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

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 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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(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

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in class I in sterile conditions, sterilized systems or procedure packs)

No. G1S 074486 0028 Rev. 00

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

Product Category(ies): **Sterile Electrical Umbilicals, Manual Retraction Kit, Sterile CoAxial Umbilicals.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 72152811

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

Date, 2020-05-05

Christoph Dicks
Head of Certification/Notified Body

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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
Coaxial Umbilical Cable	203CX, 203CXC	Class I sterile / Rule 1
Electrical Umbilical Cable	2035U, 2035UC	Class I sterile / Rule 1
Manual Retraction Kit	20MRK	Class I sterile / 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 0028 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 0024 Rev. 00

Manufacturer:

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

Product:

Introducer
FlexCath Advance™ and FlexCath Select™
Steerable sheaths and dilators

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.: 72147943

Valid from: 2019-09-06
Valid until: 2022-12-11

Date, 2019-09-06

Stefan Preiß
Head of Certification/Notified Body

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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 074486 0024 Rev. 00

Facility(ies):

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

Model(s):

Deflectable introducers to facilitate placement of CryoCath Cryoablation Catheters (4FC12, 990065)

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