



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**

...making excellence a habit.™

Page 1 of 7

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 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**

...making excellence a habit.™

Page 2 of 7

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

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**

...making excellence a habit.™

Page 3 of 7

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

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**

...making excellence a habit.™

Page 4 of 7

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

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)	Symplcity Spyral™ Multi-Electrode Renal Denervation Catheter & Symplcity G3™ Renal Denervation RF Generator	The Symplcity G3™ Renal Denervation RF Generator when used with the Symplcity 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**

...making excellence a habit.™

Page 5 of 7

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

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**

...making excellence a habit.™

Page 6 of 7

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

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**

...making excellence a habit.™

Page 7 of 7

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 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

...making excellence a habit.™

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

...making excellence a habit.™

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

...making excellence a habit.™

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

...making excellence a habit.™

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

...making excellence a habit.™

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), Rociale 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.

...making excellence a habit.™

Page 1 of 5

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

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. Reworking 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.

...making excellence a habit.™

Page 2 of 5

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

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 19 th December 2012 on the certificate history page.

...making excellence a habit.™

Page 3 of 5

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

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.

...making excellence a habit.™

Page 4 of 5

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

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	<p>Certificate Renewal.</p> <p>Added product table per MDP4500 Appendix A.</p> <p>Clarified addresses of subcontractors to exactly align with their ISO certificate name and address.</p> <p>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.</p> <p>Remove Assurant Cobalt product (iliac product scope) it is no longer manufactured and the last product builds expired in April 2019.</p> <p>Remove subcontractors – Admedes Schuessler GmbH, Germany, Flextronics Medical, Austria, Sterigenics, Corona, CA, Synergy Health, Ireland related to removed products above.</p> <p>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.</p>

...making excellence a habit.™

Page 5 of 5

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.

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:

EN ISO 13485:2016
ISO 9001:2015

Scope:

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

Certificate expiry date: 1 July 2021

Certificate effective date: 1 July 2018

Certified since: 1 July 2006

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

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
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 Portugal LDA-
Rua Tomas da Fonseca Torre E, 11
 piso
1600 Lisboa
Portugal

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

Warehousing and distribution of medical devices, including spine
loaner operations

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

Sales, order management and distribution of medical devices.
Including technical service and customer education.
Promotion, invoice and order management of medicinal
products.

Medtronic Danmark A/S.
Arne Jacobsens Allé 17
2300 Copenhagen
Denmark

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

Medtronic Medikal Teknoloji Ticaret Ltd
Sti
Saray Mah. Esnaf Sk.
Akkom Ofis Park Laodik Plaza
Sitesi B Blok Apt: 2/8
00000 Umraniye - Istanbul
Turkey

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

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

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

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 technical service and customer education.

Medtronic Norge AS
Martin Linges vei 25
1364 Fornebu
Norway

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

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

Sales, Order Management and distribution of medical devices Including technical service and 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 Service & Repair CoE
C-Mill gebouw K
Jan Campertstraat 21-A
6416 SG Heerlen

Service and repair of medical devices (excluding Imaging and Navigation products).

Medtronic Ibérica S.A.
Polígono Industrial La Garena
Calle Francisco Rabal 7
28806 Alcalá De Heneras, Madrid
Spain

Spine loaner operations.

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

Warehousing and distribution of medical devices, including spine loaner operations

Medtronic France SAS
27/33 Quai Alphonse Le Gallo
92513 Boulogne-Billancourt
France

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

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

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

Medtronic GmbH
Earl-Bakken-Platz 1
40670 Meerbusch
Germany

Distribution of medical Devices, medical equipment and related services.

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

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

Medtronic (Schweiz) AG
Talstrasse 9
3053 Munchenbuchsee
Switzerland

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

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

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

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

Sales, order management and distribution of medical devices.

Medtronic Hungária Kft.
Bocskai út 134-146
Céptület 3. emelet
1113 Budapest
Hungary

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

Medtronic CCO SSC Warsaw
Polna 11
00-633 Warszawa
Poland

Order management of medical devices.

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 Finland Oy
Lentäjätie 3
01530 Vantaa
Finland

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

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

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

Medtronic Trading Ltd.
10 Hamada Street
4673344 Herzlya
Israel

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

Addendum expiry date: 1 July 2021
Addendum effective date: 1 July 2018