010501
DVAC3D4	Visia AF S VR	0763000B00009958Y	III	8	J010501
DTBA2D1	Viva XT CRT-D	0763000B000099692	III	8	J010503
DTBA2D4	Viva™ XT CRT-D	0763000B000099692	III	8	J010503
DTBA2Q1	Viva™ CRT-D	0763000B000099692	III	8	J010503
DTBA2D1	Viva™ XT CRT-D	0763000B000099692	III	8	J010503
DTBA2QQ	Viva™ Quad XT CRT-D	0763000B000099692	III	8	J010503
DTBB2D1	Viva™ S CRT-D	0763000B000099692	III	8	J010503
DTBB2D4	Viva™ S CRT-D	0763000B000099692	III	8	J010503
DTBB2Q1	Viva™ CRT-D	0763000B000099692	III	8	J010503
DTBB2QQ	Viva™ Quad S CRT-D	0763000B000099692	III	8	J010503
DTBC2D1	Brava™ CRT-D	0763000B000099692	III	8	J010503
DTBC2D4	Brava™ CRT-D	0763000B000099692	III	8	J010503
DTBC2Q1	Brava™ Quad CRT-D	0763000B000099692	III	8	J010503
DTBC2QQ	Brava™ Quad CRT-D	0763000B000099692	III	8	J010503
DDMB2D1	Evera MRI XT DR SureScan ™	0763000B00009958Y	III	8	J010502
DDMB2D4	EVERA MRI XT DR SURESCAN™	0763000B00009958Y	III	8	J010502
DDMC3D1	Evera MRI S DR SureScan™	0763000B00009958Y	III	8	J010502
DDMC3D4	EVERA MRI S DR SURESCAN™	0763000B00009958Y	III	8	J010502
DVMB2D1	Evera MRI XT VR SureScan™	0763000B00009958Y	III	8	J010501
DVMB2D4	EVERA MRI XT VR SURESCAN™	0763000B00009958Y	III	8	J010501
DVMC3D1	EVERA MRI S VR SURESCAN™	0763000B00009958Y	III	8	J010501
DVMC3D4	EVERA MRI S VR SURESCAN™	0763000B00009958Y	III	8	J010501
DVFB2D1	Visia AF MRI XT VR SureScan™	0763000B00009958Y	III	8	J010501
DVFB2D4	Visia AF MRI XT VR SureScan™	0763000B00009958Y	III	8	J010501

DVFC3D1	Visia AF MRI S VR SureScan™	0763000B00009958Y	III	8	J010501
DVFC3D4	Visia AF MRI S VR SureScan™	0763000B00009958Y	III	8	J010501
DDMD3D1	PRIMO MRI DR SURESCAN™	0763000B00009958Y	III	8	J010502
DDMD3D4	PRIMO MRI DR SURESCAN™	0763000B00009958Y	III	8	J010502
DDME3D1	MIRRO MRI DR™ SURESCAN™	0763000B00009958Y	III	8	J010502
DDME3D4	MIRRO MRI DR SURESCAN™	0763000B00009958Y	III	8	J010502
DVMD3D1	PRIMO MRI VR SURESCAN™	0763000B00009958Y	III	8	J010501
DVMD3D4	PRIMO MRI VR SURESCAN™	0763000B00009958Y	III	8	J010501
DVME3D1	MIRRO MRI VR SURESCAN™	0763000B00009958Y	III	8	J010501
DVME3D4	MIRRO MRI VR SURESCAN™	0763000B00009958Y	III	8	J010501
SW016	Application Software (external)	0763000B00010006M	III	9	J019002
SW033	Application Software (external)	0763000B00010006M	III	9	J019002
SW035	Application Software (external)	0763000B00010006M	III	9	J019002

Table B: Intended Purpose

Table B: Intended Purpose

Article/ Model Number	Article/Model Name	Intended Purpose	Brief Product Description
DDBB2D1	Evera XT DR	The Evera and Visia AF Implantable cardioverter defibrillators are intended for long-term use to monitor and regulate the patient's heartrate. The devices sense intrinsic electrical activity through lead electrodes placed in direct contact with the heart. These devices analyze the sensed activity based on programmed detection parameters. The primary function of the device is to deliver, antitachycardia pacing therapies, cardioversion, and defibrillation therapies to treat life threatening ventricular tachyarrhythmias. The devices also treat bradyarrythmias with pacing therapies. The device software is intended to work with an external instrument. It provides diagnostic information which enables the clinician to choose from an array of available therapies and adjust them according to patient needs.	Implantable Cardioverter Defibrillator
DDBB2D4	Evera XT DR		
DDBC3D1	Evera S DR		
DDBC3D4	Evera S DR		
DVBB2D1	Evera XT VR		
DVBB2D4	Evera XT VR		
DVBC3D1	Evera S VR		
DVBC3D4	Evera S VR		
DVAB2D1	Visia AF XT VR		
DVAB2D4	Visia AF XT VR		
DVAC3D1	Visia AF S VR		
DVAC3D4	Visia AF S VR		
DTBA2D1	Viva XT CRT-D	The Viva and Brava Cardiac resynchronization therapy defibrillators are intended for long-term use to monitor and regulate the patient's heart rate. The devices sense intrinsic electrical activity through lead electrodes, analyze heart rhythms based on programmed detection parameters. The devices deliver pacing therapies to treat bradyarrhythmias and heart failure, and provide antitachycardia pacing, cardioversion and defibrillation therapies to treat life-threatening ventricular tachyarrhythmias. The device software is intended to work with an external instrument. It provides diagnostic information which enables the	Implantable Cardioverter Defibrillator with Cardiac Resynchronization Therapy Defibrillator
DTBA2D4	Viva XT CRT-D		
DTBA2Q1	Viva CRT-D		
DTBA2D1	Viva XT CRT-D		
DTBA2QQ	Viva Quad XT CRT-D		
DTBB2D1	Viva S CRT-D		

Article/ Model Number	Article/Model Name	Intended Purpose	Brief Product Description
DTBB2D4	Viva S CRT-D	clinician to choose from an array of available therapies and adjust them according to patient needs.	
DTBB2Q1	Viva CRT-D		
DTBB2QQ	Viva Quad S CRT-D		
DTBC2D1	Brava CRT-D		
DTBC2D4	Brava CRT-D		
DTBC2Q1	Brava Quad CRT-D		
DTBC2QQ	Brava Quad CRT-D		
DDMB2D1	Evera MRI XT DR SureScan	The Evera MRI and Visia AF MRI Implantable cardioverter defibrillators are intended for long-term use to monitor and regulate the patient's heartrate. The devices sense intrinsic electrical activity through lead electrodes placed in direct contact with the heart. These devices analyze the sensed activity based on programmed detection parameters. The primary function of the device is to deliver antitachycardia pacing therapies, cardioversion, and defibrillation to treat life threatening ventricular tachyarrhythmias. The devices also treat bradyarrhythmias with pacing therapies. The device software is intended to work with an external instrument. It provides diagnostic information which enables the clinician to choose from an array of available therapies and adjust them according to patient needs.	Implantable Cardioverter Defibrillator
DDMB2D4	EVERA MRI XT DR SURESCAN		
DDMC3D1	Evera MRI S DR SureScan		
DDMC3D4	EVERA MRI S DR SURESCAN		
DVMB2D1	Evera MRI XT VR SureScan		Implantable Cardioverter Defibrillator
DVMB2D4	EVERA MRI XT VR SURESCAN		
DVMC3D1	EVERA MRI S VR SURESCAN		
DVMC3D4	EVERA MRI S VR SURESCAN		
DVFB2D1	Visia AF MRI XT VR SureScan		
DVFB2D4	Visia AF MRI XT VR SureScan		
DVFC3D1	Visia AF MRI S VR SureScan		
DVFC3D4	Visia AF MRI S VR SureScan		
DDMD3D1	PRIMO MRI DR SURESCAN	The Mirro MRI/Primo MRI Implantable cardioverter defibrillators are intended for long-term use to monitor and regulate the patient's heartrate. The devices sense intrinsic electrical activity through lead electrodes placed in direct contact with the heart. These devices analyze the sensed activity based on programmed detection parameters. The primary function of the device is to deliver antitachycardia pacing therapies, , cardioversion, and defibrillation to treat life threatening ventricular tachyarrhythmias. The devices also treat bradyarrhythmias with pacing therapies. The device software is intended to work with an external instrument. It provides diagnostic information which enables the clinician to choose from an array of available therapies and adjust them according to patient needs.	
DDMD3D4	PRIMO MRI DR SURESCAN		
DDME3D1	MIRRO MRI DR SURESCAN		
DDME3D4	MIRRO MRI DR SURESCAN		
DVMD3D1	PRIMO MRI VR SURESCAN		
DVMD3D4	PRIMO MRI VR SURESCAN		
DVME3D1	MIRRO MRI VR SURESCAN		
DVME3D4	MIRRO MRI VR SURESCAN		

Article/Model Name	Article/ Model Number	Intended Purpose	
Programmer Software Application-for Viva/Brava CRT-D and Evera ICD devices Model SW016	SW016	The application software (external) SW016 is intended to work with an external instrument. It provides diagnostic information which enables the clinician to choose from an array of available therapies and adjust them according to patient needs.	Application Software (External)
Programmer Software Application forEvera MRI and Primo MRI /Mirro MRI Model SW033	SW033	The application software (external) SW033 is intended to work with an external instrument. It provides diagnostic information which enables the clinician to choose from an array of available therapies and adjust them according to patient needs.	Application Software (External)
Programmer Software Application for Visia AF ICD and Visia AF MRI Model SW035	SW035	The application software (external) SW035 is intended to work with an external instrument. It provides diagnostic information which enables the clinician to choose from an array of available therapies and adjust them according to patient needs.	Application Software (External)

Common Specification(s)

Not Applicable.

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title

Revision History

Revision	Date Effective	Description of Change
A	Upon Release	Initial Release
B	Upon Release	Added Conformity Assessment document numbers
C	Upon Release	Corrected Manufacturer SRN
D	Upon Release	Updated Intended Purposes to align with IFU

Document
Approval Report

Medtronic

Report Generated By: Lungu, Mihaela Luminita

Report Create Date/Time: 2023-05-11 14:01 GMT

Change Number:	RCH00328804
Change Originator:	Pierce, Nathan

Document/Part Information

Number:	Lifecycle Phase:	Description:	Revision:	Effective Date/Time of Revision:	Type|Category:	Document Owner:
D00538069	Released	Blackwell EU MDR Declaration of Conformity	D RCH00328804	2023-03-06 13:12 GMT	Regulatory|Declaration of Conformity|Europe - Medical Device Regulation	Pierce, Nathan

Approvals

Approver Name:	Approver Job Function:	Action:	Approval Date/Time:	Signoff:	Workflow Status:
Pierce, Nathan	Document Owner	Approved	2023-03-02 17:36 GMT	Pierce, Nathan	Approve Change
Pierce, Nathan	Change Owner	Approved	2023-03-02 17:36 GMT	Pierce, Nathan	Approve Change
Pierce, Nathan	Engineer - Reliability	Approved	2023-03-02 17:36 GMT	Pierce, Nathan	Approve Change
Ranta, Luke	Reliability Engineering Management	Approved	2023-03-02 19:37 GMT	Ranta, Luke	Approve Change
Heimerdinger, Cathryn	Regulatory	Approved	2023-03-02 21:34 GMT	Heimerdinger, Cathryn	Approve Change

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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 1413 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 1413 Rev. 00

Report No.:	713233169, 713228520
Valid from:	2022-08-29
Valid until:	2027-08-28

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-08-29

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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 1413 Rev. 00

Classification:	III
Device Group:	J019002 - IMPLANTABLE CARDIAC DEVICES PROGRAMMERS AND ACCESSORIES
Basic UDI-DI:	0763000B00010006M
Intended Purpose:	The Application Software (external) is intended to work with an external instrument. It provides diagnostic information which enables the clinician to choose from an array of available therapies and adjust them according to patient needs.
Device(s):	Application Software (external) Model No.: SW016, SW035, SW033

Classification:	III
Device Group:	J010501 - IMPLANTABLE SINGLE CHAMBER DEFIBRILLATORS
Basic UDI-DI:	0763000B00009958Y
Intended Purpose:	Implantable cardioverter defibrillators (ICDs) are intended for long-term use to monitor and regulate the patient's heart rate. The devices sense intrinsic electrical activity through lead electrodes placed in direct contact with the heart. These devices analyze the sensed activity based on programmed detection parameters. The primary function of the device is to deliver antitachycardia pacing therapies, cardioversion, and defibrillation to treat life threatening ventricular tachyarrhythmias. The devices also treat bradyarrhythmias with pacing therapies.
Device(s):	Evera™ XT VR DVBB2D1 Evera™ XT VR DVBB2D4 Evera™ S VR DVBC3D1 Evera™ S VR DVBC3D4 Visia AF™ XT VR DVAB2D1 Visia AF™ XT VR DVAB2D4 Visia AF™ S VR DVAC3D1 Visia AF™ S VR DVAC3D4 Evera MRI™ XT VR SureScan™ DVMB2D1 Evera MRI™ XT VR SureScan™ DVMB2D4 Evera MRI™ S VR SureScan™ DVMC3D1 Evera MRI™ S VR SureScan™ DVMC3D4 Visia AF MRI™ XT VR SureScan™ DVFB2D1 Visia AF MRI™ XT VR SureScan™ DVFB2D4 Visia AF MRI™ S VR SureScan™ DVFC3D1 Visia AF MRI™ S VR SureScan™ DVFC3D4

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(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1413 Rev. 00

Classification:	III
Device Group:	J010501 - IMPLANTABLE SINGLE CHAMBER DEFIBRILLATORS
Basic UDI-DI:	0763000B00009958Y
Intended Purpose:	Implantable cardioverter defibrillators (ICDs) are intended for long-term use to monitor and regulate the patient's heart rate. The devices sense intrinsic electrical activity through lead electrodes placed in direct contact with the heart. These devices analyze the sensed activity based on programmed detection parameters. The primary function of the device is to deliver antitachycardia pacing therapies, cardioversion, and defibrillation to treat life threatening ventricular tachyarrhythmias. The devices also treat bradyarrhythmias with pacing therapies.
Device(s):	Primo MRI™ VR SureScan™ DVMD3D1 Primo MRI™ VR SureScan™DVMD3D4 Mirro MRI™ VR SureScan™ DVME3D1 Mirro MRI™ VR SureScan™ DVME3D4

Classification:	III
Device Group:	J010502 - IMPLANTABLE DUAL CHAMBER DEFIBRILLATORS
Basic UDI-DI:	0763000B00009958Y
Intended Purpose:	Implantable cardioverter defibrillators (ICDs) are intended for long-term use to monitor and regulate the patient's heart rate. The devices sense intrinsic electrical activity through lead electrodes placed in direct contact with the heart. These devices analyze the sensed activity based on programmed detection parameters. The primary function of the device is to deliver antitachycardia pacing therapies, cardioversion, and defibrillation to treat life threatening ventricular tachyarrhythmias. The devices also treat bradyarrhythmias with pacing therapies.
Device(s):	Evera™ XT DR DDBB2D1 Evera ™ XT DR DDBB2D4 Evera ™ S DR DDBC3D1 Evera ™ S DR DDBC3D4 Evera MRI™ XT DR SureScan™ DDMB2D1 Evera MRI™ XT DR SureScan™ DDMB2D4 Evera MRI™ S DR SureScan™ DDMC3D1 Evera MRI™ S DR SureScan™ DDMC3D4 Primo MRI™ DR SureScan™ DDMD3D1 Primo MRI™ DR SureScan™ DDMD3D4 Mirro MRI™ DR SureScan™ DDME3D1 Mirro MRI™ DR SureScan™ DDME3D4

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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 1413 Rev. 00

Classification:	III
Device Group:	J010503 - IMPLANTABLE TRIPLE CHAMBER DEFIBRILLATORS
Basic UDI-DI:	0763000B000099692
Intended Purpose:	Cardiac resynchronization therapy defibrillators are implantable devices intended for long-term use to monitor and regulate the patient's heart rate. The devices sense intrinsic electrical activity through lead electrodes and analyze heart rhythms based on programmed detection parameters. The devices deliver pacing therapies to treat bradyarrhythmias and heart failure, and provide antitachycardia pacing, cardioversion and defibrillation therapies to treat life-threatening ventricular tachyarrhythmias.
Device(s):	Viva™ XT CRT-D DTBA2D1 Viva™ XT CRT-D DTBA2D4 Viva™ QUAD XT CRT-D DTBA2Q1 Viva™ QUAD XT CRT-D DTBA2QQ Viva™ S CRT-D DTBB2D1 Viva™ S CRT-D DTBB2D4 Viva™ QUAD S CRT-D DTBB2Q1 Viva™ QUAD S CRT-D DTBB2QQ Brava™ CRT-D DTBC2D1 Brava™ CRT-D DTBC2D4 Brava™ QUAD CRT-D DTBC2Q1 Brava™ QUAD CRT-D DTBC2QQ
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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