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
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 1379 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 1379 Rev. 00

Report No.: 713190982

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 1379 Rev. 00

Classification:	III
Device Group:	C020302 - ARRHYTHMOGENIC FOCI CRYOENERGY ABLATION LEADS
Basic UDI-DI:	0763000B00000256W
Intended Purpose:	To ablate cardiac tissue in the left atrium
Device(s):	Arctic Front Advance Article/Model Numbers - 2AF233 - 2AF283 Arctic Front Advance Pro Article/Model Numbers - AFAPRO23 - AFAPRO28
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

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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Product Service

EU Quality Management System Certificate (MDR)

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

No. G12 039709 1406 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 established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system 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 conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System 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:G12 039709 1406 Rev. 00

Report No.: 72172299

Valid from: 2022-03-28
Valid until: 2027-03-27

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-03-28

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

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

No. G12 039709 1406 Rev. 00

Classification:	III
Device Group:	C0502 - CARDIOVASCULAR INTRODUCER SHEATHS, VALVED
Intended Purpose:	The intended purpose of FlexCathAdvance Steerable Sheath is to provide percutaneous introduction into the vasculature and chambers of the heart, and to facilitate positioning of compatible devices.
Classification:	III
Device Group:	C02010499 - ARRHYTHMOLOGY MULTIPOLAR LEADS - OTHER
Intended Purpose:	To collect intracardiac electrograms from multiple electrodes for evaluation on an electrophysiology (EP) recording system and to use for cardiac stimulation during electrophysiology studies. The mapping catheter is compatible for use with, and may be used to support and position, all catheters in the Medtronic Arctic Front family of cardiac cryoablation catheters.
Classification:	III
Device Group:	C020302 - ARRHYTHMOGENIC FOCI CRYOENERGY ABLATION LEADS
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.
Classification:	III
Device Group:	C020302 - ARRHYTHMOGENIC FOCI CRYOENERGY ABLATION LEADS
Intended Purpose:	The intended purpose of the Arctic Front family of cardiac cryoablation catheters is to ablate cardiac tissue in the left atrium.
The validity of this certificate depends on conditions and/or is limited to the following:	-

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Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 039709 1402 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 established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system 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 conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. 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:G11 039709 1402 Rev. 00

Report No.: 72172299

Valid from: 2022-05-30
Valid until: 2027-05-29

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-05-30

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Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 039709 1402 Rev. 00

Classification:	I
Device Group:	C0280 - ARRYTHMOLOGY DEVICES - ACCESSORIES NOT INCLUDED IN OTHER CLASSES
The validity of this certificate depends on conditions and/or is limited to the following:	-

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EU MDR Declaration of Conformity (DoC)

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis MN 55432 USA

Product	Manufacturing facilities
Coaxial umbilical	**Medtronic Mexico** Medtronic Mexico S. De R.L.De C.V. Av. Paseo Cucapah 10510 El Lago Tijuana Baja California, Mexico C.P. 22210
Electrical umbilical	**CEA Global Dominicana d.b.a** **Nissha Medical Technologies** Zona Franca Industrial San Pedro De Macoris, DO 21000 Dominican Republic

Manufacturer SRN: US-MF-000019977

Authorized Representative:

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

Authorized Representative SRN: NL-AR-000006050

Notified Body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Munich, Germany
Notified Body number: 0123

Conformity Assessment Certificate(s): Full Quality Assurance - G11 039709 1402

Conformity Assessment Procedure: Annex IX, Chapter 1
Risk Class: Class 1 -Sterile

Classification Rule: Rule 1

Intended Purpose:

Device Name	Intended Purpose
Coaxial umbilical	The coaxial umbilical is used to deliver the nitrous oxide (N_2O) gas from the CryoConsole to the catheter and to transport refrigerant vapors from the catheter back to the CryoConsole, which is vented into the hospital scavenging system.
Electrical umbilical	The Electrical Umbilical is used to make the electrical connection from the CryoConsole to the catheter (via the auto connection box).

Statement:

We, Medtronic, Inc., hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Other Union Legislation(s):

Union Legislation	Applicable Declaration of Conformity Document Number
ROHS 3 Directive 2015/863 on restriction of the use of certain hazardous substances in electrical and electronic equipment (ROHS Directive)	D00275956

Place: Minneapolis

Name: Greg Haider

Title: Post Market Quality Director

Signature:

DocuSigned by:
Greg Haider
Signer Name: Greg Haider
Signing Reason: I approve this document
Signing Time: 15 August 2023 | 07:14 PDT
B45F58EE829A4D5C93C89B1C1C698041

Date:

Products Covered

Product Name	Medtronic Product Identifier CFN	Basic UDI-DI	
Coaxial umbilical	203CX & 203CXC	0763000B00003357G	
Electrical umbilical	2035U &2035UC	0763000B00003367J	

Common Specification(s)

Not applicable

The following common specifications were used to demonstrate conformity:

Revision History

Revision	Date Effective	Description of Change
A	July 2022	Initial release of the document
B	September 2022	Release signed version in MAP Agile
C	Upon approval in MAP Agile	Update to remove GMDN code column and update the manufacturing facility name listed for Electrical Umbilical to align with ISO certificate

EU MDR Declaration of Conformity (DoC)

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
Manufacturer SRN:	US-MF-000019977
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Authorized Representative SRN:	NL-AR-000006050
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich, Germany Notified Body Number: 0123
Conformity Assessment Certificate(s):	Technical Documentation Assessment Certificate: **G70 039709 1379** Quality Management System Certificate: **G12 039709 1406**
Conformity Assessment Procedure:	Annex IX
Risk Class:	Class III
Classification Rule:	Rule 7
Intended Purpose:	The intended purpose of the Arctic Front family of cardiac cryoablation catheters is to ablate cardiac tissue in the left atrium.

Statement:

We, Medtronic, Inc., hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Other Union Legislation(s):

Union Legislation	Applicable Declaration of Conformity Document Number
RoHS 3 Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment	D00275956

Place: ***Refer to electronic signature***

Name: ***Refer to electronic signature***

Title: ***Refer to electronic signature***

Signature: ***Refer to electronic signature***

Date: ***Refer to electronic signature***

Products Covered

Product Name	Medtronic Product Identifier CFN	Basic UDI-DI
Arctic Front Advance™	2AF233, 2AF283	0763000B00000256W
Arctic Front Advance Pro™	AFAPRO23, AFAPRO28	

Common Specification(s)

Not Applicable

Revision History

Revision	Date Effective	Description of Change
A	TBD	Initial release of document

EU MDR Declaration of Conformity (DoC)

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
Manufacturer SRN:	US-MF-000019977
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Authorized Representative SRN:	NL-AR-000006050
Notified Body:	TÜV SÜD Product Service GmbH Certification Body Ridlerstraße 65 80339 München Germany Notified Body Identification Number: 0123
Conformity Assessment Certificate(s):	Technical Documentation Assessment Certificate: G70 039709 1389 Quality Management System Certificate: G12 039709 1406
Conformity Assessment Procedure:	Annex IX chapter II
Risk Class:	Class III
Classification Rule:	Rule 7
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.

Statement:

We, Medtronic, Inc., hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Other relevant Union Legislation(s): None

Place:	Minneapolis, MN
Name:	Refer to electronic signature
Title:	Refer to electronic signature
Signature:	***Refer to electronic signature***
Date:	***Refer to electronic signature***

Products Covered

Product Name	Medtronic Product Identifier	Basic UDI-DI
	CFN	
FlexCath Advance™	4FC12	0763000B00004317D

Common Specification(s)

The following common specifications were used to demonstrate conformity:

Not applicable

Revision History

Revision	Date Effective	Description of Change
A	TBD	Initial release of document