MOBIAS BANCA

Nr. 12101-304

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.

L.Ș.

Dumitru Popa
Director filială „Stejaur"

Digitally signed by Kojevnikov Dmitrii
Date: 2022.11.25 16:29:44 EET
Reason: MoldSign Signature
Location: Moldova

Executor : Mariana Guzun
Tel: 022 812 614

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

CAMERA ÎNREGISTRĂRII DE STAT A REPUBLICII MOLDOVA L.Ș.

MD 0067985

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor 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 şi codul fiscal: **1007600044280.**
Data înregistrării de stat: **30.07.2007.**
Sediul: **MD-2032, bd. Decebal, 82, ap.(of.) 90, mun. Chişinău, Republica Moldova.**
Modul de constituire: **nou creată.**
Obiectul principal de activitate:
1 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;
2 Comerţul cu ridicata al parfumurilor şi produselor cosmetice;
3 Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă;
4 Intermedieri pentru vînzarea unui asortiment larg de mărfuri;
5 Alte tipuri de comerţ cu amănuntul în magazine nespecializate;
6 Alte tipuri de comerţ cu ridicata;
7 Închirierea altor maşini şi echipamente.
Capitalul social: **5400** lei.
Administrator: KOJEVNIKOV DMITRII, IDNP 0972305012362,
Asociaţi:
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 şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 05.05.2021.

Specialist coordonator
tel. 022-207-840
Lazari Aliona

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

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

MGMT. SYS. RvA C 589

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 Cornella 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 Milennium 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 Herzlya 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 3090-3094Lake 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

By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 84868**

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

In respect of:

The design, development and manufacture of sterile Endoluminal Stent Grafts, sterile Securement Devices and Delivery Systems for Endovascular Indications, sterile Vascular Introducer Sheaths, sterile Stent Graft Balloon Catheters, sterile Coronary Stents and Delivery Systems, Sterile Intravascular Catheters and sterile/non-sterile Catheter Systems for Renal Denervation.

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: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

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

Number	Device Name	Intended purpose per IFU
Class III products under the scope of CE 84868		
N/A	Attain Clarity Venogram Balloon Catheter	See CE 593123
N/A	Driver Sprint Rapid Exchange Coronary Stent System	See CE 545439
N/A	Endeavor Resolute Zotarolimus-Eluting Coronary Stent System Resolute Integrity Zotarolimus-Eluting Coronary Stent System	See CE 514336
N/A	Endeavor Sprint Zotarolimus-Eluting RX Coronary Stent System	See CE 86406
N/A	Endurant™ Stent Graft System Endurant™ II Stent Graft System Endurant™ IIs Stent Graft System	See CE 559659
N/A	Euphora Rapid Exchange Balloon Dilatation Catheter	See CE 622066
N/A	Heli-FX™ EndoAnchor™ Systems	See CE 669930
N/A	IN.PACT Admiral (Paclitaxel-coated PTA Balloon Catheter)	See CE 570280

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

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

Number	Device Name	Intended purpose per IFU
Class III products under the scope of CE 84868		
N/A	IN.PACT Falcon (Paclitaxel-eluting PTCA Balloon Catheter)	See CE 570282
N/A	IN.PACT Pacific (Paclitaxel-eluting PTA Balloon Catheter)	See CE 570281
N/A	Integrity Rapid Exchange Coronary Stent System	See CE 91271
N/A	Micra™ Introducer Sheath with Hydrophilic Coating	See CE 599898
N/A	NC Euphora Rapid Exchange Balloon Dilatation Catheter	See CE 612356
N/A	NC Solarice Rapid Exchange Balloon Dilatation Catheter	See CE 630635
N/A	NC Sprinter Rapid Exchange Balloon Dilatation Catheter	See CE 506473
N/A	Reliant Stent Graft Balloon Catheter	See CE 635936
N/A	Resolute Onyx Zotarolimus-Eluting Coronary Stent System	See CE 618060
N/A	Sentrant Introducer Sheath with Hydrophilic Coating	See CE 595294
N/A	Solarice Rapid Exchange Balloon Dilatation Catheter	See CE 630580
N/A	Sprinter Legend OTW Balloon Dilatation Catheter	See CE 547584

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

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

Number	Device Name	Intended purpose per IFU
Class III products under the scope of CE 84868		
N/A	Sprinter Legend RX Balloon Dilatation Catheter	See CE 525652
N/A	Sprinter Over-the-Wire Balloon Dilatation Catheter	See CE 92065
N/A	Telescope Guide Extension Catheter	See CE 701802
N/A	Valiant Navion™ Thoracic Stent Graft System	See CE 702496
N/A	Valiant Thoracic Stent Graft with the Captivia Delivery System	See CE 554030

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

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

Class IIb products under the scope of CE 84868		
GMDN #	**Device or Generic Device Group**	**Intended Purpose per IFU**
58893 (Catheter) 35156 (Generator)	Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter & Symplicity G3™ Renal Denervation RF Generator	The Symplicity G3™ Renal Denervation RF Generator when used with the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter is intended to deliver low-level radio frequency (RF) energy through the wall of the renal artery to denervate the human kidney.

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

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

Class IIb products under the scope of CE 84868		
GMDN #	**Device or Generic Device Group**	**Intended Purpose per IFU**
46777	Talent Endoluminal Occluder System	The Talent Endoluminal Occluder System is intended for endoluminal occlusion of the contralateral iliac artery in cases where an abdominal aortic aneurysm is treated with an aorto-uni-iliac stent graft and subsequent femoral-to-femoral bypass procedure

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

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

Class IIa products under the scope of CE 84868		
NBOG code	**Device or Generic Device Group**	**Intended Purpose per IFU**
MD0106	Confida™ Expandable Sheath	The Confida™ Expandable Sheath is intended to be inserted into the femoral artery, over a guidewire, and once expanded, to provide a guide for catheters or devices introduced into the femoral iliac arteries.

First Issued: **2004-08-24** Date: **2019-08-22** Expiry Date: **2024-05-26**

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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 84868**
Date:	**2019-08-22**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
Invatec S.p.A. Via Martiri della Libertà 7 25030 Roncadelle (BS) Italy	**Manufacture**
Medistri SA Rte de L'Industrie 96 1564 Domdidier Switzerland	**ETO Sterilization**
Medtronic B.V. / E.O.C. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands	**EU Representative**
Medtronic CoreValve LLC 1851 E. Deere Ave Santa Ana, CA 92705 USA	**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

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

Certificate No:	**CE 84868**
Date:	**2019-08-22**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
Medtronic Ireland Parkmore Business Park West Galway Ireland	**Design** **EU Representative** **Manufacture**
Medtronic Mexico EG Carret. Int. Km. 1969 Guad-Nogales Km. 2 85340 Empalme Sonora Mexico	**Manufacture**
Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California Mexico	**Manufacture**
Medtronic Vascular 3576 Unocal Place Santa Rosa California 95403 USA	**Design**

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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 84868**
Date:	**2019-08-22**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
Phoenix DeVentures, Inc. 18655 Madrone Parkway Suite 180 Morgan Hill California 95037 USA	**Manufacture**
Plexus Corp. Pinnacle Hill Kelso TD5 8XX United Kingdom	**Manufacture**
Plexus Manufacturing Sdn. Bhd. Bayan Lepas Free Industrial Zone Phase II, 11900 Bayan Lepas Penang Malaysia	**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

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

Certificate No:	**CE 84868**
Date:	**2019-08-22**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
SSP-SiMatrix, Inc. 1131 North US Highway 93 Victor Montana 59875 USA	**Manufacture**
Sterigenics US, LLC 4900 Gifford Avenue Los Angeles California 90058 USA	**ETO Sterilization**
Surmodics, Inc. 9924 West 74th Street Eden Prairie Minnesota 55344 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

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

Certificate No:	**CE 84868**
Date:	**2019-08-22**
Issued To:	**Medtronic, Inc.** **710 Medtronic Parkway** **Minneapolis, MN 55432** **USA**

Subcontractor:	**Service(s) supplied**
Synergy Health Ireland Ltd (Synergy Health - AST - Ireland) IDA Business & Technology Park Tullamore, Co. Offaly Ireland	**E Beam Sterilization** **ETO Sterilization**
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Daventry) Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	**E Beam Sterilization**
Teleflex Medical Annacotty Business Park Annacotty Co. Limerick Ireland	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**
Date: **2019-08-22**
Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
24 August 2004		First Issued.
15 November 2004		Transfer of the following certificates from NSAI:- Q252.322, Q252.407, Q252.426, Q252.427, Q252.428, Q252.467, Q252.480, Q252.587, and Q252.611 D252.587 and D252.407, plus incorporation of Medtronic Vascular Ireland as a subcontract manufacturer.
02 December 2004		Carotid and Coronary Stents and Delivery Systems added to the scope (transfer) Medtronic Mexico (manufacture), and Titan Scan Systems, Nutec Corporation, Sterigenics (Queensbury), Steris Corporation-Isomedix Services (Sandy), Rocialle in Health (Mid Glamorgan UK), and EBIS Iotron added as sub-contract sterilizers.
21 December 2004		PTCA Balloon Dilatation Catheters added to the range of products manufactured (transferred from another Notified Body) and Isotron Ireland Ltd added as sub-contract sterilization site.
19 August 2005		Sterilization sub-contractor name change from Titan Scan Systems to Beam One.
03 April 2006		Addition of Sterigenics UK Ltd, as sterilization sub-contractor.
07 August 2006		Addition of AD)MEDES Schuessler GmbH as a sub-contractor for manufacture.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**

Date: **2019-08-22**

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

Date	Reference Number	Action
11 January 2008	7149866	Subcontractor name change from EBIS Isotron, Harwell to Isotron Harwell. Addition of Isotron plc, Daventry as a subcontractor for E beam sterilization.
03 October 2008	7279045	Addition of Medtronic Mexico EG, Empalme as a subcontractor for manufacture.
14 April 2009	7341499	Correction of the legal name of the Medtronic Mexico facility and postcode for the Isotron PLC, Daventry facility. Addition of the activity of EU Representative for Medtronic Ireland.
13 August 2009	7432878	Certificate renewal. Addition of Accellant Inc as a manufacturing subcontractor, amendment to company name for Isotron PLC, Daventry, and Steris Corporation, Sandy, Utah. Change to address for the subcontractor, Nutek Corporation. Addition of E Beam Sterilization for Isotron Ireland. Rewording of scope for clarification purposes only.
29 July 2010	7546410	Added C.R. Bard, Inc. to the list of significant subcontractors for manufacturing. Extended the scope to include guidewires.
12 October 2011	7730209	Extension to scope to include Catheter Systems for Renal Denervation. Removal of Carotid Stents and Delivery Systems from the scope. Minor amendments to Isotron Daventry and Isotron Tullamore's addresses.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**

Date: **2019-08-22**

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

Date	Reference Number	Action
26 January 2012	7792125	Amendment to significant subcontractors to reflect Isotron's name change to Synergy Health and removal of Isotron Harwell.
25 May 2012	7842435	Amendment to the address format and zip code for the significant subcontractor Medtronic Mexico (Tijuana).
19 December 2012	7915649	Addition of Medtronic B.V. The Netherlands for EU Representative Activities.
22 January 2013	7945194	Extension to scope to include Superficial Femoral Artery (SFA) and Proximal Popliteal Artery (PPA) Stents and Delivery Systems.
28 February 2013	7960715	Addition of Invatec Technology Center GmbH to the list of significant subcontractors for manufacturing activities.
28 March 2013	7943883	Extension to Scope to include Vascular Introducer Sheaths and the addition of Teleflex Medical for manufacturing activities.
16 December 2013	8082854	Addition of Plexus Manufacturing Sdn Bhd, Malaysia and Plexus Corp, UK to the list of significant subcontractors for manufacturing activities.
13 July 2014	8154862	Certificate Renewal. Various updates and changes to the list of significant subcontractors. Correction of the reference number for the reissue dated 19th December 2012 on the certificate history page.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**
Date: **2019-08-22**
Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
31 July 2015	8350802	Addition of SSP SiMATrix Inc. as balloon supplier for the Attain Clarity.
01 July 2016	8545838	C. R. Bard, Inc., Medtronic Ardian LLC, Nutek Corporation, Sterigenics NY and Apical Instruments Inc. were removed from the list of significant subcontractors.
09 October 2017	8696759	Certificate scope updated to add the design, development and manufacture of securement devices for endovascular indications.
01 May 2018	8895951	Specify devices covered in this certificate are sterile/non-sterile. Move 'sterile Vascular Introducer Sheaths' up in the scope after securement devices. Remove 'Renal Stents and Delivery Systems' and 'guidewires for diagnostic or interventional procedures' from scope. Correction to certificate history entry #2 from '2014' to '2004'.
06 March 2019	8786554	Traceable to NB 0086.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**
Date: **2019-08-22**
Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
Current	9736517	Certificate Renewal. Added product table per MDP4500 Appendix A. Clarified addresses of subcontractors to exactly align with their ISO certificate name and address. Remove "sterile Iliac Stents and Delivery Systems, sterile Superficial Femoral Artery (SFA) and Proximal Popliteal Artery (PPA) Stents and Delivery Systems" from scope as the Complete SE product (iliac and vascular indications) is no longer manufactured nor in the distribution chain. Remove Assurant Cobalt product (iliac product scope) it is no longer manufactured and the last product builds expired in April 2019. Remove subcontractors – Admedes Schuessler GmbH, Germany, Flextronics Medical, Austria, Sterigenics, Corona, CA, Synergy Health, Ireland related to removed products above. Add subcontractors - Phoenix DeVentures, CA, Sterigenics, Los Angeles, CA, SurModics, MN and Medtronic, Santa Ana, CA related to new Class IIa product Confida Expandable Sheath.

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039709 1259 Rev. 00

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

EC-Representative: **Medtronic Ireland**
Parkmore Business Park West, Galway, Ireland, IRELAND

Product Category(ies): **Temporary Occlusion and Aspiration System; Angioplasty and Angiography Products (Angiography Catheters, Guiding Catheters, Diagnostic Catheters, Guidewires, Introducers)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72146095

Valid from: 2019-07-23
Valid until: 2024-05-26

Date, 2019-07-23

Stefan Preiß
Head of Certification/Notified Body

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

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Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039709 1259 Rev. 00

Facility(ies):

Medtronic Vascular
37A Cherry Hill Drive, Danvers MA 01923, USA

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Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039709 1279 Rev. 00

Manufacturer:

Medtronic Inc.
710 Medtronic Parkway
Minneapolis MN 55432
USA

Product Category(ies):

Tissue Heart Valves, Annuloplasty Rings and Bands and related Accessories for Surgical Implants, and Temporary Pacing Lead Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72150078

Valid from: 2019-11-15
Valid until: 2024-05-26

Date, 2019-11-15

Christoph Dicks
Head of Certification/Notified Body

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EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039709 1279 Rev. 00

Facility(ies):

Medtronic Mexico S.de R.L.de CV
Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tijuana, Baja California, MEXICO

Medtronic Heart Valves Division
1941 Blair Avenue, Santa Ana CA 92705, USA

Medtronic Heart Valves Division
1851 E. Deere Avenue, Santa Ana, CA 92705, USA

Medtronic Fabrication S.A.S. Zone Industrielle SUD
Route D'Anor, 59610 Fourmies, FRANCE

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