

Către
Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr.5 din 12.07.2023

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

- Cadence™ Catheter-balloon inflator, Single-use

Se anexează următoarele acte:

Declarație pe proprie răspundere

CE certificate

Declarație de conformitate

Scrisoare de imputernicire

Data 12/07/2023

Semnătura _____

Tabelul de recepționare a notificării

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

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

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

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

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

- Cadence™ Catheter-balloon inflator, Single-use

Sunt autentice și corespund realității.

Numele, prenumele și funcția

Kojevnikov Dmitrii, director

Semnătura _____

Data 12/07/2023

TO WHOM IT MAY CONCERN

Date: 29.05.2023

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

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

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

Medtronic META FZ-LLC

M. N. ALANI



Name: Muzahim Al Ani

Title: Authorized Signatory

APPENDIX 1

Medtronic Manufacturing Facilities/Legal Manufacturers:

1. Medtronic, Inc., 710 Medtronic Parkway, Minneapolis MN 55432, USA
2. Medtronic, Inc., 7000 Central Avenue N.E., Minneapolis MN 55432, USA
3. Medtronic, Inc., 3800 Annapolis Lane, Minneapolis MN 55447, USA
4. Medtronic, Inc., 8200 Coral Sea Street N.E., Mounds View, MN 5512, USA
5. Medtronic Europe Sàrl, Route du Molliau 31, Case Postale, CH-1131 Tolochenaz, Switzerland
6. Medtronic Bakken Research Center B.V., Endepolsdomein 5, 6229 GW Maastricht, The Netherlands
7. Medtronic CoreValve LLC, 1851 E. Deere Avenue, Santa Ana, CA 92705, USA
8. Medtronic MiniMed, 18000 Devonshire street, Northridge CA 91325-1219, USA
9. Medtronic Heart Valves Division, 1851 East Deere Avenue, Santa Ana, CA 92705, USA
10. Medtronic Heart Valves, 1941 Blair Avenue, Santa Ana CA 92705, USA
11. Medtronic Fabrication S.A.S. Zone Industrielle SUD, Route D'Anor, 59610 Fourmies, France
12. Medtronic Sofamor Danek USA, Inc., 1800 Pyramid Place, Memphis, TN 38132, USA
13. Medtronic Sofamor Danek USA, Inc., 4340 Swinnea Road, Memphis TN 38118, USA
14. Medtronic Sofamor Danek Manufacturing, 2500 Silveus Crossing, Warsaw IN 46582, USA
15. Medtronic Sofamor Danek Deggendorf GmbH, Werfstrasse 17, 94469 Deggendorf, Germany
16. Medtronic Sofamor Danek Deggendorf GmbH, Ulrichsberger Str. 17, 94469 Deggendorf, 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, Fort Worth, Texas 76137, USA
22. Medtronic Navigation, Inc. (Littleton), 300 Foster Street, Littleton, MA 01460, USA
23. Medtronic Navigation, Inc., 826 Coal Creek Circle, Louisville, CO 80027, USA
24. Medtronic Navigation Israel, Ltd. Kochav Yokneam Building, P.O.Box 548, 20692 Yokneam Elit, Israel
25. Kyphon Sàrl, Pierre-à-Bôt 97, 2000 Neuchâtel, Switzerland
26. AF Solutions, Medtronic Inc., 8200 Coral Sea Street, Mounds View, Minneapolis MN 55112, USA
27. Medtronic Ireland, Parkmore Business Park West Galway, Ireland
28. Medtronic Vascular, 35-37a Cherry Hill Drive, Danvers, MA 01923, USA
29. Medtronic Vascular, 3576 Unocal Place, Santa Rosa, CA 95403, USA
30. Medtronic Puerto Rico Operations Co., Juncos, Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos PR 00777, USA
31. Medtronic Puerto Rico Operations Co., Villalba, Rd 149, Km 56.3, Call Box 6001, PR 00766 Villalba, USA
32. Medtronic Puerto Rico Operations, Co., Road 909 Km. 0.4 Bo, 00792 Barrio Mariana, Humacao, Puerto Rico, USA
33. Medtronic Puerto Rico Operations, Co., Parcela #21, Catano Industrial Park, Dr. John A. Smith Street, 00792 Humacao, Puerto Rico, USA
34. Medtronic Mexico S. de R.L. de CV, Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tijuana, Baja California, Mexico
35. Medtronic Mexico EG, Carreta Internacional Guadalajara – Nogales, Empalme, Sonora, Mexico 85340
36. Medtronic Singapore Operations Pte. Ltd., 49 Changi South Avenue 2, Nasaco Tec Centre, 486056 Singapore
37. Medtronic Atrial Fibrillation Technologies (AFT), 8200 Coral Sea Street NE, Mounds View, Minneapolis MN 55112, USA
38. Medtronic Perfusion Systems, 7611 Northland Drive, Minneapolis, MN 55428, USA
39. Medtronic Perfusion Systems, 18501 East Plaza Drive, Parker CO 80134-9061, USA
40. Medtronic Cardiac Surgery Division Europe, Valkenhuizerlaan 16, 6466 ND Kerkrade, The Netherlands

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

List of EC Representatives:

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

List of Medtronic Distribution Centers:

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

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

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

Covidien llc (USA)

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

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

Covidien llc (Canada)

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

Covidien llc (Mexico)

- 37 Boulevard Insurgentes, Libramiento a la P, La Mesa Tijuana, B.C., Mexico
- Calle 9 Sur No. 125 Cuidad Industrial Tijuana, Mexico CP 22500
- Boulevard Insurgentes 19030 Libramiento, 22225 Tijuana, B.C., Mexico
- Avenue Henequen No. 1181, Parque Industrial Salvarcar, 32573 Ciudad Juarez, Chihuahua, Mexico

Covidien llc (Dominican Republic)

- Zona Franca de San Isidro, Carretera San Isidro Km 17 Santo Domingo, Dominican Republic

Covidien llc (Europe)

- Wilson Way Pool Industrial Estate Redruth, Cornwall TR15 3QN United Kingdom Unit 1, Astley Lane Industrial Estate Swillington Leeds West Yorkshire LS26 8XT, United Kingdom
- IDA Business and Tehcnology Park, Srah Industrial Estate Tullamore, Co. Offaly, Republic of Ireland
- Cornamaddy Athlone, Co. Westmeath, Ireland
- Michael Collins Road Mervue, Co. Galway, Ireland
- Via G. Bove, 2/4/6/8 Mirandola (MO) Italy 41037
- Quedlinburger Strasse 39A Halberstadt, D-38820 Germany

Covidien llc (Thailand)

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

Covidien Ilc (Japan)

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

Covidien Ilc Newton (Beacon)

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

Covidien AG

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

Covidien Logistics BVBA

Weg naar Zwartberg 239, 3660 Opplabbeek, Belgium

Covidien Ireland Commercial Limited

3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1

Covidien Medical Products (Shanghai) Manufacturing LLC

Bldg. 10, No. 789 Puxing Rd. Shanghai, P.R. China

Covidien (China) Medical Devices Technology Co., Ltd.

Floor 6, Building 3, #2388 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

Given Imaging, Ltd

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

Given Imaging (Los Angeles) LLC

Los Angeles 5860 Uplander Way Culver City, CA 90230 USA

Given Imaging Vietnam Co. Ltd.

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

Wem Equipamentos Eletrônicos Ltda.

Rua. Marechal Mascarenhas de Moraes 550, Parque Industrial Lagoinha, Ribeirão Preto, São Paulo - CEP 14095-120, Brazil

**List of OEM - Original Equipment Manufacturers
and Sub-Contracting Facilities:**

MindFrame, Inc.

12 Goodyear, Suite 125, Irvine, CA 92618, USA

Buffalo Filter, LLC

5900 Genesee St., Lancaster, NY 14086, USA

SCHÖLLY FIBEROPTIC GmbH

Robert-Bosch-Strasse 1-3, 79211 Denzlingen, Germany

W.O.M. World Of Medicine GmbH

Salzufer 8, 10587 Berlin, Germany

Liebel-Flarsheim Company Llc

2111 East Galbraith Road, Cincinnati, OH 45237 USA

Mediquip SDN. BHD.

- Padang Lati, Mukim Paya, P.O. Box 25, 01700 Kangar, Perlis, Malaysia
- Batu 5, Padang Lati, Jln. Santan, Kangar, 02450 Kangar, Perlis, Malaysia

Mallinckrodt Développement France S.A.S.

10 Allee Pelletier Doisy, 54601 Villers-Lès-Nancy, France

Mallinckrodt DAR S.R.L.

Via G. Bove, 2/4/6/8, Mirandola MO 41037, Italy

Mallinckrodt Medical

Cornamaddy Athlone, Co. Westmeath, Ireland

SOMANETICS CORP.

1653 East Maple Road, Troy, MI 48083-4208, USA

Aspect Medical Systems

1 Upland Road, Norwood MA 02062, USA

POLYSUTURE

Av.Gabriel Ramos da Silva, 1245 Pq.Industrial II, São Sebastião. Paraíso, Minas Gerais, Cep: 37950-000 Brasil

Cadence™ Precision Injector Thread 1 mL Syringe EU MDR Declaration of Conformity (DoC)

Manufacturer: Micro Therapeutics, Inc.
D/b/a ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618 United States

Manufacturer SRN: US-MF-000019796

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

Authorized Representative SRN: NL-AR-000006050

Notified Body: DQS Medizinprodukte GmbH
August-Schanz-Str. 21
60433 Frankfurt am Main
Germany
Notified Body Number: 0297

Conformity Assessment Certificate(s): EU-Quality Management Certificate Registration Number: 281863
MDR2017Q

Conformity Assessment Procedure: Annex IX

Risk Class: Class I(s)

Classification Rule: Annex VIII, Rule 2
All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa:

- if they may be connected to a class IIa, class IIb or class III active device; or

Cadence™ Precision Injector Thread 1 mL Syringe EU MDR Declaration of Conformity

D00124770

Revision A

Page 2 of 6

Form

Medtronic

- if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; blood bags are classified as class IIb
In all other cases, such devices are classified as class I.

Intended Purpose:

The Cadence™ Precision Injector Thread 1ML Syringe is intended for the controlled delivery of fluids in the inflation and deflation of temporary occlusion balloons.

Statement:

We, Micro Therapeutics, Inc. d/b/a ev3 Neurovascular, a wholly owned subsidiary of Medtronic, Inc., hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Other Union Legislation(s):

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

Cadence™ Precision Injector Thread 1 mL Syringe
EU MDR Declaration of Conformity

D00124770

Revision A

Page 3 of 6

Form

Medtronic

Place: Irvine, CA 92618, USA

Name: Kara Madsen

Title: Vice President, Regulatory Affairs, Neurovascular

Signature:



Date: 16 NOV 2022

Cadence™ Precision Injector Thread 1 mL Syringe EU MDR Declaration of Conformity

D00124770

Revision A

Page 4 of 6

Form

Medtronic

Products Covered

Product Name	Medtronic Product Identifier	GTIN	Basic UDI-DI	GMDN
	CFN			
Cadence™ Precision Injector Thread 1mL Syringe	103-0304	20763000293424	0763000B00011647L	GMDN 17541-Catheter-balloon inflator, Single-use

Common Specification(s)

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title
EN ISO 13485	2016/AC:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes. (ISO 13485:2016)
EN ISO 14971	2019	Medical Devices. Application of Risk Management to Medical Devices (ISO 14971:2019)
EN ISO 14644-1	2015	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
EN ISO 14644-2	2015	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
EN ISO 14644-3	2019	Cleanrooms and associated controlled environments – Part 3: Test Methods (ISO 14644-3:2019)
EN ISO 14644-4	2001	Cleanrooms and associated controlled environments – Part 4: Design, construction, and start-up (ISO 14644-4:2001)
EN ISO 14644-5	2004	Cleanrooms and associated controlled environments – Part 5: Operations (ISO 14644-5:2004)
EN ISO 80369-7	2017	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ISTA 2A	2012	Partial Simulation Performance Test Procedure – Packaged Products 150lb (68kg) or less
EN ISO 11607-1	2020	Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems (ISO 11607-1:2019)
EN ISO 11607-2	2020	Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing, and Assembly Processes (ISO 11607-2:2019)
EN ISO 15223-1	2021	Medical Devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General Requirements (ISO 15223-1:2021)
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 (ISO 11135:2014/ Corr1 2018)

Cadence™ Precision Injector Thread 1 mL Syringe EU MDR Declaration of Conformity

D00124770

Revision A

Page 6 of 6

Form

Medtronic

EN ISO 11737-1	2018	Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
EN ISO 11737-2	2020	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2: 2020)
EN ISO 10993-1	2020	Biological Evaluation of Medical Devices Part 1 – Evaluation and Testing with a risk management process (ISO 10993-1:2018)
EN ISO 10993-4	2017	Biological Evaluation of Medical Devices Part 4: Selection of Tests for Interaction with Blood (ISO 10993-4:2017)
EN ISO 10993-5	2009	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-7	2008/AC: 2022	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals (ISO 10993-7:2008/Cor 1:2022)
EN ISO 10993-10	2013	Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
EN ISO 10993-11	2018	Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
EN ISO 10993-23	2021	Biological evaluation of medical devices — Part 23: Tests for irritation (ISO 10993-23:2021)

Revision History

Revision	Date Effective	Description of Change
A	16 NOV 2022	Initial release of document



EU Quality Management Certificate

This is to certify that the company

Micro Therapeutics Inc, d/b/a Ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
United States of America

SRN: US-MF-000019796

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745 Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

Certificate registration no.	281863 MDR2017Q
Certificate ID	170781340
Effective date	2022-09-30
Expiry date	2027-03-23
Frankfurt am Main,	2022-09-30



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745
of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.



Annex to EU Quality Management Certificate
SRN of Manufacturer: US-MF-000019796
Certificate ID: 170781340

Authorised Representative of the company:

EU Representative

Medtronic BV
B.V.,Earl Bakkenstraat 10
6422 PJ Heerlen,
The Netherlands

SRN of EU Representative: NL-AR-000006050

Device categories covered by this certificate:

Device category:	Vascular Microcatheter
Risk classification:	III
Intended purpose:	The Phenom™ Delivery Catheters are intended for the introduction of interventional devices or diagnostic agents into the neuro, peripheral, and coronary vasculatures.
Device category:	Thrombectomy wire-net
Risk classification:	III
Intended purpose:	The Solitaire™ X Revascularization Device is designed for use in the flow restoration of patients with ischemic stroke due to large intracranial vessel occlusion. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.
Device category:	Suction system tubing, single-use
Risk classification:	Is
Intended purpose:	The Riptide™ Aspiration System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.
Device category:	Vascular implant detacher, single-use, sterile
Risk classification:	Is
Intended purpose:	The Instant Detacher (I.D.) is intended for use with the compatible detachable coil devices (Axiom, Axiom Prime, Concerto and Concerto Versa) for the corresponding device indication for use.
Device category:	Electrical-only medical device connection cable, single-use
Risk classification:	Is
Intended purpose:	The Solitaire™ Detachment System is intended for use with the Solitaire™ AB device. The Solitaire™ Detachment System is not intended to be used with coils.
Device category:	IV line/syringe luer connector
Risk classification:	Is
Intended purpose:	The Onyx™ Syringe-Catheter Interface-Adapter (SCIFA) is intended for use as an accessory to the Onyx™ Liquid Embolic System (LES) and Marathon™ Micro Catheter during Onyx™ LES injection.



Annex to EU Quality Management Certificate
SRN of Manufacturer: US-MF-000019796
Certificate ID: 170781340

Device category:	Catheter-balloon inflator, single-use
Risk classification:	Is
Intended purpose:	The Cadence™ Precision Injector is intended for the controlled delivery of fluids in the inflation and deflation of temporary occlusion balloons.
Device category:	General-purpose syringe, single use
Risk classification:	Is
Intended purpose:	The device is indicated for the injection or aspiration of fluids to or from the body. This is a general-purpose syringe.
Device category:	Surgical irrigation/aspiration system
Risk classification:	IIa
Intended purpose:	The Riptide™ Aspiration System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment..
Device category:	Vascular embolization coil detacher, single-use
Risk classification:	IIa
Intended purpose:	"The Artisse™ Detachment Device is intended for use only with the Artisse™ Intracardiac Device."
Device category:	Non-Neurovascular Embolization Coil
Risk classification:	IIb implantable
Intended purpose:	The Concerto™ Detachable Coil is indicated for arterial and venous embolizations in the peripheral vasculature.
Device category:	Peripheral/Coronary Vascular Micro Catheter, single use
Risk classification:	III
Intended purpose:	The Apollo™ Onyx™ Delivery Micro Catheter is intended to access the neurovasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast media.
Device category:	Vascular Embolization coil detacher, reusable
Risk classification:	IIa
Intended purpose:	The Solitaire™ Detachment System is intended for use with the Solitaire™ AB device. The Solitaire™ Detachment System is not intended to be used with coils.

Examinations and tests performed:

2021-11-07_A209224MED_MicroTherapeuticsInc.dbaev3neurovascular_420_11e_Report_MED
dated 2022-03-12



Annex to EU Quality Management Certificate

SRN of Manufacturer: US-MF-000019796
Certificate ID: 170781340

Further conditions for or limitations to the validity of the certificate:

The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.

For placing class III medical devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

In case of products that are placed on the market in sterile condition, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects of manufacture concerned with securing and maintaining sterile condition.

For placing class IIb implantable medical devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2022-03-24	170777415	Addition of Is devices and IIa devices to certificate in accordance with sampling plan
02	2022-06-10	170780189	Addition of new products Peripheral/Coronary Vascular Micro Catheter, single use and Non-Neurovascular Embolization Coil
03	2022-08-25	170780934	Addition of the product "Solitaire™ Detachment System" to the Vascular Embolization coil detacher, reusable product family

Nr.	Numărul de catalog (referință)*	Denumire	Denumire comercială (brand)*	Modelul	Tip dispozitiv	Cod GMDN*
1	103-0304	Cadence™ Precision Injector Thread 1ml Thread 1ml Syringe	Cadence™ Precision Injector Thread 1ml Thread 1ml Syringe	103-0304	Catheter-balloon inflator, Single- use	17541