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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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.

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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
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.

EC Design-Examination Certificate

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

No. **CE 596967**

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

In respect of:

Export Advance Aspiration Catheters

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2013-04-22** Date: **2019-03-06** Expiry Date: **2023-04-21**

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EC Design-Examination Certificate

Supplementary Information to CE 596967

Issued To:

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

Product Listing: Export Advance™ Aspiration Catheter

Description	**Model No.**
6 French Export Advance Catheter (Using Stylet tip without a coil)	ADVANCECE

First Issued: **2013-04-22** Date: **2019-03-06** Expiry Date: **2023-04-21**

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bsi.

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EC Design-Examination Certificate

Supplementary Information to CE 596967

Issued To:

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

Certificate History

Date	Reference Number	Action
22 April 2013	10140717	First Issue
06 October 2015	10157079	Dupont Tyvek Change.
28 October 2015	10158164	Design modifications to the dual lumen section of the Export Advance aspiration catheter.
29 January 2018	8868105	Certificate renewal. Removal of Model No. ADVANCECET.
Current	8786554	Traceable to NB 0086.

First Issued: **2013-04-22** Date: **2019-03-06** Expiry Date: **2023-04-21**

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Declaration of Conformity

DAN-DOC-020

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA
EC Authorized Representative	Medtronic Ireland Parkmore Business Park West Galway, Ireland
Design Facility:	Medtronic Vascular 37A Cherry Hill Drive Danvers, MA 01923 USA
Manufacturing Facility:	Medtronic Vascular 37A Cherry Hill Drive Danvers, MA 01923 USA
Product Family:	**Export Advance™ Aspiration Catheter**
Products:	See Attached Product Listing
Classification:	Class III, Rule 7
Notified Body:	BSI (Identification No. 2797)
EC Full Quality Certificate:	CE596966 (Annex II, Section 3)

EC Design Examination Certificate: CE596967 (Annex II, Section 4)

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of Directive 93/42/EEC (MDD), including amendments issued, which apply to them, as transposed into the national laws of the EU member states.

This declaration is supported by a conformity assessment according to Annex II, section 3 & 4 of Council Directive No 93/42/EEC as well as the EC Design Examination Certificate listed above.

Medtronic

Signed on behalf of the manufacturer exclusively responsible for the declaration of conformity:

Place: *Medtronic Vascular Danvers* Date: 14-Mar-2019

Name: *Nisarg Shah*

Title *Manager, Regulatory Affairs* Signature:

Medtronic

DAN-DOC-020

Product Listing: ***Export Advance™ Aspiration Catheter***

Description	**Model No.**
6 French Export Advance Catheter *(Using Stylet tip without a coil)*	ADVANCECE

Medtronic

Attachment 2

The below mentioned Standard(s) apply to all the product(s) mentioned on the applicable CE Mark certificate.

Standard Number	Description
EN ISO 13485:2016	Quality Management Systems – Requirements for Regulatory Purposes

Medtronic

Revision History

Revision	Date	Description of Change
00	March 21, 2013	New Product - Export Advance™ catheter
01	August 31st, 2015	Change EC Authorized Rep street address from Parkmore Industrial Estate to Parkmore Business Park West. Add attachment 2.
03	October 6, 2017	Update the DoC to revise the name and title of the person approving the Declaration of Conformity
04	April 24, 2017	Update to remove ADVANCECET from model listing
05	14-Mar-2019	1-Brexit- BSI has opened an office in The Netherlands, which operates under its own NB number (2797). Migrating current certificates from BSI UK to BSI NL is an administrative process where the cert number is retained but will now be issued from BSI NL. 2-ISO 13485- Update year from 2012 to 2016. Full compliance. Medtronic have been audited in Jun 2018 for ISO 13485: 2016 compliance. All Medtronic quality system procedures have been updated to this new standard. There were no product changes because of this standard change.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 039709 1317 Rev. 00

Manufacturer:

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

Product:

Catheters for Single Use
Guiding Catheters for Coronary and Peripheral Use

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713180071

Valid from: 2020-03-18
Valid until: 2023-05-25

Date, 2020-03-18

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 039709 1317 Rev. 00

Model(s):

Zuma (6-9F) Guiding Catheter
Z2 (5-8F) Guiding Catheter
Launcher (5-8F) Guiding Catheter
5F Sherpa NX Active Guiding Catheter
6F Sherpa NX Active Guiding Catheter
6F Sherpa NX Balanced Guiding Catheter
7F Sherpa NX Balanced Guiding Catheter
8F Sherpa NX Balanced Guiding Catheter
6F Taiga Guiding Catheter

Parameter:

Model Number	Designation	Variables
1 2XXXXXXXX 1.1 1.2 ZMYXXXXXXX ZSYXXXXXXX ZTYXXXXXXX Z2YXXXXXXX LAYXXXXXXX SAYXXXXXXX SBYXXXXXXX TA6XXXXXXX	**First two digits designate the model of Guide Catheter (Example: LA8JR40SH).**	ZM: Zuma Guiding Catheter ZS: Zuma Flexible Segment ZT: Zuma Tungsten Ring Z2: Z2 Guiding Catheter LA: Launcher Guiding Catheter SA: Sherpa NX Active SB: Sherpa NX Balanced TA: Taiga Guiding Catheter
Y	**Y designates the French Size**	5 = 5 French 6 = 6 French 7 = 7 French 8 = 8 French 9 = 9 French

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

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 039709 1317 Rev. 00

XXXXXXX	**XXXXXXX designates the curve shape and size***	**Major curves:** JL = Judkins Left JR = Judkins Right AL = Amplatz Left AR = Amplatz Right MB = Multiple Purpose FL = Femoral Left FR = Femoral Right HS = Hockey Stick DC = Doctor's Choice SR = Short right SL = Short Left IMA = International Mammary Artery EBU = Extra Backup LCB = Left Coronary Bypass RCB = Right Coronary Bypass JCL = Judkins Coronary Left JCR = Judkins Coronary Right SAR = Short Amplatz Right SAL = Short Amplatz Left SCR = Shepard's Cook Right RDC = Renal Double Curve PK1 = Renal Curve MPH = Hockey Stick MP1 = Multipurpose Curve MB1 = Multipurpose Curve MB2 = Multipurpose Curve MAC = Multi-Aortic Curve ARANI, BONRT, BOUL, ECR, MRADIAL, LARA, RAD, 3DRIGHT, 3DRC, IMA, CHAMP, EL GAMAL, NOTO, MPIK, MBXT, MP2, MRADIAL, MULTIA, PK1W, MPHK, RDCK, RICA, RRAD, RB, RBU, PER, STRAIGHT, WHB, RDND1K, IMAK

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

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 039709 1317 Rev. 00

***Curve Sizes:** Vary from 0.5 to 6.5 for different curves.
Other Size Variables:

- **Shaft length:** 30 – 130 cm (Letter added to item number), Standard Length is 100 cm. Suffix: A = 110cm, B = 95cm, C = 51cm, D = 90cm, E = 85cm, F = 80cm, H = 70cm, I = 65cm, J = 60cm, K = 55cm, L = 50cm, M = 88cm, N = 30cm, Q = 93cm, R = 75cm, T = 35cm, U = 40cm, V = 45cm, W = 47cm.

Shaft length:
-5F & 6F Launcher guide: 30 - 130 cm
-7F & 8F Launcher guide: 30 – 120 cm
-5F Sherpa NX /6F Sherpa NX Active & Balanced: 30 - 130 cm
-7F & 8F Sherpa: 30 – 120 cm
-ZUMA, ZUMA II, and Taiga : 30 - 120 cm

Sideholes: Optional (SH added to item number).

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

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TÜV®

144876-19-04-08

EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

CE Certiso Ltd. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

PulseCath B.V.

Headquarters: **Nieuwe Stationsstraat 20, 14th floor, 6811 KS Arnhem, The Netherlands**

Scope:

Catheter based ventricular circulatory support device and accessories

The certificate covers the following devices:

Name of the device	Intended use	Type	Model	Risk class
Catheter based left ventricular circulatory support device and accessories	circulatory support	LV17	PulseCath iVAC2L	III*

*In case of devices in Class III, this certificate independently does not authorize the manufacturer for the use of CE mark on the devices.

This certificate is valid only in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 65-CE-181101

Issue: 1
Issued: 08 April 2019
First issued: 08 April 2019
Start date of certified status: 08 April 2019

Expires:
07 April 2024

Valter PAPP, Dr.
General Manager

CE Certiso Ltd. NB2409 Notified Body

CE Certiso Ltd.
H-2040 Budaörs, Gyár u. 2.
Tel.: +36 23 880 830 / Fax: +36 23 880 831 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409

144877-19-04-08

EC DESIGN-EXAMINATION CERTIFICATE

Directive 93/42/EEC on Medical devices, Annex II (4)

CE Certiso Ltd. (NB 2409) certifies that the design of the device concerning to the listed devices and device categories conforms to the requirements of the directive.

Name of the manufacturer:

PulseCath B.V.

Headquarters: **Nieuwe Stationsstraat 20, 14th floor, 6811 KS Arnhem, The Netherlands**

Scope:

Catheter based ventricular circulatory support device and accessories
LV17

The certificate covers the following devices:

Name of the device	Intended use	Type	Model	Risk class
Catheter based left ventricular circulatory support device and accessories	circulatory support	LV17	PulseCath iVAC2L	III

This certificate is valid only with the system certificate No. **144876-19-04-08**, in case of successfully conducted annual surveillance audits.

ID number of the related design examination report: 65-G1-181101

Issue: 1
Issued: 08 April 2019
First issued: 08 April 2019
Start date of certified status: 08 April 2019

Expires:
07 April 2024

Valter PAPP, Dr.
General Manager

CE Certiso Ltd.
NB2409
Notified Body

CE Certiso Ltd.
H-2040 Budaörs, Gyár u. 2.
Tel.: +36 23 880 830 / Fax: +36 23 880 831 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate number: 145185-22-02-06

Name of certified organisation:

Pulsecath B.V.

Headquarters:

Nieuwe Stationsstraat 20, 14th floor, 6811 KS Arnhem, The Netherlands

Scope:

Design, manufacture, sales and distribution of heart and circulatory support systems and accessories

CE Certiso Kft. certifies that the quality management system applied by the organisation above meets the requirements of the following standard on the listed scope:

MSZ EN ISO 13485:2016
(ISO 13485:2016)

CE Certiso
Orvos- és Kórháztechnikai
Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

Issue: 1
Issued: 06 February 2022
First issued: 06 February 2022
Start date of certified status: 01 February 2014

Valter PAPP, dr.
General Manager

Expires:
05 February 2025

ISO 13485

NAH-4-0136/2019
MANAGEMENT SYSTEM CERTIFICATION BODY

M0985

CE Certiso Kft.
H-2092 Budakeszi, Erdő utca 101.
Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu

Design Dossier

Type	:	DD
Title	:	**Statement of Conformity**
Document No	:	DD LV17 6.1
Revision	:	5
Date of Issue	:	24 May 2022

Approved TT	:	25-May-2022	25-May-2022
Date of approval	:	Marc Klinkhamer Marc Klinkhamer (May 25, 2022 07:28 GMT+2)	O. Ma[illegible] (May 25, 2022 08:23 GMT+2)

Changes:

Rev 5: update to mention the PTFE insertion tubing

Rev 4: update of the Declaration after recertification of the product; change of certification numbers.

Rev 3: terminology on page 2 “Authorized Representative” changed in “signatory” in order to prevent confusion.

Rev 2: PTFE insertion tubing added to product list.

Rev 1: first review and approval of the product; in connection with the re-location of the company to Arnhem the new address specified.

DECLARATION OF CONFORMITY

iVAC 2L

We hereby declare that the distributed CE-marked product, specified in the annexed product list, conform to the type(s) covered by the EC Design Examination Certificate, reference number 144877-19-04-08, issued for the first time on 8 April 2019 and delivered by CE Certiso Ltd. Hungary, Notified Body Identification Number 2409, in accordance with Annex II excluding (4) of the European Directive on Medical Devices (Council Directive EC DIR 93/42/EEC of June 14th concerning Medical Devices)

In addition, we ensure and declare that the distributed CE-marked products, as mentioned, falling in Risk Class III, meet the provisions of the European Medical Device Directive, which apply to them.

This declaration is based on the application of a Quality Management System approved for the manufacture and final inspection of the products concerned, in accordance with Annex V of the European Medical Device Directive on Medical Devices. The conformity of the Product Quality Assurance set out in Annex V, coupled with the procedure set out in Annex II, is described in the EC Certificate for Full Quality Assurance System, reference number 144876-19-04-08, issued for the first time on 8 April 2019 and delivered by CE Certiso Ltd.

This Declaration of Conformity covers the iVAC 2L (LV17) as specified in the product list attached to this declaration, and is valid for all products concerned bearing the CE-mark and manufactured at the following address:

PulseCath B.V.

Nieuwe Stationsstraat 20

K1401

6811 KS ARNHEM

The Netherlands

Signatory: O. Malchin (May 25, 2022 08:23 GMT+2)

Oren Malchin

Acting CEO

PulseCath B.V.

Arnhem, date: 25-May-2022

Annex: Product List

PRODUCT LIST

This product list belongs to the Declaration of Conformity and specifies the CE-marked products concerned that PulseCath B.V. intends to distribute in conformity with the provisions of the European Directive on Medical Devices (Council Directive EC DIR 93/42/EEC of June 14th concerning Medical Devices). The following list identifies the products by name, article number and the first lot number.

Product name	Article number	First Lot number
PulseCath iVAC 2L (17Fr.) (Class III)	LV17	03B13001

- LV17 catheter with insertion set
- PTFE insertion tubing
- Membrane Pump
- Catheter Protector

The PulseCath iVAC 2L is a catheter based left ventricular circulatory support device.

DD LV17 6 1-5 Declaration of Conformity

Final Audit Report 2022-05-25

Created:	2022-05-24
By:	Bastiaan Vliegenthart (bastiaan.vliegenthart@propharmagroup.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAACcTXR2hUxyCstBmWszxe4t_opQh0QzpM

"DD LV17 6 1-5 Declaration of Conformity" History

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Agreement completed.
2022-05-25 - 6:23:33 AM GMT

EC Certificate - Full Quality Assurance System

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

No. **CE 01906**

Issued To: **Fiab SpA**
Via P. Costoli, 4
Vicchio
Firenze
50039
Italy

In respect of:

The design, development and manufacture of sterile leads for transoesophageal cardiac and temperature monitoring, cardiac stimulation, cardiac defibrillation and electrophysiological studies; percutaneous introducers; electronic equipments for oesophageal temperature monitoring, electrophysiological studies and emergency cardiac stimulation; sterile and non sterile electrosurgical electrodes and related accessories; electrodes for defibrillation/pacing; sterile single use neuropacers; sterile single use and reusable electrocauteries and associated accessories; sterile and non sterile, single use and reusable needle electrodes for EEG and EMG.

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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **1998-05-11** Date: **2018-05-10** Expiry Date: **2023-05-10**

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