Anexă

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 3 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:

- Cardiac resynchronization therapy implantable pacemaker
- Cardiac pulse generator software

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 15:23:29 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:

- Cardiac resynchronization therapy implantable pacemaker
- Cardiac pulse generator software

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

Medtronic	Document Title: **EC DoC- Percepta/Serena/Solara Family of Devices**	Document Number: **DSN024248** DHF Project Name: **CRT-P Quad** Deliverable: **Declaration of Conformity**
EC DECLARATION OF CONFORMITY	**Percepta/Serena/Solara CRT-P MRI SureScan devices**	

Revision/History description	Revision level	Impl. Date
Initial Release for Percepta™/Percepta™ Quad, Serena™/Serena™ Quad, and Solara™/Solara™ Quad CRT-P MRI SureScan™ devices (Percepta/Serena/Solara family of devices) and Application Software (external) Model SW040	2.0	13-Feb-2017
Updated to template Rev AA Added "DHF Project Name: CRT-P Quad" to Header Updated EC Quality System certificate I1 17 11 39709 01115 (effective November 21, 2017) replaces I1 12 11 39709 842 Updated 'Validity DoC from date: Refer to cover page' to 21-November-2017 in line with new certificate effective date Updated approver name and title Updated Standard Titles to EN 1041 and EN ISO 10993-1 Updated to correct prefix and title of EN ISO 11135 Updated to correct revision of EN ISO 11607-1 Updated to correct omitted Part Number in EN 62366-1 to agree with revision year Updated Standards EN 60601-1, EN 60601-1-6, EN 62304	3.0	20-Oct-2017
Updated to reflect new EC Quality System certificate number. New certificate (I1 18 03 39709 01185) replaces certificate I1 13 02 39709 855 and becomes effective May 2, 2018. As such, validity date updated to reflect May 2, 2018.	4.0	20-Apr-2018
Updated to reflect new EC certificate number. New certificate (I7 18 04 39709 01191) replaces certificate I7 15 07 39709 987 and is effective as of April 30, 2018.	5.0	03-May-2018
Updated to reflect new EC Certificate number. New certificate (I7 039709 1199) replaces certificate I7 18 04 39709 01191 and becomes effective September 30, 2018. As such, validity date updated to reflect September 30, 2018.	6.0	09-Sep-2018
Updated to add Device App for SmartSync and updating Standards	7.0	18-Jan-2019
-Correct standard "ISO 15223-1" to "EN ISO 15223-1".Update "EN 60601-1" standard date of issue to "2006/A12:2014". -Application D00U004 is approved on June 17, 2019, updated to reflect effective date of new certificate. -Updated approver name and title on certificate	A	30-May-2019
Updated from EN ISO 10993-1:2009/AC:2010 to ISO 10993-1:2018 Changed "cover page" to "change record" to match Agile approval process	B	02-Dec-2019
Updated EN ISO 11607-1:2009+A1:2014 to EN ISO 11607-1:2020 Added Amendment 1 :2018 to EN ISO 11135:2014	C	01-Apr-2020
Updated to reflect compliance to EN 82304-1:2017 NOTE: EN 82304-1: 2017 is identical to IEC 82304-1:2016.	D	13-Apr-2020
Updated Quality System Certificate Number. New certificate (I1 039709 1115) replaces existing certificate (I1 17 11 39709 01115) and becomes effective 01 June 2020.	E	02-Jun-2020
Updated EN ISO 11135:2014+A1:2018 to EN ISO 11135:2014+A1:2019	F	12-Oct-2020
Updated EC Quality System Certificate Number. New certificate (I1 039709 1185) replaces existing certificate and becomes effective 23 April 2021.	G	18-May-2021
Updated EN ISO 14971 revision from 2012 to 2019 Updated ISO 10993-7 revision from 2008/AC:2009 to 2008 + Amd1:2019 Updated EN ISO 10993-1 revision from 2018 to 2020	H	04-Oct-2021

Added standards ISO 14708-1, ISO 14708-2 Clause 6, and ISO 14708-6		
Added Standard ISO 27186:2020 Updated EN ISO 14971:2019 to EN ISO 14971:2019 +A11:2021 Updated Document Owner from Jeffrey Chaput to Luke Ranta	J	06-Oct-2022
Update the Declaration of Conformity to include requirements of amended Regulation (EU) 2023/607 Updated to current revision of document template. Updated implementation date of last revision. Updated approver name and title.	K	Upon Approval

Medtronic

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 :	Percepta™, Serena™, Solara™ implantable cardiac pacemakers with cardiac resynchronization therapy (CRT-P) and SureScan Technology and Programmer Application Software (External)
Model number:	See Attachment 2
Variants:	None
GMDN Code and Description	47263, Cardiac resynchronization therapy implantable pacemaker 47206, Cardiac pulse generator software
Classification, rule	AIMD
Conformity Assessment Route:	Annex 2.3 combined with 2.4
EC Certificate number:	I7 039709 1199 (for device models and SW040 & D00U004, external application software)
EC Quality System Certificate:	I1 039709 1185 (for device models) I1 039709 1115 (for application software)
Name & Address of Notified Body:	TUV SÜD PS 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/EEC[1] 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 document approval date in the change record. Place: Minneapolis Date: ***Refer to 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 Percepta/Serena/Solara model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN ISO 15223-1	2016	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements Second Edition
EN 1041	2008 + Amd1: 2013	Information supplied by the manufacturer of medical devices
ISO 5841-3	2013	Implants for surgery - Cardiac pacemakers - Part 3: Low-profile connectors (IS-1) for implantable pacemakers
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
EN ISO 11135	2014 + A1:2019	Sterilization of health-care products – Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for 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 14971	2019 + A11:2021	Medical devices - Application of risk management to medical devices
EN 45502-1	2015	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 Clause 6	2003	Implants for surgery - Active implantable medical devices -- Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (includes cardiac pacemakers) – Second edition
ISO 14708-2 Clause 6	2019	Implants for surgery - Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (includes cardiac pacemakers) – Second edition
EN 45502-2-2	2008/AC: 2009	Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)
ISO 14708-6	2019	Implants for surgery - Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators) – Second edition
EN 62304	2006 + A1:2015	Medical device software. Software life-cycle processes
EN 62366-1	2015	Medical devices – Part 1: Application of usability engineering to medical devices
EN 82304-1: 2017	2017	Health software – Part 1: General requirements for product safety NOTE: EN 82304-1: 2017 is identical to IEC 82304-1:2016.
ISO 27186	2020	Active implantable medical devices – Four-pole connector system for implantable cardiac rhythm management devices – Dimensional and test requirements

The below mentioned Standard(s) apply to the external software (SW040 & D00U004) included under the scope of this DoC.

Number	Date of issue	Title
EN ISO 15223-1	2016	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements Second Edition
EN 1041	2008 + Amd1:2013	Information supplied by the manufacturer of medical devices
EN ISO 14971	2019 + A11:2021	Medical devices - Application of risk management to medical devices
EN 45502-1	2015	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 60601-1 Clause 14	2006 + A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-6	2010 + A1:2015	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
EN 62304	2006 + A1:2015	Medical device software. Software life-cycle processes
EN 62366-1	2015	Medical devices – Part 1: Application of usability engineering to medical devices
EN 82304-1: 2017	2017	Health software – Part 1: General requirements for product safety NOTE: EN 82304-1: 2017 is identical to IEC 82304-1:2016.

Attachment 2: Model Listing

The following models are included under the scope of this DoC:

Model Name	Model Number(s)	Variant(s)
Percepta™ Quad CRT-P MRI SureScan™	W4TR04	Not applicable
Percepta™ CRT-P MRI SureScan™	W1TR04	Not applicable
Serena™ Quad CRT-P MRI SureScan™	W4TR05	Not applicable
Serena™ CRT-P MRI SureScan™	W1TR05	Not applicable
Solara™ Quad CRT-P MRI SureScan™	W4TR06	Not applicable
Solara™ CRT-P MRI SureScan™	W1TR06	Not applicable
External application software (2090, Encore) for Percepta/Serena/Solara Family of Devices	SW040	Not applicable
External application software (SmartSync) for Percepta/Serena/Solara Family of Devices	D00U004	Not applicable

Document
Approval Report

Medtronic

Report Generated By: Lungu, Mihaela Luminita

Report Create Date/Time: 2023-09-26 08:18 GMT

Change Number:	RCH00343800
Change Originator:	Pierce, Nathan

Document/Part Information

Number:	Lifecycle Phase:	Description:	Revision:	Effective Date/Time of Revision:	Type|Category:	Document Owner:
DSN024248	Released	EC DoC- Percepta/Serena/Solara Family of Devices	K RCH00343800	2023-04-28 18:55 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:
Nelson, Makehba	Regulatory	Approved	2023-04-28 17:01 GMT	Nelson, Makehba	Approve Change
Ranta, Luke	Quality Management	Approved	2023-04-28 16:33 GMT	Ranta, Luke	Approve Change
Ranta, Luke	Document Owner	Approved	2023-04-28 16:33 GMT	Ranta, Luke	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

Full Quality Assurance System
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 excluding (4)
(Other devices than custom made or intended for clinical investigation)

No. I1 039709 1185 Rev. 01

Manufacturer:

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

Product:

Brady IPGs
Tachy IPGs/ICDs
Implantable Monitoring and Recording Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with AIMDD Annex 2. 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 2 (4) 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:I1 039709 1185 Rev. 01

Report no.: 713194270

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

TÜV®

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

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 02

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

Product: **Implantable Pacemaker Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 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:I7 039709 1199 Rev. 02

Report no.: 713195947

Valid from: 2021-04-16
Valid until: 2023-09-29

Date, 2021-03-22

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

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

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 02

Model(s): see below

Implantable Pacemaker System: SureScan™

Product: **Implantable Pacemaker**

Test Report No.: 71350692

Model:	**Model no.:**	**Variant:**
Advisa DR MRI™ SureScan™	A3DR01	MR Conditional

Test Report No.: 71366167

Model:	**Model no.:**	**Variant:**
Ensura DR MRI™ SureScan™	EN1DR01	MR Conditional

Test Report No.: 713039269

Model:	**Model no.:**	**Variant:**
Advisa SR MRI™ SureScan™	A3SR01	MR Conditional
Ensura SR MRI™ SureScan™	EN1SR01	MR Conditional

Product: **Application Software (external)**

Test Report No.: 71338901

Model:	**Model no.:**	**for Programmer:**	**Implants to be programmed:**
Application Software (external)	SW005	2090	EnRhythm EMDR01

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

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

TÜV®

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

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 02

Test Report No.:	71351141		
Model:	**Model no.:**	**for Programmer:**	**Implants to be programmed:**
Application Software (external)	9995	2090 29901	Advisa A3DR01
Test Report No.:	71368678		
Model:	**Model no.:**	**for Programmer:**	**Implants to be programmed:**
Application Software (external)	9995	2090 29901	Ensura EN1DR01
Test Report No.:	713006624		
Model:	**Model no.:**	**for Programmer:**	**Implants to be programmed:**
Application Software (external)	SW018	2090	RevoMRI (US only)
Test Report No.:	713039234		
Model:	**Model no.:**	**for Programmer:**	**Implants to be programmed:**
Application Software (external)	9995	2090 29901	Advisa SR MRI SureScan A3SR01 Ensura SR MRI SureScan EN1SR01

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

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

TÜV®

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

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 02

Product: **Implantable Pacemakers**

Test Report No.: 713095776

Model:	**Model no.:**	**Variant:**
Percepta™ Quad CRT-P MRI SureScan™	W4TR04	MR Conditional
Serena™ Quad CRT-P MRI SureScan™	W4TR05	MR Conditional
Solara™ Quad CRT-P MRI SureScan™	W4TR06	MR Conditional
Percepta™ CRT-P MRI SureScan™	W1TR04	MR Conditional
Serena™ CRT-P MRI SureScan™	W1TR05	MR Conditional
Solara™ CRT-P MRI SureScan™	W1TR06	MR Conditional

Product: **Application Software (external)**

Test Report No.: 713095780

Model:	**Model no.:**	**for Programmer:**	**Implants to be programmed:**
Application Software (external)	SW040	2090 29901	Percepta™ Quad CRT-P MRI SureScan™ W4TR04 Serena™ Quad CRT-P MRI SureScan™ W4TR05 Solara™ Quad CRT-P MRI SureScan™ W4TR06 Percepta™ CRT-P MRI SureScan™ W1TR04 Serena™ CRT-P MRI SureScan™ W1TR05 Solara™ CRT-P MRI SureScan™ W1TR06

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

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

TÜV®

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

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 02

Product: **Application Software**

Test Report No.: 713095771

Model:	**Model no.:**	**for Programmer:**	**Implants to be programmed:**
Azure / Astra Application Software	SW030	2090 29901	Azure™ XT DR MRI SureScan™ W2DR01 Azure™ S DR MRI SureScan™ W3DR01 Azure™ XT SR MRI SureScan™ W2SR01 Azure™ S SR MRI SureScan™ W3SR01 Astra™ XT DR MRI SureScan™ X2DR01 Astra™ S DR MRI SureScan™ X3DR01 Astra™ XT SR MRI SureScan™ X2SR01 Astra™ S SR MRI SureScan™ X3SR01

Product: **Implantable Pacemakers**

Test Report No.: 713095773

Model: **Model no.:** **Variant:**

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

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 02

Azure™ XT DR MRI SureScan™	W2DR01	MR Conditional
Azure™ S DR MRI SureScan™	W3DR01	MR Conditional
Azure™ XT SR MRI SureScan™	W2SR01	MR Conditional
Azure™ S SR MRI SureScan™	W3SR01	MR Conditional
Astra™ XT DR MRI SureScan™	X2DR01	MR Conditional
Astra™ S DR MRI SureScan™	X3DR01	MR Conditional
Astra™ XT SR MRI SureScan™	X2SR01	MR Conditional
Astra™ S SR MRI SureScan™	X3SR01	MR Conditional

Product: **Implantable Pacemakers**

Test Report No.: 713105247

Model:	**Model no.:**	**Variant:**
Attesta™ DR MRI SureScan™	ATDR01	MR Conditional
Attesta™ L DR MRI SureScan™	ATDRL1	MR Conditional
Attesta™ S DR MRI SureScan™	ATDRS1	MR Conditional
Attesta™ SR MRI SureScan™	ATSR01	MR Conditional
Sphera™ DR MRI SureScan™	SPDR01	MR Conditional
Sphera™ L DR MRI SureScan™	SPDRL1	MR Conditional
Sphera™ SR MRI SureScan™	SPSR01	MR Conditional

Product: **Application Software (external)**

Test Report No.: 713105248

Model:	**Model no.:**	**for Programmer:**	**Implants to be programmed:**
Application Software	SW043	2090 29901	Attesta™ DR MRI SureScan™ ATDR01 Attesta™ L DR MRI SureScan™

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

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

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 039709 1199 Rev. 02

ATDRL1
Attesta™ S DR MRI SureScan™
ATDRS1
Attesta™ SR MRI SureScan™
ATSR01
Sphera™ DR MRI SureScan™
SPDR01
Sphera™ L DR MRI SureScan™
SPDRL1
Sphera™ SR MRI SureScan™
SPSR01

Product:	**Application Software (external)**	
Test Report No.:	713127914	
Model:	**Model no.:**	**External Device Manager System supported:**
CareLink SmartSync Azure Astra App	D00U003	CareLink SmartSync Device Manager Patient Connector 24967
Product:	**Application Software (external)**	
Test Report No.:	713147242	
Model:	**Model no.:**	**External Device Manager System supported:**
CareLink SmartSync Percepta Serena Solara App	D00U004	CareLink SmartSync Device Manager Patient Connector 24967

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

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

TÜV®