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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 1277 Rev. 00

Manufacturer:

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

Product:

Cardiac Ablation Catheters
Intracardiac Electrode Ablation Catheters

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.: 713158392

Valid from: 2020-05-11
Valid until: 2024-05-26

Date, 2020-05-11

Christoph Dicks
Head of Certification/Notified Body

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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 1277 Rev. 00

Model(s):

RF CONDUCTR
RF CONTACTR
RF ENHANCR II
RF MARINR
RF MARINR Unipolar

Parameter:

RF CONDUCTR	0786042, 0786044, 0787533, 0787544, 07887533, 07887544, 07886042, 07886044
RF CONTACTR	70256034, 70257533, 70286034, 70287533
RF ENHANCR II	31744523, 31745523, 31745533, 39745533, 39746534
RF MARINR	075302, 075312, 075402, 075405, 076514, 076515, 076583, 076584, 076585, 076586
RF MARINR Unipolar	075802

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(TUV logotipas)

CE SERTIFIKATAS

Kokybės užtikrinimo sistemos pagal
Medicininių prietaisų direktyvos 93/42/EEC, Priedas II išskyrus(4)
III klasė
Nr. G7 0397091277 Rev.00

Gamintojas: **Medtronic Inc.**
710 Medtronic Parkway N.E.
Minneapolis MN55432
USA

Produktų kategorijos: **Širdies abliacijos kateteriai,**
Intrakardiniai elektrodai abliacijos kateterims

Sertifikavimo organizacija TUV SUD užtikrina, kad aukščiau paminėtas gamintojas įgyvendino kokybės vadybos sistemos reiklavimus kuriant, gaminant ir tikrinant išvardintų gaminių atitikimą medicininių prietaisų direktyvos 93/42/EEC Priedo II reikalavimams ir yra prižiūrima . III klasės gaminių pardavimui reikalingas papildomas sertifikatas pagal Priedą II (4). Taip pat žiūrėkite pastabas kitame puslapyje.

pranešimo Nr.: **713158392**
Galioja nuo: **2020-05-11**
Galioja iki: **2024-05-26**

(parašas) **(logotipas)**

Data, 2020-05-11 **Christoph Dicks**

TUV SUD produktų priežiūros yra įgaliotas atstovas, patvirtinantis atitikima medicininių prietaisų direktyvos 93/42/EEC sąlygoms, identifikavimo nr. 0123

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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 1325 Rev. 00

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

Product: **Catheters for Single Use Diagnostic Catheter**

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.: 713158388

Valid from: 2020-04-28
Valid until: 2024-05-26

Date, 2020-04-28

Christoph Dicks
Head of Certification/Notified Body

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 1325 Rev. 00

Model(s):

Soloist
StableMapr
Torqr
Marinr

Parameters:

Model name	Model Numbers:
Soloist	441016U
	441016JF
	44216U
	44216J
	44216JF
	44516U
	44516UB
	44516J
	448142J
	448142CL

Model name	Model Numbers:
StableMapr	04401SM
	04402SM

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EC Certificate

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

No. G7 039709 1325 Rev. 00

Model name	Model Numbers:
Torqr	04120DS
	04130DS
	04122UM
	04122JM
	04125UM
	04125JM
	041002UM
	041002JM
	041005UM
	041005JM
	041005DM
	041010UM
	041010JM
	041565CS
	041590CS
	041890CS
	041865CS

Model name	Model Numbers:
Marinr	043302M
	043325M
	043328M
	072302
	072322M
	072402

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Quality System Approval Certificate
Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Medtronic Inc.

710 Medtonic Parkway
Minneapolis
MN 55432
USA

to the Product Family

Electrophysiology cardiac catheter, single use (Achieve Mapping Catheter)

GMDN Code: 46355

on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex II, excluding (4)

*The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product family is hereby authorised.*

Registration Number:	**252.1064**
Original Approval:	**24 August 2010**
Last Amended on:	**4 February 2020**
Remains valid until:	**26 May 2024**

Signed:

Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

Medtronic

DECLARATION OF CONFORMITY
European Medical Device Directive 93/42/EEC

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA Tel. +1 763-514-4000
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands Tel: 31-45-566-8000

Device Name(s)/ Model Number(s)/Class:

Device Name	Model Number	Classification / Rule
Achieve Advance™ Mapping Catheter	2ACH15, 2ACH20, 2ACH25	Class III / Rule 7

Conformity Assessment Route:	Medical Devices Directive (93/42/EEC) Annex II (4), Full Quality Assurance System
Certificate(s) number(s):	EC Design Examination: G7 039709 1248 Rev. 00 EC Full Quality Assurance: G1 039709 1243 Rev. 00
Notified Body (or Quality System Registrar):	TUV SUD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Notified Body Number:	0123
Standards Applied:	Harmonized Standards per Essential Requirements Checklist

Statement

We, the manufacturer, hereby declare that the above-mentioned products comply with the European Medical Device Directive 93/42/EEC, including amendments issued. All supporting documentation is retained under the premises of the manufacturer.

Approval

Place:	Minneapolis, MN, USA
Date of Declaration validity:	***Refer to Effectivity Date in the electronic documentation system***
Name & Title:	***Refer to electronic signature***
Signature & Date:	***Refer to electronic signature***

Non-electronic signature and date available upon request

Medtronic

DECLARATION OF CONFORMITY
European Medical Device Directive 93/42/EEC

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Manufacturer:	Medtronic CryoCath LP 9000 Autoroute Transcanadienne Pointe-Claire, Quebec, H9R 5Z8 Canada
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands Tel: 31-45-566-8000

Device Name(s)/ Model Number(s)/Class:

Device Name	Model Number	Classification / Rule
Coaxial Umbilical Cable	203CX, 203CXC	Class I / Rule 1
Electrical Umbilical Cable	2035U, 2035UC	Class I / Rule 1
Manual Retraction Kit	20MRK	Class I / Rule 1

Conformity Assessment Route:	Medical Devices Directive (93/42/EEC) Annex II without II.4, Full Quality Assurance System
Certificate(s) number:	EC Full Quality Assurance: G1S 074486 0026 Rev. 00
Notified Body:	TUV SUD Product Service GmbH Ridlerstrasse 65 80339 Munich Germany
Notified Body Number:	0123
Standards Applied:	Harmonized Standards per Essential Requirements Matrix

Statement

We, the manufacturer, hereby declare that the above-mentioned products comply with the European Medical Device Directive 93/42/EEC, including amendments issued. All supporting documentation is retained under the premises of the manufacturer.

Approval

Place:	Pointe-Claire, QC, Canada
Date of Declaration validity:	***Refer to Effectivity Date in the electronic documentation system***
Name & Title:	***Refer to electronic signature***
Signature & Date:	***Refer to electronic signature***

Non-electronic signature and date available upon request

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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 074486 0030 Rev. 00

Manufacturer:

Medtronic CryoCath LP
9000 Autoroute Transcanadienne
Pointe-Claire QC H9R 5Z8
CANADA

Product:

Cardiac Ablation Catheters
Freezor® MAX Cardiac Cryoablation Catheters

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.: 72151886

Valid from: 2020-03-19
Valid until: 2024-05-26

Date, 2020-03-19

Christoph Dicks
Head of Certification/Notified Body

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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 074486 0030 Rev. 00

Model(s): **9F Catheters for Cryoablation - (209F3, 209F5)**

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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 074486 0033 Rev. 00

Manufacturer:	**Medtronic CryoCath LP** 9000 Autoroute Transcanadienne Pointe-Claire QC H9R 5Z8 CANADA
Product:	**Cardiac Ablation Catheters** **Freezor® Xtra Cardiac Cryoablation Catheters**
Model(s):	**7F Catheters for Cryoablation - (217F1, 217F3, 217F5)**
Parameter:	./.

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G7 074486 0033 Rev. 00

Report no.:	72160836
Valid from:	2021-04-30
Valid until:	2024-05-26

Date, 2021-04-30

Christoph Dicks
Head of Certification/Notified Body

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

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TÜV SÜD Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1385 Rev. 00

Manufacturer:

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

SRN Manufacturer: US-MF-000019977

Authorized Representative:

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 039709 1385 Rev. 00

Report No.: 713203024

Valid from: 2022-03-23
Valid until: 2027-03-22

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-03-23

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TÜV SÜD Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1385 Rev. 00

Classification:	III
Device Group:	C020302 - ARRHYTHMOGENIC FOCI CRYOENERGY ABLATION LEADS
Basic UDI-DI:	0763000B000038783
Intended Purpose:	The intended purpose of the Freezor family cardiac cryoablation catheters is to ablate arrhythmogenic sites in the heart by applying cryoenergy to cardiac tissue for the treatment of cardiac arrhythmias. In addition, the Freezor family catheters can detect electrical signals from multiple electrodes for evaluation on an electrophysiology (EP) recording system and to use for cardiac stimulation during electrophysiology studies.
Device(s):	Freezor Article/Model Numbers - 207F1 - 207F3 - 207F5 Freezor MAX Article/Model Numbers - 209F3 - 209F5 Freezor Xtra Article/Model Numbers - 217F1 - 217F3 - 217F5
The validity of this certificate depends on conditions and/or is limited to the following:	./.

-

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Medtronic

DECLARATION OF CONFORMITY
European Medical Device Directive 93/42/EEC

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Manufacturer:
Medtronic CryoCath LP
9000 Autoroute Transcanadienne
Pointe-Claire, Quebec, H9R 5Z8
Canada

Authorized Representative:
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel: 31-45-566-8000

Device Name(s)/ Model Number(s)/Class:

Device Name	Model Number	Classification / Rule
Auto Connection Box	2037A	Class I, Rule 1
ECG Cable	2035W	Class I, Rule 1
Foot Switch	104FS	Class I, Rule 1
N_2O Refrigerant Tank	103NE, 124NE (Empty)	Class I, Rule 1
Power Cords	1038D, 1038E, 1038SW, 1038U, 1038Y	Class I, Rule 1
Scavenging Hoses	1035C, l035D, 1035E, 1035F, 1035G, 1035H,1035CW, 1035DW, 1035EW, 1035FW	Class I, Rule 1
Adapters	1036L, 1036M, 1036N	Class I, Rule 1
Wrench	1036W	Class I, Rule 1

Conformity Assessment Route: Medical Devices Directive (93/42/EEC) Annex VII, Full Quality Assurance System

Certificate(s) number: MDSAP and ISO 13485:2016, Approval Certificate Number: 0078106

Notified Body:
Lloyd's Register Quality Assurance
1 Trinity Park, Bickenhill Lane
Birmingham, UK B37 7ES

Notified Body Number: 0088

Standards Applied: Harmonized Standards per Essential Requirements Matrix

Statement
We, the manufacturer, hereby declare that the above-mentioned products comply with the European Medical Device Directive 93/42/EEC, including amendments issued. All supporting documentation is retained under the premises of the manufacturer.

Approval

Place: Pointe-Claire, QC, Canada

Date of Declaration validity: ***Refer to Effectivity Date in the electronic documentation system***

Name & Title: ***Refer to electronic signature***

Signature & Date: ***Refer to electronic signature***

Benannt durch/Designated by
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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 1312 Rev. 00

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

Product: **Cardiac Ablation Catheters**
Arctic Front Cardiac Cryoablation Catheters

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.: 72153945

Valid from: 2020-03-19
Valid until: 2024-05-26

Date, 2020-03-19

Christoph Dicks
Head of Certification/Notified Body

As a registered Notary Public for the State of Minnesota, I hearby certify that this is a true and accurate copy of the original document. The original is filed at Medtronic Inc.

VLADIMIRA GREGORSKI
Notary Public
State of Minnesota
My Commission Expires
January 31, 2022

April 12, 2021

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EC Certificate

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

No. G7 039709 1312 Rev. 00

Model(s): **Arctic Front Advance Cardiac Cryoablation Catheters (2AF233, 2AF283)**

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Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1389 Rev. 00

Manufacturer:	**Medtronic, Inc.** 710 Medtronic Parkway Minneapolis, MN 55432 USA
SRN Manufacturer:	US-MF-000019977
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 039709 1389 Rev. 00

Report No.:	713215011
Valid from:	2022-02-14
Valid until:	2027-02-13

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-02-14

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Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039709 1389 Rev. 00

Classification:	III
Device Group:	C0502 - CARDIOVASCULAR INTRODUCER SHEATHS, VALVED
Basic UDI-DI:	0763000B00004317D
Intended Purpose:	The intended purpose of FlexCath Advance steerable sheath is to provide percutaneous introduction into the vasculature and chambers of the heart, and to facilitate positioning of compatible devices.
Device(s):	FlexCath Advance - 4FC12
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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bsi.

By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 747884 R000

Manufacturer: Fiab SpA

Address:
Via P. Costoli, 4
Vicchio
Firenze
50039
Italy

Single Registration Number: IT-MF-000005988

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-11-17**

Current Issue Date: **2023-04-06**

Starting Validity Date: **2023-04-06**

Expiry Date: **2026-11-16**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 747884 R000

Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Esophageal temperature monitoring system, including sterile probes and connecting cables.	Intended for the continuous detection, measurement and visualization (in °C) of esophageal temperature. The intended environments of use are operating rooms and interventional electrophysiology rooms.
External cardioversion defibrillation electrode pads.	The disposable multifunction electrodes FIAB EURODEFIPADS® are indicated for: • Transthoracic external defibrillation. • Transthoracic synchronized cardioversion. • Transthoracic ECG Monitoring. • Temporary transthoracic cardiac pacing (non-invasive). FIAB disposable multifunction electrodes allow the user to effectively operate in the treatment of rhythm disorders related to the above-mentioned applications, without the risk of accidental electrocution related to the use of normally available reusable paddles.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Accessories for oxygentherapy and aerosoltherapy.	Class IIa
Non implantable cardiac stimulators – hardware	Class Is
Cleaning pads and holsters for electrosurgery	Class Is
Accessory for percutaneous dilator sheaths	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-11-17	3415341	Issued
2023-01-23	3792161	Amended – Removal of subcontractor pages. Supplemented – addition of device group "Esophageal temperature monitoring system, including sterile probes and connecting cables". Supplemented – addition of device category "Accessories for oxygentherapy and aerosoltherapy.".
Current	3872133	Supplemented – addition of device group "External cardioversion defibrillation electrode pads.".

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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