

Către
Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 6 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:

- Enteer™ Guidewire

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:

- Enteer™ Guidewire

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, Libriamento 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

Declaration of Conformity

Legal Manufacturer:	ev3, Inc. 4600 Nathan Lane North Plymouth, MN 55442 USA
EC Authorized Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Design Facility:	ev3, Inc. 2300 Berkshire Lane North Plymouth, MN 55441 USA
Manufacturing Facility:	Lake Region Medical 340 Lake Hazeltine Drive Chaska, MN 55318 USA
Product Family:	Guidewires
Products:	Enteer™ Guidewire
Classification:	Class IIa based on Annex IX, Rule 7 of Directive 93/42/EEC (MDD)
Notified Body:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands Notified Body Number: 2797
Quality Management System Certificate:	MD 660553



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EC Certificate – Full Quality Assurance System: CE 684995

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of Directive 93/42/EEC (MDD) including amendments issued, which apply to them, as transposed into the national laws of the EU member states.

This declaration is supported by the MDD Annex II.3 Approval.

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

Place: Plymouth, Minnesota, USA Date: 4 Feb 2020

Name: Monika McDole-Russell Signature: 

Title: Sr. Regulatory Affairs Manager

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Products: Enteer™ Guidewire

Model Name	Model No.
Enteer™ Guidewire	ENW-FX-014-300
Enteer™ Guidewire	ENW-SD-014-300
Enteer™ Guidewire	ENW-SF-014-300

Revision History

Revision	Date	Description of Change
E	21-Aug-2018	Update to new template
F	16-Dec-2019	Periodic update
G	04-Feb-2020	Update Notified Body for transfer to BSI NL. Update EC Authorized Representative for transfer to Medtronic BV.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 684995
Issued To: **ev3, Inc.**
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

Design, Development and Manufacture of Sterile Self-Expanding biliary stent systems; Self-Expanding peripheral and carotid stent systems; Pre-mounted and unmounted balloon expandable stents; Support Catheters; Percutaneous Transluminal Angioplasty Catheters; Guidewires; Rotating Y-Connectors; Peripheral Vascular, Cardiovascular and Neurovascular Filtration Systems and Embolic Protection Devices; Crossing Catheters, Re-entry Catheters; Snares, Microsnares, Snare Catheters and Microcatheters.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-12-20**

Date: **2020-05-14**

Expiry Date: **2024-05-26**

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Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 684995

Issued To:

**ev3, Inc.
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA**

Number	Device Description	Intended Purpose per IFU
Class III		
---	Nitrex Nitinol Guidewires	See CE 705545
---	SpiderFX Embolic Protection Device	See CE 706624
---	Protégé RX Self-Expanding Peripheral and Carotid Stent System	See CE 706928
---	Amplatz Goose Neck Snare Kit Amplatz Goose Neck MicroSnare Kit Snare Catheter	See CE 719026
Class IIb		
47932	Self-Expanding biliary stent systems	Intended for use as a palliative treatment of malignant neoplasms in the biliary tree.
47932	Pre-mounted and unmounted balloon expandable stents	Intended for use in occlusions, lesions at high risk for abrupt closure or threatened closure following percutaneous transluminal angioplasty (PTA) or lesions believed to be at high risk of stenosis following PTA in the common and external iliac, subclavian and renal arteries. Stenting is intended to improve and maintain artery luminal diameter. Also intended for use as a palliative treatment of malignant neoplasms in the biliary tree.
47932	Self-expanding peripheral stent systems	Intended for use in the following types of occlusions or lesions: Occlusions or lesions at high risk for abrupt closure or threatened closure following percutaneous transluminal angioplasty (PTA). Lesions that appear to be at high risk for restenosis following PTA in the common iliac, external iliac, superficial femoral, proximal popliteal, or subclavian arteries. Stenting is intended to improve and maintain the artery luminal diameter.

First Issued: **2017-12-20**

Date: **2020-05-14**

Expiry Date: **2024-05-26**

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Page 2 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 684995

Issued To: **ev3, Inc.**
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

Number	Device Description	Intended Purpose
Class IIa		
MD 0106	Support Catheters	---
MD 0106	Percutaneous Transluminal Angioplasty Catheters	---
MD 0106	Guidewires	---
MD 0106	Rotating Y-Connectors	---
MD 0106	Crossing Catheters	---
MD 0106	Re-entry Catheters	---

First Issued: **2017-12-20**

Date: **2020-05-14**

Expiry Date: **2024-05-26**

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Page 3 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 684995**
Date: **2020-05-14**
Issued To: **ev3, Inc.**
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

Subcontractor:	Service(s) supplied
B. Braun Medical Inc. 901 Marcon Boulevard Allentown Pennsylvania 18109-9341 USA	Design Development Manufacture
Emerald Medical Services Pte Ltd. 8 Admiralty Street #06-16 - Lobby 1 757438 Singapore Singapore	Manufacture
ev3, Inc. 2300 Berkshire Lane Plymouth Minnesota 55441 USA	Design Development

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 684995**
Date: **2020-05-14**
Issued To: **ev3, Inc.**
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

Subcontractor:	Service(s) supplied
ev3, Inc. 3033 Campus Drive Plymouth Minnesota 55441 USA	Regulatory Compliance
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 USA	ETO Sterilization
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	Radiation (Gamma Sterilization)

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 684995**
 Date: **2020-05-14**
 Issued To: **ev3, Inc.**
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

Subcontractor:	Service(s) supplied
Lake Region Medical 340 Lake Hazeltine Drive Chaska Minnesota 55318-1029 USA	Design Development Manufacture
Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands	EU Representative
Medtronic Ireland Parkmore Business Park West Galway Ireland	EU Representative

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 684995**
Date: **2020-05-14**
Issued To: **ev3, Inc.**
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

Subcontractor:

Service(s) supplied

Surmodics, Inc.
9924 West 74th Street
Eden Prairie
Minnesota
55344
USA

Crucial Supplier

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 684995**
 Date: **2020-05-14**
 Issued To: **ev3, Inc.**
4600 Nathan Lane North
Plymouth
Minnesota
55442
USA

Certificate History

Date	Reference Number	Action
20 December 2017	8863804	First Issue – Transfer from another Notified Body.
18 July 2018	8907760	Adding Support Catheters and PTA Catheters to certificate scope per Notified Body transfer.
12 February 2019	9681801	Add Emerald Medical Services Pte Ltd. to the list of subcontractors.
06 March 2019	8786554	Traceable to NB 0086.
31 January 2020	9731127	Transfer from another Notified Body the following device families: Self-expanding carotid stent systems; Guidewires; Rotating Y-Connectors; Peripheral Vascular, Cardiovascular and Neurovascular Filtration Systems and Embolic Protection Devices; Crossing Catheters; Re-entry Catheters Snares, Microsnares, Snare Catheters and Microcatheters. Add Lake Region Medical, Medtronic BV, B. Braun, Isomedix Operations, Inc. Libertyville, and SurModics to the list of subcontractors. Add device table. Remove EverFlex+ self-expanding peripheral stent system (Class IIb) as it is no longer sold.
Current	3143228	Certificate renewal. Update supplementary information table to list GMDN codes for class IIb devices.

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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