

Către
Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 4 din 13.10.2023

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:

- Non-Neurovascular Embolization coil: Concerto™ Nylon Fiber Helix

Se anexează următoarele acte:

Declarație pe proprie răspundere

CE certificate

Declarație de conformitate

Scrisoare de imputernicire

Data 13/10/2023

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:

- Non-Neurovascular Embolization coil: Concerto™ Nylon Fiber Helix
Sunt autentice și corespund realității.

Numele, prenumele și funcția

Kojevnikov Dmitrii, director

Semnătura _____

Data 13/10/2023

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. 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, 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 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, Libriamiento a la P, La Mesa Tijuana, B.C., Mexico
- Calle 9 Sur No. 125 Ciudad 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 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

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 Sebastiao. Paraíso, Minas Gerais, Cep: 37950-000 Brasil

EC Declaration of Conformity

D00036054

Revision C

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EC DECLARATION OF CONFORMITY

General Applicable Directives/Standards:

EN ISO 13485 : 2016 + AC : 2016

Quality Management System Standard (281863 MP2016)

93/42/EEC

Council Directive Concerning Medical Devices

Conformity Assessment Route

Annex II (Section 4) 534211 MRA

Annex II (excluding Section 4) 281863 MR2

Product	Model/Reference/Catalogue Number(s)				GMDN Code	Class-Rule	Date CE Mark Affixed
Concerto™ Detachable Coil System	Concerto™ Nylon Fiber Helix				60941 Non- Neurovascular Embolization Coil	Class IIb Rule 8	27-AUG-2008
	NV-2-4-Helix	NV-4-8-Helix	NV-6-12-Helix	NV-8-30-Helix			
	NV-2-6-Helix	NV-4-10-Helix	NV-6-20-Helix	NV-9-20-Helix			
	NV-2-8-Helix	NV-5-10-Helix	NV-7-20-Helix	NV-9-30-Helix			
	NV-3-4-Helix	NV-5-15-Helix	NV-7-30-Helix	NV-10-20-Helix			
	NV-3-8-Helix	NV-5-20-Helix	NV-8-20-Helix	NV-10-30-Helix			
	Concerto™ PGLA Fiber Helix						
	PV-12-30-Helix	PV-14-30-Helix	PV-16-40-Helix	PV-20-50-Helix			
	PV-12-40-Helix	PV-14-40-Helix	PV-18-40-Helix				
	Concerto™ PGLA Fiber 3D						
	PV-2-2-3D	PV-4-10-3D	PV-7-30-3D	PV-12-40-3D			
	PV-2-4-3D	PV-4-12-3D	PV-8-20-3D	PV-14-40-3D			
	PV-2-6-3D	PV-5-10-3D	PV-8-30-3D	PV-16-40-3D			
	PV-3-4-3D	PV-5-15-3D	PV-9-20-3D	PV-18-40-3D			
	PV-3-6-3D	PV-6-15-3D	PV-9-30-3D				
	PV-3-8-3D	PV-6-20-3D	PV-10-20-3D				
	PV-4-8-3D	PV-7-20-3D	PV-10-30-3D				
	Concerto Versa™						
	CV-3-5	CV-7-20	CV-12-30	CV-20-40			
	CV-3-15	CV-7-40	CV-12-50	CV-20-65			
					Class III Rule 8	08-JUN-2017	
					Class IIb Rule 8	19-FEB-2021	

EC Declaration of Conformity

D00036054

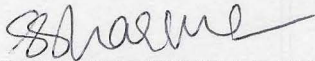
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	CV-4-5	CV-8-20	CV-14-40	CV-24-40			
	CV-4-15	CV-8-40	CV-14-65	CV-24-65			
	CV-5-20	CV-9-20	CV-16-40	CV-28-40			
	CV-5-30	CV-9-40	CV-16-65	CV-28-65			
	CV-6-20	CV-10-20	CV-18-40	CV-32-40			
	CV-6-40	CV-10-40	CV-18-65	CV-32-65			
Instant Detacher	ID-1-5				60637 Vascular Embolization coil detacher, single-use	Class Is Rule 1	07-JUN-2007
<u>Manufacturer:</u>			<u>Notified Body:</u>			<u>European Representative:</u>	
Micro Therapeutics, Inc. DBA ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 USA			DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body Number: 0297			Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands	

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the medical device directive 93/42/EEC as amended by 2007/47/EC and EN ISO 13485 : 2016 + AC : 2016. All supporting documentation is retained under the premises of the manufacturer.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:



Sanjay Sharma
Senior Manager, Regulatory Affairs

Irvine, California 92618; USA
Place of Issue

19 FEB 2021
Date of Issue

This Declaration of Conformity expires on 2024-05-26.



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
United States of America

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Implants and Instruments for Interventional Minimal Invasive Therapy according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	281863 MR2
Certificate unique ID	170773730
Effective date	2021-01-04
Expiry date	2024-05-26
Frankfurt am Main	2021-01-04

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.





Annex to certificate
Certificate registration No.: 281863 MR2
Certificate unique ID: 170773730
Effective date: 2021-01-04

Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way
 Irvine, CA 92618
 United States of America

Device family	Device	Class	
Detachable Embolization Coils	Axium™ Helix	III	
	Axium™ 3D	III	
	Axium™ Nylon Helix	III	
	Axium™ PGLA Helix	III	
	Axium™ PGLA 3D	III	
	Axium™ Prime Bare Platinum Helix	III	
	Axium™ Prime Bare Platinum 3D	III	
	Axium™ Prime Frame Complex	III	
	Concerto™ Bare Platinum Helix	IIb	
	Concerto™ Bare Platinum 3D	IIb	
	Concerto™ PGLA Fiber Helix	III	
	Concerto™ PGLA Fiber 3D	III	
	Concerto™ Nylon Fiber Helix	IIb	
	Neurovascular Remodeling Devices	Solitaire™ AB Neurovascular Remodeling Device	III
		Pipeline™ Flex Embolization Device (PFED)	III
Pipeline™ Flex Embolization Device with Shield Technology™ (SHIELD)		III	
Pipeline™ Vantage Embolization Device with Shield Technology™ (PED3)		III	
Detachment Devices	Solitaire™ NDS-2x Detachment System	IIa	
	Cable Set Sterile (NCS),	Is	
	Solitaire Cable Set (CSS),	Is	
	Instant Detacher (I.D.)	Is	
	Artisse™ Detachment Device	IIa	
Revascularization Devices	Solitaire™ 2 Revascularization Device	III	
	Solitaire™ Platinum Revascularization Device	III	
	Solitaire™ X Revascularization Device	III	
Liquid Embolic Systems	Onyx™ Liquid Embolic System (LES)	III	
Infusion Catheters	Cragg McNamara™ Catheter	IIb	
	MicroMewi™ Infusion Catheter	IIb	
Infusion Wires	ProStream™ Infusion Wire	IIb	
Balloon Occlusion Catheters	HyperGlide™ Occlusion Balloon System	III	
	HyperForm™ Occlusion Balloon System	III	

This annex is only valid in connection with the above-mentioned certificate.





Annex to certificate
Certificate registration No.: 281863 MR2
Certificate unique ID: 170773730
Effective date: 2021-01-04



Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA 92618
United States of America

Device family	Device	Class
Syringe Adapters, Syringes and Introducer Sheaths	Echelon™ Syringe Adapter	Is
	Cadence™ Precision Injector Accessory	Is
	Onyx™ Syringe Catheter Interface Adapter	Is
	1mL Syringe	Is
Guide Wires	Mirage™ Hydrophilic Guidewire	III
	X-Pedion™ Hydrophilic Guidewire	III
	Avigo™ Hydrophilic Guidewire	III
Micro Catheters	Marksman™ Catheter	III
	Nautica™ Micro Catheter	III
	Echelon™ Micro Catheter	III
	Rebar™ Micro Catheter	III
	Orion™ Micro Catheter	III
	Phenom™ Catheter	III
Flow Directed Catheters	Marathon™ Flow Directed Micro Catheter	III
	Apollo™ Onyx™ Delivery Micro Catheter	III
Guide Catheter	Navien™ A+ Intracranial Catheter	III
	React™ 68 Catheter	III
	React™ 71 Catheter	III
	Rist™ Radial Access Selective Catheter	III
	Rist™ 079 Radial Access Guide Catheter	III
Surgical irrigation/aspiration system	Riptide™ Aspirator Pump	IIa
	Riptide™ Large Bore Aspiration Tubing	Is
Embolization Devices	Artisse™ Intracascular Device	III



EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Micro Therapeutics, Inc.

DBA ev3 Neurovascular

9775 Toledo Way
Irvine, CA, 92618
United States of America

that the design of the following device(s)

Concerto™ Detachable Coil System

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.

This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 281863 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: NV-STED-Concerto Rev.10 dated 2020-02-21

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report: 411_18e_Report_TFR_Concerto_R2020_V1 dated 2020-03-19

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no. 534211 MRA

Certificate unique ID 170766955

Effective date 2020-03-19

Expiry date 2024-05-26

Frankfurt am Main 2020-03-19

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate
Certificate registration No.: 534211 MRA
Certificate unique ID: 170766955
Effective date: 2020-03-19



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Concerto™ Detachable Coil System

Concerto™ PGLA Fiber Helix
Concerto™ PGLA Fiber 3D