

# 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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## Supplementary Information to CE 84868

Issued To:

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**710 Medtronic Parkway**  
**Minneapolis, MN 55432**  
**USA**

Number	Device Name	Intended purpose per IFU
<b>Class III products under the scope of CE 84868</b>		
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

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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.

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Number	Device Name	Intended purpose per IFU
<b>Class III products under the scope of CE 84868</b>		
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

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<b>Class III products under the scope of CE 84868</b>		
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

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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.

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**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

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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.

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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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 Date: **2019-08-22**  
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**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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**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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**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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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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Subcontractor:	Service(s) supplied
Synergy Health Ireland Ltd (Synergy Health - AST - Ireland) IDA Business & Technology Park Tullamore, Co. Offaly Ireland	<b>E Beam Sterilization</b> <b>ETO Sterilization</b>
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Daventry) Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	<b>E Beam Sterilization</b>
Teleflex Medical Annacotty Business Park Annacotty Co. Limerick Ireland	<b>Manufacture</b>

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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.

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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.

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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 <sup>th</sup> December 2012 on the certificate history page.

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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.

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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>

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# 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.



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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  
Cépfület 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



## Medtronic Trading NL BV

Larixplein 4  
5616 VB Eindhoven  
The Netherlands

Tel + 31 40 7117555  
Fax + 31 40 7117522  
www.medtronic.com

Date: \_\_\_\_\_

**Subject: Notification in The Republic of Moldova**

### **LETTER OF AUTHORIZATION FOR NOTIFICATION PROCEDURE IN MOLDOVA**

#### **TO WHOM IT MAY CONCERN**

We, **Medtronic Trading NL BV** with principal place of business at Larixplein 4, 5616 VB Eindhoven, The Netherlands, hereby confirm that **OXIVIT-MED, SRL**, a Moldovan legal entity, with place of business at Bld. Moscova 14/1., Chisinau, MD-2068, Republic of Moldova, is authorized by the company Medtronic Trading NL BV, to carry out the registration of products manufactured by the following entities of the Medtronic, Inc. group, USA:

*Please refer to the attached Annex listing the Medtronic Legal Manufacturers*

before the competent Moldovan authorities and administrative bodies and to obtain registration certificates for these products. The owner of the registration documents will be Medtronic, Inc.

To implement this task Medtronic, Inc. entrusts the attorney the following rights:

- to act on our behalf (in our name and for our account) in state institutions and organizations responsible for registering medical equipment and medical use products as well as in different legal types of juridical persons that are assigned to expertise specific matter related to registration/re-registration of medical equipment and medical use products
- to conduct negotiations
- to submit documents (materials)
- to sign relevant agreements, applications and any other documents including financial ones
- to introduce changes and amendments into documents, to clarify information and provide additional services
- to make payments related to the registration process
- to receive necessary documents
- to obtain Registration certificates for Medtronic, Inc.

Any and all prior authorization letters granted to OXIVIT-MED, SRL relating to the subject matter hereof are hereby revoked. This authorization letter is valid until **31 May 2020** unless revoked earlier in writing.

**For and on behalf of Medtronic Trading NL BV**

With best regards,

  
~~VP Eastern Europe~~

*E. Leeters*  
*E. Leeters*  
Authorized signatory of Medtronic Trading NL BV

*Annex mentioned*

## 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, Fort 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-Bôt 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, Italy

# Medtronic

44. Invatec S.p.A., 26-28 Via Industria, 25030 Torbole-Casaglia, Brescia, Italy
45. Medtronic Ardian LLC, 1380 Shorebird Way, Mountain View, CA 94043, USA
46. Medtronic Neurosurgery, 125 Cremona Drive, Goleta, CA 93117, USA
47. Medtronic Advanced Energy, LLC, 180 International Drive, Portsmouth NH 03801, USA
48. Vitatron Holding B.V. Endepolsdomein 5, 6229 GW Maastricht, The Netherlands
49. HeartWare, Inc. 14400 NW 60th Avenue, Miami Lakes, Florida 33014, USA
50. BELLCO SOCIETÀ, Unipersonale A r.l., Via Camurana 1, 41037 Mirandola (MO), IT – Italy
51. Medtronic CryoCath LP., 9000 Autoroute Transcanadienne, Pointe Claire, Quebec H9R 5Z8, Canada
52. CardiolInsight Technologies Inc., 11000 Cedar Ave, Suite 210, Cleveland, OH 44106
53. Medtronic Vascular Inc., 271 Gibraltar Drive, Sunnyvale, CA 94089
54. Teleflex Medical, Annacotty Business Park, Annacotty, Co. Limerick, Ireland
55. TYRX Inc., 1 Deer Park Dr. Suite G Monmouth Junction, NJ 08852
56. HeartWare Inc., 500 Old Connecticut Path Framingham, MA 01701
57. Medtronic Sofamor Danek Inc., Airport Logistics Center, Building "A", 4340 Swinnea Road, Memphis, TN 38118, USA
58. Medtronic Monitoring Inc., 1410 Energy Park Dr. Saint Paul, MN 55108
59. Medtronic Vascular, 3850 Brickway Blvd, Santa Rosa, CA 95403 USA
60. Osteotech, Inc., 201 Industrial Way, Eatontown, New Jersey, 07724, USA
61. Medtronic Spine LLC, 1860 Barber Ln, Milpitas, CA 95035
62. Changzhou Kanghui Medical Innovation 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, Ireland
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