ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 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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BS-MDR-099

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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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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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

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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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