

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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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 |

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| 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 |

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|---|--|--------------------------|
| 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 |

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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) | Symlicity Spyral™ Multi-Electrode Renal Denervation Catheter & Symlicity G3™ Renal Denervation RF Generator | The Symlicity G3™ Renal Denervation RF Generator when used with the Symlicity 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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| 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:

Certificate No: **CE 84868**
Date: **2019-08-22**
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| 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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| 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 | 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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| 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. |

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|-----------------|------------------|--|
| 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 th December 2012 on the certificate history page. |

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|-----------------|------------------|---|
| 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> |

BSI
CE CERTIFIKATAS - Pilnas Kokybės Užtikrinimas

Nr. CE 84868
Kam išduota:

Medtronic, Inc
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Apimami produktai:
endoluminalinių stentgraftų ir endovaskulinių įvedimo sistemų, stentgraftų balioninių kateterių, koronarinių stentų įvedimo sistemų, intravaskulinių kateterių, kateterių sistemų renalinei denervacijai ir kraujagyslinių introduuserių kūrimas, projektavimas ir gamyba.

Remiantis mūsų atliktais kokybės sistemos patikrinimais pagal Europos Tarybos Direktyvą 93/42/EEC, Priedą II, išskyrus 4 sekciją. Kokybės užtikrinimo Sistema atitinka Direktyvus reikalavimus. III klasės produktų pateikimui į rinką reikalingas pagal Priedą II išduotas sertifikatas

Britų Standartų Institutas - įgaliota ir Notifikuotoji įstaiga aukščiau minėtai Direktyvai (Notifikuotos įstaigos numeris 2797) (parašas)

Gary E Slack, vyresnysis viceprezidentas medicinos prietaisams

Pirmoji sertifikavimo data: 2004 m. rugpjūčio 24 d.

Šio sertifikato data: 2019 m. rugpjūčio 22 d. Galioja iki: 2024 m. gegužės 26 d.
(rekvizitai)