

Nr. 12101-504

18.03.2016

**CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE**

Prin prezentul, BC „Mobiasbancă – Groupe Societe Generale” S.A., codul băncii (BIC): MOBBMD22, confirmă că compania OXIVIT-MED SRL, cod fiscal (IDNO) 1007600044280, deține următoarele conturi curente la BC "Mobiasbancă-Groupe Societe Generale" S.A., Filiala, 1 Stejaur :

1. MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100
2. EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100
3. USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.


Dumitru Popa
Director filială „Stejaur”



Executor : Mariana Guzun
Tel: 022 812 614

Filiala Nr. 1 „Stejaur”
Bd. Ștefan cel Mare și Sfânt 196
MD-2004, Chișinău, Moldova
Cod MOBBMD22
Cont de corespondență 35213892
la Centrul de Decontări al BNM

Tel. +373 22 81 26 15
Fax. +373 22 81 26 15
www.mobiasbanca.md

BC „Mobiasbancă – Groupe Société Générale” SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ștefan cel Mare și Sfânt 81a
MD-2012, Chișinău, Moldova

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal
1007600044280

Data înregistrării

30.07.2007

Data eliberării

30.07.2007

Bordeianu Tatiana, registrator de stat

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

semnătura

MD 0067985





I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS
din Registrul de stat al persoanelor juridice

nr. 8871 din 05.05.2021

Denumirea completă: **Societatea Comercială «OXIVIT-MED» S.R.L.**

Denumirea prescurtată: **S.C. «OXIVIT-MED» S.R.L.**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1007600044280.**

Data înregistrării de stat: **30.07.2007.**

Sediul: **MD-2032, bd. Decebal, 82, ap.(of.) 90, mun. Chișinău, Republica Moldova.**

Modul de constituire: **nou creată.**

Obiectul principal de activitate:

- 1 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 2 Comerțul cu ridicata al parfumurilor și produselor cosmetice;**
- 3 Comerțul cu amănuntul al produselor cosmetice și de parfumerie, articolelor de toaletă;**
- 4 Intermedieri pentru vânzarea unui asortiment larg de mărfuri;**
- 5 Alte tipuri de comerț cu amănuntul în magazine nespecializate;**
- 6 Alte tipuri de comerț cu ridicata;**
- 7 Închirierea altor mașini și echipamente.**

Capitalul social: **5400 lei.**

Administrator: KOJEVNIKOV DMITRII, IDNP 0972305012362,

Asociați:

1. KOJEVNIKOV DMITRII , IDNP 0972305012362

cota 5400.00 lei, ce constituie 100 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 05.05.2021.

Specialist coordonator
tel. 022-207-840

Lazari Aliona



EEI 0354094

OXIVIT MED

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chișinău, Republica Moldova

telefon: + 373 22 808002; fax: + 373 22 808003

web: www.oxivit-med.com; e-mail: info@oxivit-med.com

Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362

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

CERTIFICATE

Number: 2090418

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

including the implementation meets the requirements of the standard:

ISO 9001:2015 EN ISO 13485:2016

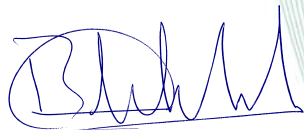
Scope:

Sales, order management, warehousing and distribution of medical devices.
Including regulatory affairs, post market surveillance, technical service, customer education and spine loaner operations

Certificate expiry date: 1 July 2024
Certificate effective date: 1 July 2021
Certified since: 1 July 2006

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Certified organization(s) and/or locations:

Different scope

Medtronic Trading NL B.V.
Larixplein 4
5616 VB Eindhoven
The Netherlands

Sales, order management and distribution of medical devices.
Including customer education

Medtronic Italia S.p.A.
Via Varesina 162
20156 Milano
Italy

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Danmark A/S.
Arne Jacobsens Alle 17
2300 Kopenhagen
Denmark

Sales, order management and distribution of medical devices.
Including customer education

Medtronic Finland Oy
Lentajantie 3
01530 Vantaa
Finland

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic AB
P.O. Box 1034
164 21 Kista
Sweden

Sales, order management and distribution of medical devices.
Including customer education

Medtronic Norge AS
Martin Linges vei 25
1364 Fornebu
Norway

Sales, order management and distribution of medical devices.
Including customer education.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Africa (Pty) Ltd.
Waterfall Distribution Campus CNR
K101 and Bridal Veil Road Waterfall
Midrand
1685 Gauteng
South Africa

Sales, order management, warehousing and distribution of medical devices. Including customer education and spine loaner operations.

Medtronic Medikal Teknoloji Ticaret Ltd
Sti
Saray Mah. Esnaf Sk. Akkom Ofis Park
Laodik Plaza Sitesi B Blok Apt: 2/8
34764 Umraniye - Istanbul
Turkey

Sales, order management and distribution of medical devices. Including customer education

Medtronic Ibérica S.A.
Calle de Maria de Portugal, 11
28050 Madrid
Spain

Sales, order management and distribution of medical devices. Including customer education.

Medtronic Ibérica S.A.
WTC Almeda Park Placa de la Pau, s/n.
Edificio 7, 3 piso Cornellà de Llobregat
08940 Barcelona
Spain

Sales, order management and distribution of medical devices.

Medtronic Portugal LDA-
Rua Tomas da Fonseca Torre E, 11
 piso
1600 Lisboa
Portugal

Sales, Order Management and distribution of medical devices including customer education.

Warehousing and distribution of medical devices, including spine loaner operations

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Portugal, LDA-
Avenida Gomes Pereira 61B
Benfica
1600 Lisboa
Portugal

Sales, Order Management and distribution of medical devices.
Including customer education.

Warehousing and distribution of medical devices, including spine
loaner operations.

Medtronic GmbH
Earl-Bakken-Platz 1
40670 Meerbusch
Germany

Scope for EN ISO 13485:2016: Sales, order management and
distribution of medical devices. Including customer education.
ISO 9001:2015 excluded

Medtronic GmbH
Mollsfeld 12
40670 Meerbusch
Germany

Scope for EN ISO 13485:2016: Sales, order management and
distribution of medical devices. Including customer education.
ISO 9001:2015 excluded

Medtronic Osterreich GmbH
Millennium Tower, 20th floor Handelskai
94-96
1200 Wien
Austria

Sales, order management, warehousing and distribution of
medical devices. Including customer education

Medtronic (Schweiz) AG
Talstrasse 9
3053 Munchenbuchsee
Switzerland

Sales, order management, warehousing and distribution of
medical devices. Including customer education

Medtronic France SAS
9, boulevard Romain Rolland
75014 Paris
France

Sales, order management and distribution of medical devices.
Including customer education

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Hellas S.A.
Avenue Kifisias 24 Building B
151 25 Marousi Pref. Attica
Greece

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Hellas S.A. Diabetes Shop
Mesogeion Avenue 2-4
115 27 Athens
Greece

Sales, order management and distribution of diabetes medical
devices. Including customer education.

Medtronic Romania SRL
Ploiesti 42-44, Building B, B2 Wing, 2nd
floor, district 1 Baneasa Business &
Technology Park
013696 Bucharest
Romania

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Hungária Kft.
Bocskai ut 134-146 Cepulet 3. emelet
1113 Budapest
Hungary

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Serbia Ltd.
Bulevar Zorana Djindjica, 64a
11070 Belgrade
Serbia

Sales, order management and distribution of medical devices.
Including customer education.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Poland Sp.z o.o Medtronic
Customer Care Center of Experience
Warsaw
Polna 11
00-633 Warszawa
Poland

Order management of medical devices.

Medtronic Trading Ltd.
10 Hamada Street
4673344 Herzliya
Israel

Import, sales, order management and distribution of medical
devices.
Including customer education

Medtronic Czechia s.r.o.
Prosek Point, Budova B, Prosecka
852/66
852 66 Praha
Czech Republic

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Bulgaria EOOD
48 Sitnyakovo blvd., R-N OBORISHTE
DISTR., floor 7
1505 Sofia
Bulgaria

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Limited
Building 9, Croxley ParkHatters Ln
WD18 8WW Watford
United Kingdom

Sales, order management and distribution of medical devices.
Including customer education.

ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Ireland Limited
Block 3090-3094 Lake Drive, Citywest
Business Campus
D24 NW2F Dublin
Ireland

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic B.V.
Medtronic Service & Repair EMEA
Jan Campertstraat 21-A
6416 SG Heerlen

Order management, warehousing and technical service of
medical devices including field service EMEA.

Medtronic Slovakia s.r.o.
CBC III, Karadzicova 12
821 08 Bratislava
Slovak Republic

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Belgium
Burgemeester E. Demunterlaan 5
1090 Brussel
Belgium

Sales, Order Management and distribution of medical devices.
Including customer education

Medtronic Croatia
Folnegoviceva 1c
10000 Zagreb
Croatia

Sales, order management and distribution of medical devices.
Including customer education.

Medtronic Slovenia
Ameriska Ulica 8
1000 Ljubljana
Slovenia

Sales, order management and distribution of medical devices

Addendum expiry date: 1 July 2024
Addendum effective date: 1 July 2021

EC Certificate - Full Quality Assurance System

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

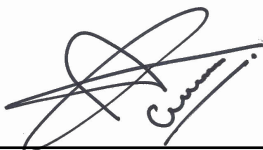
No. CE 619063
Issued To: **Medtronic CoreValve LLC**
1851 E. Deere Avenue
Santa Ana
California
92705
USA

In respect of:

Design, Development, and Manufacture of Sterile Cardiac Catheter Guidewires, Transcatheter Heart Valve Systems.

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):



Albert Roossien, Regulatory Lead

First Issued: **2015-01-14**

Date: **2019-03-06**

Expiry Date: **2020-11-07**

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Page 1 of 1

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

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 619063**
 Date: **2019-03-06**
 Issued To: **Medtronic CoreValve LLC**
1851 E. Deere Avenue
Santa Ana
California
92705
USA

Subcontractor:	Service(s) supplied
Abbyland Pork Pack, Inc. 539 N Merian Street, PO Box 67 Curtiss WI 54422 USA	Animal Tissues / Derivatives
Admedes Schuessler GmbH Rastatter Strasse 15 Pforzheim Germany	Manufacture
Banner Creek LLC 619 E 4th Street Holton KS 66436 USA	Animal Tissues / Derivatives
BOB EVANS FARMS, INC. 200 N Wolcott St Hillsdale MI 49242 USA	Animal Tissues / Derivatives

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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

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 Date: **2019-03-06**
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1851 E. Deere Avenue
Santa Ana
California
92705
USA

Subcontractor:	Service(s) supplied
Calihan Pork, Inc 1 South St Peoria IL 61602 USA	Animal Tissues / Derivatives
Danish Crown AmbA Aabenraavej 11 Skaerbaek, 6780 Denmark	Animal Tissues / Derivatives
EPflex Feinwerktechnik GmbH Im Schwöllbogen 24 72581 Dettingen/Erms Germany	Manufacture
HA2 Medizintechnik GmbH Tschalkowskistraße 2 38820 Halberstadt Germany	ETO 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:

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1851 E. Deere Avenue
Santa Ana
California
92705
USA

Subcontractor:	Service(s) supplied
Jimmy Dean Foods/Sara Lee Sausage 2000 Biffle Rd Newburn TN 38059 USA	Animal Tissues / Derivatives
Johnsonville Sausage, LLC (d.b.a. Perry Way Foods, LLC) 1222 Perry Way Watertown Wisconsin 53094 USA	Animal Tissues / Derivatives
Lenzing Plastics GmbH Werkstrale 2 4860 Lenzing Austria	Crucial Supplier

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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 619063**
Date: **2019-03-06**
Issued To: **Medtronic CoreValve LLC**
1851 E. Deere Avenue
Santa Ana
California
92705
USA

Subcontractor:	Service(s) supplied
Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands	EU Representative
Medtronic Ireland Parkmore Business Park West Galway Ireland	Manufacture
Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California Mexico	Manufacture
Momence Packing Co 334 W North Street Momence IL 60954-1157 USA	Animal Tissues / Derivatives

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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

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Date: **2019-03-06**
Issued To: **Medtronic CoreValve LLC**
1851 E. Deere Avenue
Santa Ana
California
92705
USA

Subcontractor:	Service(s) supplied
Pine Ridge Farm (d.b.a. Kansas City Sausage, LLC) 1801 Maury St Des Moines Iowa 50317 USA	Animal Tissues / Derivatives
Pork King Packing 8808 Route 23 Marengo Illinois 60152 USA	Animal Tissues / Derivatives
SP Medical Sp.z.o.o UI. Ceramiczna 2 98-220 Zdunska Wola Poland	Manufacture

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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

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Date: **2019-03-06**
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1851 E. Deere Avenue
Santa Ana
California
92705
USA

Subcontractor:	Service(s) supplied
Steripack Clara County Offaly Ireland	Packaging
Swaggerty Sausage Co., Inc. 2827 Swaggerty Rd Kodak TN 37764 USA	Animal Tissues / Derivatives
Synergy Health (Isotron) IDA Business & Technology Park Tullamore Co. Offaly Ireland	ETO Sterilization
Teleflex 375 Forbes Blvd. Mansfield MA 02048 USA	Crucial Supplier

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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

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Certificate No: **CE 619063**
Date: **2019-03-06**
Issued To: **Medtronic CoreValve LLC**
1851 E. Deere Avenue
Santa Ana
California
92705
USA

Subcontractor:

Service(s) supplied

Williams Sausage Company Inc.
5132 Old Troy Hickman Rd
Union City
Tennessee
38261
USA

Animal Tissues / Derivatives

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 619063**
 Date: **2019-03-06**
 Issued To: **Medtronic CoreValve LLC**
1851 E. Deere Avenue
Santa Ana
California
92705
USA

Date	Reference Number	Action
14 January 2015	8271736	Transfer from another Notified Body.
29 January 2015	8209459	Transferred the Transcatheter heart valves from another Notified Body. Addition of subcontractors Medtronic Mexico, Medtronic Ireland, Teleflex, Momence Packing Co, Johnsonville Sausage, LLC, Pine Ridge Farm, Calihan Pork, Inc, Banner Creek LLC, Abbyland Pork Pack, Inc., Jimmy Dean Foods/Sara Lee Sausage, F.B. Purnell Sausage Co., Inc., Swaggerty Sausage Co., Inc., Bob Evans Farms, Inc in Xenia, OH, BOB EVANS FARMS, INC. in Hillsdale, MI, and Danish Crown AmbA.
13 October 2015	8418449	Certificate renewal.
27 July 2017	8699537	Addition of new suppliers of animal substances Williams Sausage Company Inc. and Pork King Packing. Removal of Bob Evans Farms Inc. (Xenia, OH, USA) and F.B. Purnell Sausage Co Inc. as suppliers of animal substances. Update to addresses for Johnsonville Sausage and Pine Ridge Farm also suppliers of animal substances.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 619063**
 Date: **2019-03-06**
 Issued To: **Medtronic CoreValve LLC**
1851 E. Deere Avenue
Santa Ana
California
92705
USA

Date	Reference Number	Action
Current	8250502	Traceable to NB 0086. Administrative Subcontractor Service wording update for: Abbyland Pork Pack, Inc., Banner Creek LLC, BOB EVANS FARMS, INC., Calihan Pork, Inc, Danish Crown AmbA, Jimmy Dean Foods/Sara Lee Sausage, Johnsonville Sausage, LLC, Momence Packing Co, Pine Ridge Farm, Pork King Packing, Swaggerty Sausage Co., Inc. and Williams Sausage Company Inc. from "Animal Substances" to "Animal Tissues / Derivatives" Synergy Health (Isotron) from "Sterilization" to "ETO Sterilization"