Number: 2250280CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Medtronic Inc.

710 Medtronic Parkway
Minneapolis, MN 55432
United States Of America
SRN ID.: US-MF-000019977

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2007841CN

Additional certificate: 2250280TD01/ 2250280TD02/2250280TD03/2250280TD04/2250280TD05/ 2250280TD06/2250280TD07/2250280TD08/2250280TD09/2250280TD10/2250280TD11/2250280TD12/ 2250280TD13/2250280TD14/2250280TD15/2250280TD16/2250280TD17/2250280TD18/2250280TD19/ 2250280TD20/2250280TD21/2250280TD22/2250280TD23/2250280TD24
Authorized Representative: Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

[redacted]

Managing Director Principal Certification Manager

First Issued: **15 December 2021** Date: **22 October 2024** Expiry date: **1 December 2026**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

2184-7

Number: 2250280CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

This certificate covers the following device(s) / groups of device(s):

Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools (MDN1203, class Is) **Sterilization method: gamma irradiation**
Group of Devices: Model 6248VAL adjustable valve Model 6230UNI Universal II slitter Model 6232ADJ Adjustable slitter

Class III
Device Name: 6719 - DF-1 Pin Plug Kit
Device Name: 6937 TRANSVENE™
Device Name: Model 6996SQ
Device Name: Epsila EV™ EAZ101 **Device Name:** Epsila EV™ EAZ201
Device Name: Attesta MRI SureScan™ **Device Name:** Sphera MRI SureScan™ **Device Name:** Attesta™ and Sphera™ Programmer SW Application (external), SW043, For Programmers 2090 and 29901
Device Name: CapSure Sense MRI SureScan **Device Name:** CapSureFix Novus **Device Name:** CapSureFix Novus MRI SureScan
Device Name: Sprint Quattro Secure S **Device Name:** Sprint Quattro Secure S MRI SureScan **Device Name:** Sprint Quattro **Device Name:** Sprint Quattro MRI SureScan **Device Name:** Sprint Quattro Secure **Device Name:** Sprint Quattro Secure MRI SureScan
Device Name: Attain Stability™ Quad MRI SureScan™
Device Name: CapSure™ EPI Lead
Device Name: HV Splitter/Adaptor Kit (model 5019)
Device Name: Micra™ Introducer
Device Name: Stylet Kit 6093
Device Name: Rotation Tool Kit, Model 6056
Device Name: Wrench Kit, Model 5873W
Device Name: CapSure® VDD-2 Leads
Device Name: Myocardial Screw-In 5071 Pacing Lead
Device Name: SelectSecure (model 3830)
Device Name: SelectSecure MRI SureScan (model 3830)
Device Name: Lead Introducer Kits

First Issued: **15 December 2021** Date: **22 October 2024** Expiry date**: 1 December 2026**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 2250280CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Class III
Device Name: Attain Ability MRI SureScan
Device Name: Attain Ability Plus MRI SureScan
Device Name: Attain Ability Straight MRI SureScan
Device Name: Attain PERFORMA™ MRI SURESCAN™
Device Name: Attain PERFORMA™ STRAIGHT MRI SURESCAN™
Device Name: Attain PERFORMA™ S MRI SURESCAN™
Device Name: Lead accessory kit, Model 6056M
Device Name: Tunneling Tool
Device Name: Lead Anchoring Sleeve Kit
Device Name: Lead stylet kit
Device Name: Attain Select II + SureValve Delivery System **Device Name:** Attain Command + SureValve Delivery System **Device Name:** Attain Command + SureValve Delivery System Kits **Device Name:** Attain 6227DEF Deflectable Catheter Delivery System **Device Name:** SelectSite C304 Deflectable Catheter System **Device Name:** SelectSite C304-HIS Deflectable Catheter System **Device Name:** C315 Delivery System
Device Name: Lead End Cap Kit **Device Name:** Service Kit **Device Name:** Pin-Plug Kit

Conditions for or limitations to the validity of this certificate:

- For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions

First Issued: **15 December 2021** Date: **22 October 2024** Expiry date**: 1 December 2026**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 2250280CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	15-12-2021	2007841CN107	First Issue
1	21-03-2022	2007841CN108	Revised
2	08-04-2022	2007841CN109	Revised
3	19-07-2022	2007841CN110	Revised
4	29-07-2022	2007841CN111	Revised
5	24-08-2022	2007841CN112	Revised
6	25-11-2022	2007841CN113	Revised
7	02-02-2023	2007841CN113	Revised
8	27-02-2023	2007841CN113	Revised
9	27-05-2023	2007841CN115	Revised
10	12-06-2023	2007841CN116	Revised
11	16-06-2023	2007841CN117	Revised
12	03-07-2023	2007841CN118	Revised
13	21-12-2023	2007841CN122	Revised
14	11-01-2024	2007841CN122	Revised
15	18-01-2024	2007841CN122	Revised
16	07-05-2024	2007841CN129	Revised
17	22-10-2024	2007841CN133	Revised

First Issued: **15 December 2021** Date: **22 October 2024** Expiry date**: 1 December 2026**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

EU MDR Declaration of Conformity (DoC)

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
Manufacturer SRN:	US-MF-000019977
Contract Manufacturing Site:	Donatelle Plastics, Inc. 501 County Road E-2 Extension New Brighton, MN 55112 USA
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Authorized Representative SRN:	NL-AR-000006050
Notified Body:	DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands Notified Body Number: 0344
Conformity Assessment Certificate(s):	2250280CE01 (Quality)
Conformity Assessment Procedure:	Annex IX excluding Chapter II
Risk Class:	Class I Sterile (Class Is)
Classification Rule:	Rule 1
Intended Purpose:	The Medtronic Model 6230UNI universal II and Model 6232ADJ adjustable slitters are intended to facilitate the removal of a Medtronic slittable delivery catheter from a transvenous device.

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
Not Applicable	Not Applicable

Place: Mounds View, MN

Name: Luke Ranta

Title: Engineering Manager Post Market Quality

Signature: [redacted]

Date: 09 MAY 2024

Products Covered

Product Name	Medtronic Product Identifier	Basic UDI-DI	Optional: Additional nomenclature identifier (e.g., EMDN)
	CFN		
Medtronic Model 6230UNI Universal II slitter	6230UNI	0763000B00008928M	C010280
Medtronic Model 6232ADJ Adjustable slitter	6232ADJ	0763000B000091282	

Common Specification(s)

Not Applicable.

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 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 065652 0014 Rev. 00

Manufacturer:

Shenzhen Launch Electrical Co., Ltd.
Building F
Zhonggangxing Industrial Estate
Zhangge Community, Guanlan Street
Longhua New District
518110 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000028780

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G11 065652 0014 Rev. 00

Report No.: GZ2412902

Valid from: 2024-10-18
Valid until: 2029-10-17

[redacted]

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-10-18

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
BS-MDR-099

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
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 065652 0014 Rev. 00

Classification:	Class I
Device Group:	C020280 - TEMPORARY CARDIAC ELECTRICAL STIMULATION DEVICES - ACCESSORIES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2024-10-18	GZ2412902	Initial issuance

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

EC TYPE-EXAMINATION CERTIFICATE

Number: 2007841TE04

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 3
(Other devices than custom made or intended for clinical investigation)

Manufacturer:

Medtronic Inc.

710 Medtronic Parkway
Minneapolis MN 55432
United States Of America

For the product / product category

Active fixation transvenous pacing lead

Documents, that form the basis of this certificate:

Certification Notice 2007841CN, initially dated 1 January 2001
Addendum, initially dated 31 January 2003

DEKRA hereby declares that the type of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Actieve Implantaten', the Dutch transposition of the Directive 90/385/EEC of 20 July 1990 concerning Active implantable medical devices, including all subsequent amendments, based on an examination in accordance with Annex 3 (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex 3 (4) of Council Directive 90/385/EEC of 20 July 1990 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 February 2023
Issued for the first time: 31 January 2003
Reissued: 1 February 2018

[redacted]

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2007841TE04

EC TYPE-EXAMINATION
ACTIVE IMPLANTABLE MEDICAL DEVICES

Active fixation transvenous pacing lead

Issued to:

Medtronic Inc.
710 Medtronic Parkway
Minneapolis MN 55432
United States Of America

This certificate covers the following product(s):

SelectSecure, model 3830 (length 20-110 cm)
SelectSecure MRI™ SureScan™, model 3830 (lead lengths 59, 69, 74 cm)

The product is designed in the facility:

Medtronic, Inc., 8200 Coral Sea Street, Mounds View, MN 55112, USA

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

Initial date: 31 January 2003
Revision date: 1 February 2017

DEKRA Certification B.V.

[redacted]

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

DECLARATION OF CONFORMITY
COMPLIANCE TO MEDICAL DEVICE REGULATION 2017/745

MANUFACTURER:	NAME: SHENZHEN LAUNCH ELECTRICAL CO. LTD. ADDRESS: BUILDING F, ZHONGGANGXING INDUSTRIAL ESTATE ZHANGGE COMMUNITY, GUANIAN STREET, LONGHUA NEW DISTRICT, SHENZHEN 518110, CHINA SRN: CN-MF-000028780
EUROPEAN REPRESENTATIVE:	NAME: SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE) ADDRESS: EIFFESTRASSE 80, 20537 HAMBURG, GERMANY SRN: DE-AR-000000001
MEDICAL DEVICE	ROTATABLE CONNECTOR
MODELS:	5944RL
CLASSIFICATION - *ANNEX VIII*:	CLASS I, RULE 1
EMDN CODE*:*	C020280, TEMPORARY CARDIAC ELECTRICAL STIMULATION DEVICES - ACCESSORIES
BASIC UDI-DI CODE (GMN) :	69474379CompassBP
IDENTIFICATION AND TRACEABILITY:	06947437902535
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX CHAPTER I AND III
INTENDED PURPOSE:	The device is used as part of a temporary cardiac pacing system based on the principle of transmitting electrical signals between the cardiovascular stimulating instrument and the cardiac pacing leads. The device allows real-time continuous and accurate pacing and sensing electrical connection during lead implantation. After the implantation procedure is finished, the device is disconnected and discarded. The rotatable connector is intended to be used with: • Medtronic cardiovascular stimulating instruments • Implanted IS-1 leads • Implanted IS-4/DF-4 leads

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE MEDICAL DEVICE REGULATION 2017/745; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER AND EUROPEAN REPRESENTATIVE.

STANDARDS APPLIED:

IEC60601-1 Edition 3.2 2020-08, IEC 60601-1-2 Edition 4.1 2020-09, ISO 15223-1:2021, ISO 20417: 2021, EN ISO 14971:2019/A11:2021, ISO 14971:2019, ISO 10993-1:2018, ISO 10993-5:2009,

DECLARATION OF CONFORMITY
COMPLIANCE TO MEDICAL DEVICE REGULATION
2017/745

ISO 10993-7：2008+COR 1:2009+AMD 1：2019, ISO 10993-10:2021, ISO 10993-23:2021,
IEC 60601-1-6 Edition 3.2 2020-07, IEC 62366-1:2015/AMD 1:2020, ISO 11135:2014/AMD 1:2018,
ISO 11737-1:2018/A1:2021, ISO 11737-2 Third edition 2019-12, EN 556-1:2001/AC 2006, ISO 11607-1:2019,
ISO 11607-2:2019, ASTM D4169-22, WEEE (2012/19/EC), EU RoHS (2015/863/EU, 2011/65/EU),
EU POPs (EU) 2019/1021, EU REACH Regulation (EC 1907/2006), EU packaging (Directive 94/62/EC)
ISO 2859-1:1999, ISO 11138-1:2017, ISO 11138-2:2017, ISO 11138-7:2019 ISO 27186:2010,
MDR (EU) 2017/745, IEC 60601-2-31: 2020

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTRAßE 65 80339 MUNICH GERMANY
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE(S):	NO. G11 065652 0014 REV. 00

START OF CE-MARKING: 2024-05-06

PLACE, DATE OF DECLARATION: SHENZHEN, 2024.10.18

SIGNATURE: [redacted] _____

JINHAI XU

MANAGEMENT REPRESENTATIVE

WE, AS THE MANUFACTURER, DECLARE UNDER OUR SOLE RESPONSIBILITY FOR THE DECLARATION OF CONFORMITY.

EC Design Examination Certificate
Active Implantable Medical Devices Directive 90/385/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. 253 of 1994)*

HAS EXAMINED THE DESIGN DOSSIER
Submitted by

Medtronic, Inc.

710 Medtronic Parkway
Minneapolis, MN 55432
USA

For Product Family

Heart Therapy Delivery Systems

GMDN Code: 17846

CONCLUSION of EXAMINATION:

Complies with the requirements of Directive 90/385/EEC on Active Implantable Medical Devices Annex II (4)

Registration Number:	**253.100**
Original Approval:	**12 June 2002**
Last Amended on:	**03 March 2021**
Remains valid until:	**26 May 2024**

Signed: [redacted]

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

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

CONDITIONS OF VALIDITY:

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.

Approved model numbers are included in the associated attachment

Not valid without a valid Annex II Section 3 certificate

Note: Changes which could affect conformity with the essential requirements of Directive 90/385/EEC, or with the conditions prescribed for use of the product must receive further approval from NSAI.

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

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

File Ref	Model Reference	Detail
253.100.03 253.100.13 253.100.19 253.100.21 253.100.35	C304-S59	SelectSite™ C304-S59 Deflectable Catheter System
253.100.34 253.100.35	C304-HIS	SelectSite™ C304-HIS Deflectable Catheter system
253.100.03 253.100.13 253.100.19 253.100.21 253.100.35	C304-L69	SelectSite™ C304-L69 Deflectable Catheter System
253.100.13 253.100.19 253.100.21 253.100.35	C304-XL74	SelectSite™ C304-XL74 Deflectable Catheter System
253.100.13 253.100.19 253.100.35	6227DEF	Attain® 6227DEF Deflectable Catheter Delivery System
253.100.23 253.100.26 253.100.33 253.100.35	C315S4	C315S4 Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315S5	C315S5 Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315S10	C315S10 Delivery Catheter

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

253.100.23 253.100.26 253.100.33 253.100.35	C315J	C315J Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315HIS	C315HIS Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315H20	C315H20 Delivery Catheter
253.100.23 253.100.26 253.100.33 253.100.35	C315H40	C315H40 Delivery Catheter
253.100.27 253.100.33 253.100.35	6250VIS	Attain Command™ + SureValve™ 6250VIS Left-Heart Delivery System
253.100.27 253.100.33 253.100.35	6250VIC	Attain Command™ + SureValve™ 6250VIC Left-Heart Delivery System
253.100.27 253.100.33 253.100.35	6250VI-MB2	Attain Command™ + SureValve™ 6250VI-MB2 Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-EH	Attain Command™ + SureValve™ 6250VI-EH Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-EHXL	Attain Command™ + SureValve™ 6250VI-EHXL Guide Catheter for Left-Heart Delivery

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

253.100.27 253.100.33 253.100.35	6250VI-MPR	Attain Command™ + SureValve™ 6250VI-MPR Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-MP	Attain Command™ + SureValve™ 6250VI-MP Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-AM	Attain Command™ + SureValve™ 6250VI-AM Guide Catheter for Left Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-MB2X	Attain Command™ + SureValve™ 6250VI-MB2X Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-45S	Attain Command™ + SureValve™ 6250VI-45S Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-50S	Attain Command™ + SureValve™ 6250VI-50S Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-57S	Attain Command™ + SureValve™ 6250VI-57S Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-MPX	Attain Command™ + SureValve™ 6250VI-MPX Guide Catheter for Left-Heart Delivery
253.100.27 253.100.33 253.100.35	6250VI-3D	Attain Command™ + SureValve™ 6250VI-3D Guide Catheter for Left-Heart Delivery

Attachment to Certificate 253.100 dated 12 June 2002

This Certificate covers 34 model(s)

253.100.27 253.100.35 253.100.36	6248VI-90	Attain Select™ II + SureValve™ 6248VI-90 Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90S	Attain Select™ II + SureValve™ 6248VI-90S Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90L	Attain Select™ II + SureValve™ 6248VI-90L Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-130	Attain Select™ II + SureValve™ 6248VI-130 Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-130L	Attain Select™ II + SureValve™ 6248VI-130L Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90P	Attain Select™ II + SureValve™ 6248VI-90P Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-90SP	Attain Select™ II + SureValve™ 6248VI-90SP Delivery Catheter System
253.100.27 253.100.35 253.100.36	6248VI-130P	Attain Select™ II + SureValve™ 6248VI-130P Delivery Catheter System

NSAI (logotipas)
CE sertifikatas

CE prietaiso tikrinimo sertifikatas
Pagal 90/385/EEC Aktyvių implantuojamų med. prietaisų direktyvą

Airijos nacionalinė standartų tarnyba yra tinkamai paskirta Notifikuotoji įstaiga (identifikavimo numeris 0050), skirta Europos Bendrijoms (Medicinos prietaisų) nuostatai (S.I. Nr. 253, 1994)

Pateikė:

Gamintojas: Medtronic Inc.
710 Medtronic Parkway
Mineapolis MN 55432
Jungtinės Amerikos Valstijos

Dėl produktų grupės:
Širdies terapijos įvedimo sistemos

GMDN kodas: 17846
TYRIMO IŠVADA:
Atitinka Direktyvos 90/385 / EEB dėl aktyvių implantuojamų medicinos prietaisų II priedo 4 dalies reikalavimus

Registracijos numeris: 253.100

Originalus patvirtinimas: 2002 m. Birželio 12 d

Paskutinį kartą pakeista: 2021 m. Kovo 3 d

Galioja iki: 2024 m. Gegužės 26 d

Pasirašė:

Daktarė Caroline Dore Geraghty
Direktorius, medicinos prietaisai

Daktarė Elaine Darcy
Europos medicinos prietaisų operacijų vadybininkas

GALIOJIMO SĄLYGOS:
Šis sertifikatas lieka galioti su sąlyga, kad patvirtinta kokybės sistema bus palaikoma tinkamai ir veiksmingai.
Patvirtinti modelio numeriai yra įtraukti į susietą priedą
Negalioja be galiojančio II priedo 3 skirsnio pažymėjimo
Pastaba: Pakeitimai, kurie gali turėti įtakos atitikčiai esminiams Direktyvos 90/385 / EEB reikalavimams arba sąlygoms, naudoti produktą, turi gauti tolesnį NSAI patvirtinimą.
Nacionalinė Airijos standartų tarnyba, 1 Swift aikštė, Northwood, Santry, Dublin 9, Airija.

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Medtronic, Inc.
Manufacturer address and contact details	710 Medtronic Parkway Minneapolis, MN 55432 USA Tel: 1.763.514.4000 www.medtronic.com
Single Registration Number (SRN) (if available)	US-MF-000019977

Authorised Representative name (if applicable)	Medtronic B.V.
Authorised Representative address and contact details	Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Single Registration Number (SRN) (if available)	NL-AR-000006050

Notified body name (if applicable)	□ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Notified body number (if applicable)	□ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	□ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ See attached schedule
End date of extended validity/transition period	□ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☒Expired *before* 20 March 2023:

  ☒Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☐A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☒Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

Choose one applicable statement:

☐A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☒A QMS in accordance with Article 10(9) MDR is in place.

☐A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Medtronic, Inc.
8200 Coral Sea St. NE
Mounds View, MN 55113
USA

[redacted] Oct. 11, 2023

Shellee LaRowe — Date
Regulatory Affairs Program Manager
Mounds View, MN
shellee.k.larowe@medtronic.com

Schedule of Devices - Expired/expires before 20 March 2023:

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
CapSure Epi	4965-15 4965-25 4965-35 4965-50 4968-25 4968-35 4968-60	2007841TE25	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
CapSure VDD-2	5038-58 5038-65 5038L-65 5038S-52 5038S-58	2007841TE25	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Screw-in Lead	5071-25 5071-35 5071-53	2007841TE25	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Lead End Cap Kit	5867-3M	2007841TE25	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Service Kit	5873C	2007841TE25	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Wrench Kit	5873W	2007841TE25	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Stylet Kit	6052-45 6052-53 6052-58 6054-52 6054-58 6054-65 6057-45 6057-52 6057-58 6057-65 6057-75 6057-110 6082-45 6082-52 6082-58 6082-65 6082-75 6082-110 6091-45 6091-53 6091-58 6091-65 6094-45 6094-52	2007841TE25	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
	6094-58						
Percutaneous Lead Introducer	6207-S1 6207-S5 6208-S1 6208-S5 6209-S1 6209-S5 6210-S1 6210-S5 6211-S1 6211-S5 6212-S1 6212-S5 6214-S1 6214-S5	2007841TE25	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Rotation Tool Kit	6056	2007841TE25	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Pin Plug Kit	6725	2007841TE25	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Lead Anchoring Sleeve	5867-2	2007841TE25	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	5867AS
Select Secure	3830-49 3830-110	2007841TE04	01-Feb-2023	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Select Secure MRI SureScan	3830-59 3830-69 3830-74	2007841TE04	01-Feb-2023	DEKRA 0344	DEKRA 0344	31-Dec-2027	

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Sprint Quattro Secure S	6935M97 6935M72 6935M49	2007841TE26	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Transvene SVC Lead	6937-35 6937-52 6937-58 6937-110	2007841TE26	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Lead Accessory Kit	6056M	2007841TE26	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Stylet Kit	6093-52 6093-58 6093-65 6093-75 6093-85	2007841TE26	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Sprint Quattro Lead	6946M72	2007841TE26	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Sprint Quattro Secure Lead	6947M49 6947M72 6947M97	2007841TE26	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Sprint Quattro Secure S	693552 693575 6935100	2007841TE26	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Sprint Quattro Secure Lead	694775 6947100	2007841TE26	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Subcutaneous, unipolar lead with defibrillation coil electrode	6996SQ41 6996SQ58 6996SQ85	2007841TE26	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Tunnelling Tool	6996T	2007841TE26	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Pin Plug Kit	6719	2007841TE26	20-Nov-2022	DEKRA 0344	DEKRA 0344	31-Dec-2027	
HV Splitter/Adaptor	5019	2007841TE30	06-Oct-2021	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Adapta	ADD01 ADDR01 ADDR03 ADDR06 ADDRL1 ADDRS1 ADSR01 ADSR03 ADSR06 ADVDD01	I7 17 07 39709 01126	20-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Application Software (external) (for Adapta Sensia Versa)	SW003	I7 039709 1124	20-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Application Software (external) (for Viva Brava Evera)	SW016	I7 039709 1124	20-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Attain Venogram Balloon Catheter	6215	G7 17 08 39709 01118	02-Feb-2023	TUV SUD 0123	DEKRA 0344	31-Dec-2027	Attain Command Ease 6250B
CareLink SmartSync Base	24970A	I7 17 05 39709 01095	06-Jun-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
CareLink SmartSync Patient Connector	24967	I7 17 05 39709 01095	06-Jun-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
CareLink SmartSync PSA Application	D00U002	I7 17 06 39709 01099	06-Jun-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
CareLink SmartSync Common Application	M01A02	I7 17 06 39709 01099	06-Jun-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Evera XT DR	DDBB2D1 DDBB2D4	I7 17 07 39709 01123	20-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Evera S DR	DDBC3D1 DDBC3D4	I7 17 07 39709 01123	20-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Viva XT CRT-D	DTBA2D1 DTBA2D4	I7 17 07 39709 01123	20-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Viva Quad XT CRT-D	DTBA2Q1 DTBA2QQ	I7 17 07 39709 01123	20-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Viva S CRT-D	DTBB2D1 DTBB2D4	I7 17 07 39709 01123	20-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Viva Quad S CRT-D	DTBB2Q1 DTBB2QQ	I7 17 07 39709 01123	20-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Brava CRT-D	DTBC2D1 DTBC2D4	I7 17 07 39709 01123	20-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Brava Quad CRT-D	DTBC2Q1 DTBC2QQ	I7 17 07 39709 01123	20-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Visia AF XT VR	DVAB2D1 DVAB2D4	I7 17 07 39709 01123	20-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Visia AF S VR	DVAC3D1 DVAC3D4	I7 17 07 39709 01123	20-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Evera XT VR	DVBB2D1 DVBB2D4	I7 17 07 39709 01123	20-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Evera S VR	DVBC3D1 DVBC3D4	I7 17 07 39709 01123	20-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Primo MRI VR SureScan	DVMD3D1 DVMD3D4	17 10 39709 01141	09-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Primo MRI DR SureScan	DDMD3D1 DDMD3D4	17 10 39709 01141	09-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Mirro MRI DR SureScan	DDME3D1 DDME3D4	17 10 39709 01141	09-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Mirro MRI VR SureScan	DVME3D1 DVME3D4	17 10 39709 01141	09-Nov-2022	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Reveal LINQ Mobile Manager App	MSW002	I7 039709 1067	07-Nov-2023	TUV SUD 0123	DEKRA 0344	31-Dec-2027	
Application Software (external) (for Reveal LINQ)	SW026	I7 039709 1067	07-Nov-2023	TUV SUD 0123	DEKRA 0344	31-Dec-2027	
Reveal LINQ	LNQ11	I7 039709 1067	07-Nov-2023	TUV SUD 0123	DEKRA 0344	31-Dec-2027	

Schedule of Devices - Expired/expires after 20 March 2023:

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Sprint Quattro Secure S MRI SureScan	6935M55 6935M62	2007841TE29	30-Mar-2024	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Sprint Quattro MRI SureScan Lead	6946M55 6946M62	2007841TE29	30-Mar-2024	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Sprint Quattro Secure MRI SureScan Lead	6947M55 6947M62	2007841TE29	30-Mar-2024	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Sprint Quattro Secure S MRI SureScan	693558 693565	2007841TE29	30-Mar-2024	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Sprint Quattro Secure MRI SureScan Lead	694758 694765	2007841TE29	30-Mar-2024	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Adjustable Valve	6248VAL	2007841TE13	01-May-2023	DEKRA 0344	DEKRA 0344	31-Dec-2028	
Adjustable Slitter	6232ADJ	QMS: G2S 18 04 39709 01190 (Class Is)	09-Jul-2023	TUV SUD 0123	DEKRA 0344	31-Dec-2028	
Universal Slitter	6230UNI	QMS: G2S 18 04 39709	09-Jul-2023	TUV SUD 0123	DEKRA 0344	31-Dec-2028	

[4] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
		01190 (Class Is)					
Patient Cable	5487 5487L	QMS: G2S 18 04 39709 01190 (Class Is)	09-Jul-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2028	
Surgical Cable	5833S 5833SL	QMS: G2S 18 04 39709 01190 (Class Is)	09-Jul-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2028	
Disposable Safety Patient Cable	5846A 5846AL 5846V 5846VL	QMS: G2S 18 04 39709 01190 (Class Is)	09-Jul-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2028	
RF Head Cover	6177	QMS: G2S 18 04 39709 01190 (Class Is)	09-Jul-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2028	
Cobalt XT DR MRI SureScan	DDPA2D1 DDPA2D4	I7 039709 1265	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Cobalt DR MRI SureScan	DDPB3D1 DDPB3D4	I7 039709 1265	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Crome DR MRI SureScan	DDPC3D1 DDPC3D4	I7 039709 1265	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Cobalt XT HF CRT-D MRI SureScan	DTPA2D1 DTPA2D4	I7 039709 1265	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Cobalt XT HF Quad CRT-D MRI SureScan	DTPA2Q1 DTPA2QQ	I7 039709 1265	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Cobalt HF CRT-D MRI SureScan	DTPB2D1 DTPB2D4	I7 039709 1265	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Cobalt HF Quad CRT-D MRI SureScan	DTPB2Q1 DTPB2QQ	I7 039709 1265	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Crome HF CRT-D MRI SureScan	DTPC2D1 DTPC2D4	I7 039709 1265	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Crome HF Quad CRT-D MRI SureScan	DTPC2Q1 DTPC2QQ	I7 039709 1265	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Cobalt XT VR MRI SureScan	DVPA2D1 DVPA2D4	I7 039709 1265	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Cobalt VR MRI SureScan	DVPB3D1 DVPB3D4	I7 039709 1265	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Crome VR MRI SureScan	DVPC3D1 DVPC3D4	I7 039709 1265	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Cobalt Crome Application Software	D00U005	I7 039709 1265	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Evera MRI XT DR SureScan	DDMB2D1 DDMB2D4	I7 039709 1192	30-Mar-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Evera MRI S DR SureScan	DDMC3D1 DDMC3D4	I7 039709 1192	30-Mar-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Claria MRI CRT-D SureScan	DTMA2D1 DTMA2D4	I7 039709 1192	30-Mar-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Claria MRI Quad CRT-D SureScan	DTMA2Q1 DTMA2QQ	I7 039709 1192	30-Mar-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Amplia MRI CRT-D SureScan	DTMB2D1 DTMB2D4	I7 039709 1192	30-Mar-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Amplia MRI Quad CRT-D SureScan	DTMB2Q1 DTMB2QQ	I7 039709 1192	30-Mar-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Compia MRI CRT-D SureScan	DTMC2D1 DTMC2D4	I7 039709 1192	30-Mar-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Compia MRI Quad CRT-D SureScan	DTMC2QQ	I7 039709 1192	30-Mar-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Visia AF MRI XT VR SureScan	DVFB2D1 DVFB2D4	I7 039709 1192	30-Mar-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Visia AF MRI S VR SureScan	DVFC3D1 DVFC3D4	I7 039709 1192	30-Mar-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Evera MRI XT VR SureScan	DVMB2D1 DVMB2D4	I7 039709 1192	30-Mar-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Evera MRI S VR SureScan	DVMC3D1 DVMC3D4	I7 039709 1192	30-Mar-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Application Software (external) (for Visia AF MR)	SW035	I7 039709 1192	30-Mar-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Application Software (external) (for Evera MRI ICD)	SW033	I7 039709 1192	30-Mar-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Application Software (external) (for Claria	SW034	I7 039709 1192	30-Mar-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
MRI, Amplia MRI, Compia MRI)							
Attain 6227DEF Deflectable Catheter Delivery System	6227DEF	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Select II + SureValve 6248VI-130 Delivery Catheter System	6248VI-130	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Select II + SureValve 6248VI-130L Delivery Catheter System	6248VI-130L	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Select II + SureValve 6248VI-130P Delivery Catheter System	6248VI-130P	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Select II + SureValve 6248VI-90 Delivery Catheter System	6248VI-90	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Select II + SureValve 6248VI-90L Delivery Catheter System	6248VI-90L	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Attain Select II + SureValve 6248VI-90P Delivery Catheter System	6248VI-90P	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Select II + SureValve 6248VI-90S Delivery Catheter System	6248VI-90S	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Select II + SureValve 6248VI-90SP Delivery Catheter System	6248VI-90SP	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Command + SureValve 6250VI-3D Guide Catheter for Left-Heart Delivery System	6250VI-3D	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Command + SureValve 6250VI-45S Guide Catheter for Left-Heart Delivery System	6250VI-45S	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Command + SureValve 6250VI-50S Guide Catheter for Left-Heart Delivery System	6250VI-50S	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Command + SureValve 6250VI-57S	6250VI-57S	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Guide Catheter for Left-Heart Delivery System							
Attain Command + SureValve 6250VI-AM Guide Catheter for Left-Heart Delivery System	6250VI-AM	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Command + SureValve 6250VIC Left-Heart Delivery System	6250VIC	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Command + SureValve 6250VI-EH Guide Catheter for Left-Heart Delivery System	6250VI-EH	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Command + SureValve 6250VI-EHXL Guide Catheter for Left-Heart Delivery System	6250VI-EHXL	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Command + SureValve 6250VI-MB2 Guide Catheter for Left-Heart Delivery System	6250VI-MB2	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Command + SureValve 6250VI-MB2X Guide Catheter	6250VI-MB2X	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
for Left-Heart Delivery System							
Attain Command + SureValve 6250VI-MP Guide Catheter for Left-Heart Delivery System	6250VI-MP	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Command + SureValve 6250VI-MPR Guide Catheter for Left-Heart Delivery System	6250VI-MPR	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Command + SureValve 6250VI-MPX Guide Catheter for Left-Heart Delivery System	6250VI-MPX	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Attain Command + SureValve 6250VIS Left-Heart Delivery System	6250VIS	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
SelectSite C304-HIS Deflectable Catheter System	C304-HIS	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
SelectSite C304-L69 Deflectable Catheter System	C304-L69	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
SelectSite C304-S59 Deflectable Catheter System	C304-S59	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
SelectSite C304-XL74 Deflectable Catheter System	C304-XL74	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
C315H2O Delivery Catheter	C315H20	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
C315H40 Delivery Catheter	C315H40	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
C315HIS Delivery Catheter	C315HIS	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
C315J Delivery Catheter	C315J	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
C315S10 Delivery Catheter	C315S10	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
C315S4 Delivery Catheter	C315S4	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
C315S5 Delivery Catheter	C315S5	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
Micra Introducer	MI2355A	CE 599898	04-Sep-2023	BSI (NL) 2797	DEKRA 0344	31-Dec-2027	
Patient Assistant	PA96000	I7 039709 0948	26-May-2024	TUV SUD 0123	DEKRA 0344	31-Dec-2027	
Application Software (external) (for Micra VR)	SW022	I7 039709 0979	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Patient Assistant	PA97000	I7 039709 1284	26-May-2024	TUV SUD 0123	DEKRA 0344	31-Dec-2027	

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
LINQ II	LNQ22	I7 039709 1284	26-May-2024	TUV SUD 0123	DEKRA 0344	31-Dec-2027	
LINQ II Insertion Tools	LNQ22TK	I7 039709 1284	26-May-2024	TUV SUD 0123	DEKRA 0344	31-Dec-2027	
CapSureFix Novus	4076110	2007841TE08	26-May-2024	DEKRA 0344	DEKRA 0344	31-Dec-2027	
CapSureFix Novus MRI SureScan	407635 407645 407652 407658 407665 407685	2007841TE08	26-May-2024	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Attain Hybrid Guidewires	GWR419478 GWR419488 GWR419578 GWR419588 GWR419678 GWR419688	2007841TE15	26-May-2024	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Attain Ability MRI SureScan	419678 419688	2007841TE16	26-May-2024	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Attain Ability Plus MRI SureScan	429678 429688	2007841TE17	01-Jan-2024	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Attain Ability Straight MRI SureScan	439678 439688	2007841TE18	01-Jan-2024	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Attain Performa MRI SureScan	429878 429888	2007841TE22	01-Jan-2024	DEKRA 0344	DEKRA 0344	31-Dec-2027	

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Attain Performa Straight MRI SureScan	439878 439888	2007841TE22	01-Jan-2024	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Attain Performa S MRI SureScan	459878 459888	2007841TE22	01-Jan-2024	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Attain Stability Quad MRI SureScan	479878 479888	2007841TE24	24-May-2024	DEKRA 0344	DEKRA 0344	31-Dec-2027	
CapSure Sense MRI SureScan	4074-52 4074-58	2007841TE28	29-Sep-2023	DEKRA 0344	DEKRA 0344	31-Dec-2027	
CapSureFix Novus MRI SureScan	5076-35 5076-45 5076-52 5076-58 5076-65 5076-85	2007841TE28	29-Sep-2023	DEKRA 0344	DEKRA 0344	31-Dec-2027	
Dual Chamber Temporary Pacemaker	5392	QMS: G1 039709 1144 (Class IIb)	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
External Pulse Generator	53401	QMS: G1 039709 1144 (Class IIb)	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Implantable Pacemaker Systems (Micra)	MC1VR01	I7 039709 0978	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Implantable Pacemaker Systems (Micra)	MC1AVR1	I7 039709 1301	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
MyCareLink Patient Monitor	24952	I7 039709 1286	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2028	

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
MyCareLink Reader	24955	I7 039709 1286	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2028	
MyCareLink Smart Patient Reader	25000	I7 039709 1286	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2028	
CareLink Express App	31302	I7 039709 1286	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2028	
Triage HF	5242	I7 039709 1290	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Application Software (external) (for Micra AV)	SW044	I7 039709 1302	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Azure XT DR MRI SureScan	W2DR01	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Azure XT SR MRI SureScan	W2SR01	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Azure S DR MRI SureScan	W3DR01	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Azure S SR MRI SureScan	W3SR01	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Astra XT DR MRI SureScan	X2DR01	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Astra XT SR MRI SureScan	X2SR01	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Astra S DR MRI SureScan	X3DR01	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Astra S SR MRI SureScan	X3SR01	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Azure/Astra Application Software	SW030	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
CareLink SmartSync Azure Astra App	D00U003	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Percepta CRT-P MRI SureScan	W1TR04	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Serena CRT-P MRI SureScan	W1TR05	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Solara CRT-P MRI SureScan	W1TR06	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Percepta Quad CRT-P MRI SureScan	W4TR04	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Serena Quad CRT-P MRI SureScan	W4TR05	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Solara Quad CRT-P MRI SureScan	W4TR06	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
CareLink SmartSync Percepta/Serena/Solara App	D00U004	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Application Software (for Percepta/Serena/Solara)	SW040	I7 039709 1199	29-Sep-2023	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
Attesta DR MRI SureScan	ATDR01	I7 039709 1199	29-Sep-2023	TUV SUD 0123	DEKRA 0344	31-Dec-2027	

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Sphera DR MRI SureScan	SPDR01	I7 039709 1199	29-Sep-2023	TUV SUD 0123	DEKRA 0344	31-Dec-2027	
Attesta L DR MRI SureScan	ATDRL1	I7 039709 1199	29-Sep-2023	TUV SUD 0123	DEKRA 0344	31-Dec-2027	
Attesta S DR MRI SureScan	ATDRS1	I7 039709 1199	29-Sep-2023	TUV SUD 0123	DEKRA 0344	31-Dec-2027	
Attesta SR MRI SureScan	ATSR01	I7 039709 1199	29-Sep-2023	TUV SUD 0123	DEKRA 0344	31-Dec-2027	
Sphera L DR MRI SureScan	SPDRL1	I7 039709 1199	29-Sep-2023	TUV SUD 0123	DEKRA 0344	31-Dec-2027	
Sphera SR MRI SureScan	SPSR01	I7 039709 1199	29-Sep-2023	TUV SUD 0123	DEKRA 0344	31-Dec-2027	
Application Software (for Attesta, Sphera)	SW043	I7 039709 1199	29-Sep-2023	TUV SUD 0123	DEKRA 0344	31-Dec-2027	
QMS	6227DEF, 6248VI, 6250VI, 6250VIS, C304-HIS, C304-L6901, C304-S5901, C304-XL74, C315	253.100	26-May-2024	NSAI 0050	DEKRA 0344	31-Dec-2027	
QMS	MI2355A	CE 84868	26-May-2024	BSI (NL) 2797	DEKRA 0344	31-Dec-2027	

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
QMS	MC1VR01, MC1AVR1	I1 039709 0972	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
QMS	24952, 24955, 24967, 24970A, 25000, 31302, D00U002, D00U003, D00U004, D00U005, M01A02, MSW002, PA96000, PA97000, SW003, SW016, SW022, SW026, SW030, SW034, SW035, SW040, SW043, SW044	I1 039709 1115	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	
QMS	ADD01, ADDR01,	I1 039709 1185	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
	ADDR03, ADDR06, ADDRL1, ADDRS1, ADSR01, ADSR03, ADSR06, ADVDD01, ATDR01, ATDRL1, ATDRS1, ATSR01, DDBB2D1, DDBB2D4, DDBC3D1, DDBC3D4, DDMB2D1, DDMB2D4, DDMC3D1, DDMC3D4, DDMD3D1, DDMD3D4, DDME3D1, DDME3D4, DDPA2D1, DDPA2D4,						

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
	DDPB3D1, DDPB3D4, DDPC3D1, DDPC3D4, DTBA2D1, DTBA2D4, DTBA2Q1, DTBA2QQ, DTBB2D1, DTBB2D4, DTBB2Q1, DTBB2QQ, DTBC2D1, DTBC2D4, DTBC2Q1, DTBC2QQ, DTMA2D1, DTMA2D4, DTMA2Q1, DTMA2QQ, DTMB2D1, DTMB2D4, DTMB2Q1, DTMB2QQ, DTMC2D1, DTMC2D4,						

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
	DTMC2QQ, DTPA2D1, DTPA2D4, DTPA2Q1, DTPA2QQ, DTPB2D1, DTPB2D4, DTPB2Q1, DTPB2QQ, DTPC2D1, DTPC2D4, DTPC2Q1, DTPC2QQ, DVAB2D1, DVAB2D4, DVAC3D1, DVAC3D4, DVBB2D1, DVBB2D4, DVBC3D1, DVBC3D4, DVFB2D1, DVFB2D4, DVFC3D1, DVFC3D4, DVMB2D1,						

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
	DVMB2D4, DVMC3D1, DVMC3D4, DVMD3D1, DVMD3D4, DVME3D1, DVME3D4, DVPA2D1, DVPA2D4, DVPB3D1, DVPB3D4, DVPC3D1, DVPC3D4, LNQ11, LNQ22, LNQ22TK, SPDR01, SPDRL1, SPSR01, W1TR04, W1TR05, W1TR06, W2DR01, W2SR01, W3DR01, W3SR01,						

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
	W4TR04, W4TR05, W4TR06, X2DR01, X2SR01, X3DR01, X3SR01						
QMS	3830, 4074, 4076, 4196, 4296, 4298, 4396, 4398, 4598, 4798, 4965, 4968, 5019, 5038, 5038L, 5038S, 5071, 5076, 5867-2, 5867-3M, 5873C, 5873W, 6052, 6054, 6056, 6056M, 6057, 6082, 6091, 6093, 6094, 6207, 6208, 6209, 6210, 6211, 6212,	I2 039709 1117	26-May-2024	TUV SUD 0123	TUV SUD 0123	31-Dec-2027	

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)		**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
	6214, 6248VAL, 6719, 6725, 6935, 6935M, 6937, 6946M, 6947, 6947M, 6996SQ, 6996T, GWR419478, GWR419488, GWR419578, GWR419588, GWR419678, GWR419688						

Declaration Letter Revision History

Date	Action
Upon release	Initial issue and release

bsi.

By Royal Charter

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):

[redacted]

Stewart Brain, Head of Compliance & Risk - Medical Devices

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

...making excellence a habit.™

BSI

CE SERTIFIKATAS - Visiškas Kokybės Užtikrinimas

Europos Tarybos Direktyva 93/42/EEC, Priedas II, Dalis 4

Nr. CE 01906

Kam išduota:

FIAB SpA
Via P. Costoli, 4
Vicchio
Firenze
50039
Italija

Dėl:
Kūrimo, projektavimo ir gamybos sterilių zondų perstempliniams širdies stebėjimams, stimuliacijai ir defibriliacijai; prietaisų elektrofiziologiniams tyrimams ir ekstrinei širdies stimuliacijai; sterilių ir nesterilių kaniulių, kaukių, rinkiniams ir priemonių deguonies terapijai, sterilių ir nesterilių elektrochirurginių rankenų antgaliai, elektrodai ir susijusių priemonių, sterilių vienkartinių neurostimuliatorių ir elektrokauterių

Remiantis mūsų atliktais patikrinimais pagal Europos Tarybos Direktyvą 93/42/EEC, Priedą II, Dalį 4.

Britų Standartų Institutas - įgaliota ir Notifikuotoji įstaiga aukščiau minėtai Direktyvai (Notifikuotos įstaigos numeris 0086):

(parašas)

_____

Stewart Brain, Kokybės vadovas

Pirmoji sertifikavimo data: 1998 gegužės 11d.

Šio sertifikato data: 2018 gegužės 10 d.

Galioja iki: 2023 gegužės 10d.

(rekvizitai)

Vicchio (FI), 12/04/2023

TO WHOM IT MAY CONCERN

Subject: Extension of the MDR 2017/745 transitional period – confirmation of validity of FIAB MDD 93/42/EEC Certificates CE 01906, CE 649635, CE 720326

The amendment of the Medical Devices regulation (MDR) 2017/745 introduced by the *Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices* (**Attachment 1** of this letter) aims – among other things – to give Manufacturers and Notified Bodies sufficiently more time to carry out, in accordance with the MDR, the conformity assessment of devices covered by a certificate issued in accordance with Medical Devices Directive (MDD) 93/42/EEC that is going to expire or is already expired.

Such devices, also known as 'legacy devices' can benefit from an extended transitional period as set in the Regulation (EU) 2023/607, for the application of MDR.
'Legacy devices' should be understood as devices, which, in accordance with the MDR's transitional provisions, are placed on the market after the MDR's date of application (i.e. 26 May 2021) if certain conditions are fulfilled. Those devices covered by a valid EC certificate issued in accordance with MDD prior to 26 May 2021benefit of an extension of the transitional period beyond 26 May 2024 if the conditions laid down in Article 120(3c) MDR are fulfilled, for the relevant certificates expired or going to expire after 20 March 2023.

As the Manufacturer of the medical devices listed in **Attachment 2** of this letter, FIAB SpA herewith confirms that the products covered by the following MDD 93/42/EEC certificates

- CE 01906, MDD Annex II.3 (Full Quality Assurance system certificate)
- CE 649635, CE 720326 MDD Annex II.4 (Design Dossier Examination certificate)

fulfil the requirements defined by Regulation (EU) 2023/607.
Consequently, the above mentioned certificates can be considered as valid, respectively, until 31/12/2028 for class IIa and class IIb medical devices (CE 01906) and until 31/12/2027 for class III medical devices (CE 649635, CE 720326), when FIAB SpA continues to comply with the relevant requirements in Regulation (EU) 2017/745 as amended by Regulation (EU) 2023/607.

The confirmation is made taking into account the following aspects

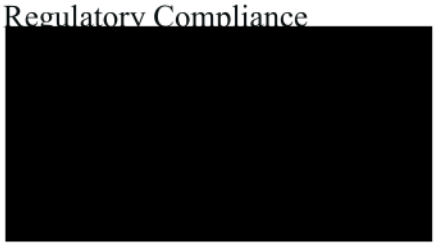
- Regulation (EU) 2023/607 extends the validity of CE certificates under MDD, considering limited capacity of Notified Bodies accredited for conformity assessment procedures under MDR
- Important condition of this extension is that the Manufacturer shall submit an MDR certification application for these devices to a MDR Notified Body not later than 26/05/2024 and shall sign MDR certification agreement with the MDR Notified Body no later than 26/09/2024
- Other requirements for this extension includes e.g.: the devices continue to comply with MDD there are no significant changes in the design and intended purpose; devices do not present an unacceptable risk to the health or safety; the Manufacturer has put in place a quality management system in accordance with MDR; a Notified Body is still performing surveillance activity

FIAB SpA is providing appropriate evidences demonstrating that the relevant requirements in Regulation (EU) 2017/745 as amended by Regulation (EU) 2023/607 have been fulfilled by now. In particular

- for each of the medical devices listed in **Attachment 2** of this letter, an MDR certification application was already submitted by FIAB to the MDR Notified Body 2797 (BSI) and the respective MDR certification agreement has been signed, as listed in Attachment 2;
- the devices continue to comply with MDD, according to the surveillance activity performed by the same Notified Body 2797 to FIAB; this ensures that there are no significant changes and the devices do not present an unacceptable risk;
- FIAB has already put in place a quality management system in accordance with MDR, as attested by the EU Quality Management System Certificate, MDR 747884 in **Attachment 3**, according to MDR Annex IX chapter I and III. Such MDR certificate already cover the medical devices for which the Notified Body 2797 completed the certification assessment

Francesco Batistini
Quality Assurance Manager
Person Responsible for Regulatory Compliance
FIAB S.p.A.

e-mail quality@fiab.it
tel +39 055 8497943



Vicchio (FI), 2023 04 12

VISIEMS, KAM TAI GALI BŪTI AKTUALU

Tema: MDR 2017/745 pereinamojo laikotarpio pratęsimas - FIAB MDD 93/42/EEB sertifikatų CE 01906, CE 649635, CE 720326 galiojimo patvirtinimas

Medicinos prietaisų reglamento (MDR) 2017/745 pakeitimu, padarytu *2023 m. kovo 15 d. Europos Parlamento ir Tarybos reglamentu (ES) 2023/607, kuriuo iš dalies keičiamos reglamentų (ES) 2017/745 (MDR) ir (ES) 2017/746 (IVDR) nuostatos dėl pereinamojo laikotarpio nuostatų, susijusių su tam tikrais medicinos prietaisais ir in vitro diagnostikos medicinos prietaisais* (šio laiško **1 priedas),** siekiama, be kita ko, suteikti gamintojams ir notifikuotosioms įstaigoms pakankamai daugiau laiko, prietaisų, kuriems taikomas pagal Medicinos prietaisų direktyvą (MDD) 93/42/EEB išduotas sertifikatas, kurio galiojimas baigsis arba jau baigėsi, atitikties vertinimą pagal MDR.

Tokiems prietaisams, dar vadinamiems "senaisiais prietaisais", gali būti taikomas Reglamente (ES) 2023/607 nustatytas ilgesnis pereinamasis laikotarpis MDR taikyti.
"Senosios priemonės" turėtų būti suprantamos kaip priemonės, kurios, vadovaujantis MDR pereinamojo laikotarpio nuostatomis, pateikiamos rinkai po MDR taikymo pradžios datos (t. y. 2021 m. gegužės 26 d.), jei įvykdomos tam tikros sąlygos. Tiems prietaisams, kuriems taikomas galiojantis EB sertifikatas, išduotas pagal MDD iki 2021 m. gegužės 26 d., pereinamasis laikotarpis gali būti pratęstas po 2024 m. gegužės 26 d., jei įvykdomos MDR 120 straipsnio 3c dalyje nustatytos sąlygos dėl atitinkamų sertifikatų, kurių galiojimo laikas baigėsi arba baigsis po 2023 m. kovo 20 d.

Kaip šio laiško **2 priede** išvardytų medicinos prietaisų gamintojas, FIAB SpA patvirtina, kad gaminiai, kuriems išduoti šie MDD 93/42/EEB sertifikatai

- CE 01906, MDD II.3 priedas (Visiško kokybės užtikrinimo sistemos sertifikatas)
- CE 649635, CE 720326 MDD II.4 priedas (Projekto dokumentų rinkinio tyrimo

sertifikatas) atitinka Reglamente (ES) 2023/607 nustatytus reikalavimus.
Todėl pirmiau minėti sertifikatai gali būti laikomi galiojančiais atitinkamai iki 2028 m. gruodžio 31 d. IIa ir IIb klasės medicinos prietaisams (CE 01906) ir iki 2027 m. gruodžio 31 d. III klasės medicinos prietaisams (CE 649635, CE 720326), kai "FIAB SpA" ir toliau atitinka atitinkamus Reglamento (ES) 2017/745 su pakeitimais, padarytais Reglamentu (ES) 2023/607, reikalavimus.

Patvirtinimas atliekamas atsižvelgiant į šiuos aspektus

- Reglamentu (ES) Nr. 2023/607 pratęsiamas CE sertifikatų galiojimas pagal MDD, atsižvelgiant į ribotus paskelbtųjų įstaigų, akredituotų atitikties vertinimo procedūroms pagal MDR, pajėgumus.
- Svarbi šio pratęsimo sąlyga yra ta, kad gamintojas ne vėliau kaip 2024-05-26 turi pateikti MDR notifikuotajai įstaigai šių prietaisų MDR sertifikavimo paraišką ir ne vėliau kaip 2024-09-26 turi pasirašyti MDR sertifikavimo sutartį su MDR notifikuotąja įstaiga.
- Kiti reikalavimai šiam pratęsimui: prietaisai ir toliau atitinka MDD, nėra reikšmingų konstrukcijos ir paskirties pakeitimų, prietaisai nekelia nepriimtino pavojaus sveikatai ar saugai, gamintojas įdiegė kokybės valdymo sistemą pagal MDR, notifikuotoji įstaiga vis dar atlieka priežiūros veikla.

"FIAB SpA" pateikia tinkamus įrodymus, kad atitinkami Reglamento (ES) 2017/745 su pakeitimais, padarytais Reglamentu (ES) 2023/607, reikalavimai jau įvykdyti. Visų pirma

- FIAB jau pateikė paraišką dėl kiekvieno iš šio rašto **2 priede** išvardytų medicinos prietaisų MDR sertifikavimo 2797 notifikuotajai įstaigai (BSI) ir pasirašė atitinkamą MDR sertifikavimo sutartį, kaip nurodyta 2 priede;
- prietaisai ir toliau atitinka MDD pagal tos pačios notifikuotosios įstaigos 2797 FIAB atliktą priežiūros veiklą; taip užtikrinama, kad nėra reikšmingų pokyčių ir prietaisai nekelia nepriimtinos rizikos;
- FIAB jau yra įdiegusi kokybės valdymo sistemą pagal MDR, tai patvirtina ES kokybės valdymo sistemos sertifikatas, MDR 747884, pateiktas **3 priede,** pagal MDR IX priedo I ir III skyrius. Toks MDR sertifikatas jau taikomas medicinos prietaisams, kurių sertifikavimo vertinimą atliko notifikuotoji įstaiga 2797

Francesco Batistini
Kokybės užtikrinimo vadybininkas
Už teisės aktų laikymąsi atsakingas asmuo FIAB
S.p.A.

el. paštas
quality@fiab.it tel.
+39 055 8497943

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):

[redacted]
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**

...making excellence a habit.™

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.

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.	

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

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

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

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

...making excellence a habit.™

By Royal Charter

EU Quality Management System Certificate

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

MDR 747884 R000

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.".

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

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

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

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

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 2, excluding Section 4

No. **CE 709523**

Issued To: **Medtronic, Inc**
8200 Coral Sea Street NE
Mounds View
Minnesota
55112
USA

In respect of:

Design and Manufacture of fully absorbable surgical implants coated with ancillary medicinal substances.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 90/385/EEC, Annex 2, excluding Section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of devices covered by this certificate an EC design-examination certificate according to 90/385/EEC, Annex 2, section 4 is required.

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

[redacted]

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-05-03** Date: **2019-09-01** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance

Supplementary Information to CE 709523

Issued To:

Medtronic, Inc
8200 Coral Sea Street NE
Mounds View
Minnesota
55112
USA

Number	Device Name	Intended purpose per IFU
Class III – AIMD		
---	TYRX™ Absorbable Antibacterial Envelope	See CE 709608

First Issued: **2019-05-03** Date: **2019-09-01** Expiry Date: **2024-05-26**

By Royal Charter

EC Certificate - Full Quality Assurance

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 2, excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 709523**
Date:	**2019-09-01**
Issued To:	**Medtronic, Inc** **8200 Coral Sea Street NE** **Mounds View** **Minnesota** **55112** **USA**

Subcontractor:	**Service(s) supplied**
Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands	**EU Representative**
Medtronic, Inc. 7000 Central Avenue N.E., Minneapolis, MN 55432 USA	**Control of Sterilization** **Manufacture**
Sterigenics US, LLC 108 Lake Denmark Road Rockaway New Jersey 07866 USA	**Gamma Sterilization**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 709523**

Date: **2019-09-01**

Issued To: **Medtronic, Inc**
8200 Coral Sea Street NE
Mounds View
Minnesota
55112
USA

Date	Reference Number	Action
03 May 2019	9755704	First Issue (Mirror to CE 585213)
Current	3058104	Certificate Renewal

By Royal Charter

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 2 Section 4

No. **CE 709608**

Issued To: **Medtronic, Inc**
8200 Coral Sea Street NE
Mounds View
Minnesota
55112
USA

In respect of:

TYRX™ Absorbable Antibacterial Envelope

BSI has performed a design examination on the above devices in accordance with the Council Directive 90/385/EEC, Annex 2 Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex 2 excluding Section 4 certificate is required.

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

[redacted]

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-05-07** Date: **2021-02-22** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 709608

Issued To:

Medtronic, Inc
8200 Coral Sea Street NE
Mounds View
Minnesota
55112
USA

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CMRM6122INT, NMRM6122INT	TYRX™ Absorbable Antibacterial Envelope	Size: 6.3cm x 6.9cm	The envelope is intended to hold the following CIED and INS securely to create a stable environment when implanted in the body at the following locations: • CIED: Implantable Pulse Generator (IPG), Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy Devices (CRT-P and CRT-D); implant locations are pectoral, abdominal, or flank (lateral to the body midline and superior to the gluteal) regions. • INS: Deep Brain Stimulator (DBS) implanted in the pectoral or abdominal region; Sacral Neuromodulator (SNM) implanted in the gluteal and abdominal regions; Spinal Cord Stimulator (SCS) implanted in the gluteal, abdominal, or flank regions.	AIMD

First Issued: **2019-05-07** Date: **2021-02-22** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 709608

Issued To:

Medtronic, Inc
8200 Coral Sea Street NE
Mounds View
Minnesota
55112
USA

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CMRM6133INT, NMRM6133INT	TYRX™ Absorbable Antibacterial Envelope	Size: 7.4cm x 8.5cm	The envelope is intended to hold the following CIED and INS securely to create a stable environment when implanted in the body at the following locations: • CIED: Implantable Pulse Generator (IPG), Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy Devices (CRT-P and CRT-D); implant locations are pectoral, abdominal, or flank (lateral to the body midline and superior to the gluteal) regions. • INS: Deep Brain Stimulator (DBS) implanted in the pectoral or abdominal region; Sacral Neuromodulator (SNM) implanted in the gluteal and abdominal regions; Spinal Cord Stimulator (SCS) implanted in the gluteal, abdominal, or flank regions.	AIMD

First Issued: **2019-05-07** Date: **2021-02-22** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 709608

Issued To:

Medtronic, Inc
8200 Coral Sea Street NE
Mounds View
Minnesota
55112
USA

Certificate History

Date	Reference Number	Action
05 May 2019	9755989	First Issue (Mirror to CE:579049)
01 September 2019	3058107	Certificate renewal and clarification in the intended purpose of the IFU. Change of wording in the indication text from 'The TYRX Absorbable Antibacterial Envelope' to 'the envelope'
11 November 2019	3090344	Addendum - Update IFU terminology and package labels to include MR Safe information.
15 July 2020	3041605	Addendum – Extension of the product shelf life from 6 months to 12 months. Removal of CMRM6122EU and CMRM6133EU catalogue numbers.
03 August 2020	3146296	Addendum - Change to the elution test parameters. Change was reviewed and accepted by the MEB as supplementary consultation with case Number 807935.
12 August 2020	3204870	Addendum - Change to API Aliquoting manufacturing process.

First Issued: **2019-05-07** Date: **2021-02-22** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 709608

Issued To:

Medtronic, Inc
8200 Coral Sea Street NE
Mounds View
Minnesota
55112
USA

Certificate History

Date	Reference Number	Action
Current	3146295	Addendum - Change of API packaging to a smaller drum size. Change of Rifampicin primary package from double polyethylene to polyethylene/polyamide bag and Rifampicin retest period extension from 12 months to 24 months. Changes were reviewed and accepted by MEB as supplementary consultation with case Number 806759.

First Issued: **2019-05-07** Date: **2021-02-22** Expiry Date: **2024-05-26**

...making excellence a habit.™

Medtronic, Inc.
8200 Coral Sea Street NE
Mounds View, MN 55112
USA

October 09, 2023

Notified Body Confirmation Letter

Reference: EU2023-607/ 704257

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Medtronic, Inc.
8200 Coral Sea Street NE
Mounds View, MN 55112
USA

SRN Number (if available): US-MF-000023316

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been

withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

[redacted]

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
0763000B000082688	Class III	*CMRM6122INT* *CMRM6133INT* *NMRM6122INT* *NMRM6133INT*	*CE 709608, 26-May-2024, NB# 2797* *CE 709523, 26-May-2024, NB# 2797*

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/10/09	Initial issue

Medtronic	Document Title: DoC- TYRX Absorbable Antibacterial Envelope	Document Number: D00051670, Rev. P
EC DECLARATION OF CONFORMITY	TYRX Absorbable Antibacterial Envelope	

Revision/History description	Revision level	Impl. Date
Initial Release. New document to reflect transition to Medtronic, Inc. as the legal manufacturer.	A	27-JUN-2019
Updated applicable standards from EN ISO 10993-1:2009/AC:2010 to ISO 10993-1:2018 Changed wording of signature block to reflect correct document repository approval process Removed inapplicable standard BS EN 7373-2: 2001 Product Specifications - Part 2: Guide to Identifying Criteria for a Product Specification and to Declaring Product Conformity.	B	22-OCT-2019
Updated from EN ISO 11607-1:2009+A1:2014 to ISO 11607-1:2019	C	04-MAR-2020
Removed EU model numbers (this configuration is no longer manufactured; the last lots were manufactured and shipped to the distribution warehouse in August 2019); clarify product name does not include envelope size.	D	31-JUL-2020
Updated standard from EN ISO 11137-1:2015 to EN ISO 11137-1:2015/ A2:2019	E	19-OCT-2020
Updated EN ISO 14971 revision from 2012 to 2019, EN ISO 10993-1 revision from 2018 to 2020, and ISO 11607-1 revision form 2019 to 2020	F	29-Sep-2021
Included requirements of amended Regulation (EU) 2023/607, updated to current revision of document template, updated implementation date of last revision, updated approver name and title, updated standards.	G	7-Aug-2023
Corrected a typo in the standards table in attachment 1	H	09-Aug-2023
Aligned DoC with recent ERM changes: Removed references to EN ISO 10993-3, -5, -6, -10, -11, and -12. Removed "(R) 2015" from EN ISO 11137-1 2015+A2:2019. Removed reference to EN ISO 11137-2, -3. Added "+A11:2022" to EN ISO 14971. Updated EN ISO 15223-1 to 2016. Updated to EN 62366-1 2015.	J	25-Mar-2024
Added manufacturing facility address	K	31-Jul-2024
Updated standard EN 62366-1:2015 to EN 62366-1:2015+A1:2020	L	19-Sep-2024
Corrected standards list to include amendment inadvertently excluded from EN 62366-1:2015 in revision L	M	21-Jan-2025
Updated EN ISO 11607-1: 2020+A11:2022 to EN ISO 11607-1:2020+A1:2023	N	09-Apr-2025
Updated to include hand signature	P	Upon Approval

EC Declaration of Conformity

Manufacturer:	Medtronic, Inc. 8200 Coral Sea St. NE Mounds View, MN 55112, USA
Manufacturing Facility:	Medtronic, Inc. 7000 Central Avenue NE, Minneapolis, MN 55432 USA
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Description of device concerned:	TYRX™ Absorbable Antibacterial Envelope
Model number:	See Attachment 2
Variants:	Sizes: 6.3 cm x 6.9 cm, 7.4 cm x 8.5 cm
GMDN Code and Description	61126, Implantable Pulse Generator Mesh Bag, Bioabsorbable
Classification, rule	Active Implantable Medical Device (AIMD)
Conformity Assessment Route:	Annex II and Annex II Section 4
EC Certificate number:	CE 709608
EC Quality System Certificate:	CE 709523
Name & Address of Notified Body:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam
Identification Number Notified Body:	2797
Conformity with the following standard(s) or other normative document(s)	See Attachment 1

Statement:

We, Medtronic, Inc., hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive EC Directive 90/385/EEC[1] which apply to them. In addition, Medtronic declares compliance to Article 120 of the Regulation (EU) 2017/745 and the Regulation (EU) 2023/607, amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards to the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive and the evidence of compliance to the conditions presented under Article 1 Paragraph 3c of the amended Regulation (EU) 2023/607. This declaration applies to all devices specified above distributed from the signature date through the amended Regulation extension date of 31 December 2027. The validity of the certificates listed on this DoC are valid through 31 December 2027.

Validity DoC from date: *Refer to document approval date in the change record* Place: Mounds View Date: 09 APR 2025

Name: Luke Ranta
Title: Engineering Manage

Signatu [redacted]

[1] *Including amendments issued in the years following*

Attachment 1:

Title and/or number and date of issue of the Standard(s) or other normative document(s) (if applicable) following the Essential Requirements of the applicable EC Directive.

The below mentioned Standard(s) apply to the model(s) included under the scope of this DoC.

Number	Date of issue	Title
EN 1041	2008 + A1: 2013	Information supplied by the manufacturer of medical devices
EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation And testing within a risk management process
EN ISO 11137-1	2015 + A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11607-1	2020+A11:2022+A1:2023	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 14971	2019+A11: 2021	Medical devices - Application of risk management to medical devices
EN 45502-1	2015	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
EN 45502-2-1	2003	Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)
EN 45502-2-2	2008 + AC 2009	Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)
EN ISO 15223-1	2016	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements Second Edition
EN 62366-1	2015+A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices

Attachment 2: Model Listing

The following models are included under the scope of this DoC:

Model Name	Model Number(s)	Variant(s)
TYRX™ Absorbable Antibacterial Envelope	CMRM6122INT	Size: 6.3cm x 6.9cm
TYRX™ Absorbable Antibacterial Envelope	CMRM6133INT	Size: 7.4cm x 8.5cm
TYRX™ Absorbable Antibacterial Envelope	NMRM6122INT	Size: 6.3cm x 6.9cm
TYRX™ Absorbable Antibacterial Envelope	NMRM6133INT	Size: 7.4cm x 8.5cm

Declaration of Conformity

Legal Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA
EC Authorized Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Design Facility:	Medtronic Inc. 8200 Coral Sea Street Mounds View, MN 55112 USA
Manufacturing Facility:	Medtronic Ireland Parkmore Business Park West Galway Ireland
Product Family/ies:	Heart Therapy Delivery Systems
Products:	See Attachment
Classification:	Directive 90/385/EEC (AIMD)

Notified Body	NSAI (0050)
EC Quality Certificate	253.100 issued on 12 June 2002
EC Design Certificate	253.100

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of Directive 90/385/EEC (AIMD), including amendments issued, which apply to them, as transposed into

the national laws of the EU member states, as well as the following applicable standards and guidance documents:

- Reference standards listed on the appropriate ER Checklist for each product family.

This declaration is supported by the AIMD, Annex II.3 Approval as well as the EC Design Examination Certificate listed above.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Place: Medtronic Inc. Date: 03-MAR-2021

Name: Ryan Calabrese

Title Sr. Regulatory Affairs Director Signature [redacted]

Products: Heart Therapy Delivery Systems

Model Name	Model No.	Approval Date	Approval Number
SelectSite™ C304-S59 Deflectable catheter system	C304-S59	Mar. 24, 2004 October 11, 2006 October 3, 2008 April 13, 2010 March 3, 2021	253.100/03 253.100/13 253.100/19 253.100/21 253.100/35
SelectSite™ C304-L69 Deflectable catheter system	C304-L69		
SelectSite™ C304-XL74 Deflectable catheter system	C304-XL74	October 11, 2006 October 3, 2008 April 13, 2010 March 3, 2021	253.100/13 253.100/19 253.100/21 253.100/35
SelectSite™ C304-HIS Deflectable catheter system	C304-HIS	July 29, 2020 March 3, 2021	253.100/34 253.100/35
Attain® 6227DEF Deflectable Catheter Delivery System	6227DEF	October 11, 2006 October 3, 2008 March 3, 2021	253.100/13 253.100/19 253.100/35

Model Name	Model No.	Approval Date	Approval Number
C315S4 Delivery Catheter	C315S4	October 28, 2010 June 28, 2012 January 21, 2020 March 3, 2021	253.100/23 253.100/26 253.100/33 253.100/35
C315S5 Delivery Catheter	C315S5		
C315S10 Delivery Catheter	C315S10		
C315J Delivery Catheter	C315J		
C315HIS Delivery Catheter	C315HIS		
C315H20 Delivery Catheter	C315H20		
C315H40 Delivery Catheter	C315H40		

Model Name	Model No.	Approval Date	Approval Number
Attain Command™ + SureValve™ 6250VIC Left-Heart Delivery System	6250VIC	March 06, 2013 January 21, 2020 March 3, 2021	253.100/27 253.100/33 253.100/35
Attain Command™ + SureValve™ 6250VIS Left-Heart Delivery System	6250VIS		
Attain Command™ + SureValve™ 6250VI-45S Guide Catheter for Left-Heart Delivery	6250VI-45S		
Attain Command™ + SureValve™ 6250VI-50S Guide Catheter for Left-Heart Delivery	6250VI-50S		
Attain Command™ + SureValve™ 6250VI-57S Guide Catheter for Left-Heart Delivery	6250VI-57S		
Attain Command™ + SureValve™ 6250VI-AM Guide Catheter for Left-Heart Delivery	6250VI-AM		
Attain Command™ + SureValve™ 6250VI-EH Guide Catheter for Left-Heart Delivery	6250VI-EH		
Attain Command™ + SureValve™ 6250VI-EHXL Guide Catheter for Left-Heart Delivery	6250VI-EHXL		
Attain Command™ + SureValve™ 6250VI-MB2 Guide Catheter for Left-Heart Delivery	6250VI-MB2		
Attain Command™ + SureValve™ 6250VI-MB2X Guide Catheter for Left-Heart Delivery	6250VI-MB2X		
Attain Command™ + SureValve™ 6250VI-MP Guide Catheter for Left-Heart Delivery	6250VI-MP		
Attain Command™ + SureValve™ 6250VI-MPR Guide Catheter for Left-Heart Delivery	6250VI-MPR		
Attain Command™ + SureValve™ 6250VI-MPX Guide Catheter for Left-Heart Delivery	6250VI-MPX		
Attain Command™ + SureValve™ 6250VI-3D Guide Catheter for Left-Heart Delivery	6250VI-3D		

Model Name	Model No.	Approval Date	Approval Number
Attain Select™ II + SureValve™ 6248VI-90 Delivery Catheter System	6248VI-90	March 06, 2013 May 27, 2020 March 3, 2021	253.100/27 253.100/36 253.100/35
Attain Select™ II + SureValve™ 6248VI-90S Delivery Catheter System	6248VI-90S		
Attain Select™ II + SureValve™ 6248VI-90L Delivery Catheter System	6248VI-90L		
Attain Select™ II + SureValve™ 6248VI-130 Delivery Catheter System	6248VI-130		
Attain Select™ II + SureValve™ 6248VI-130L Delivery Catheter System	6248VI-130L		
Attain Select™ II + SureValve™ 6248VI-90P Delivery Catheter System	6248VI-90P		
Attain Select™ II + SureValve™ 6248VI-90SP Delivery Catheter System	6248VI-90SP		
Attain Select™ II + SureValve™ 6248VI-130P Delivery Catheter System	6248VI-130P		

Revision History

Revision	Date	Description of Change
1A	September 2010	Updated to include amendment number for the modified Attain Select II 6248DEL (Amendment # 253.100/22)
1B	November 2010	Updated to include the amendment number for the modified SelectSite™ C304 Deflectable Catheter System (Amendment # 253.100/21) and to add reference to the C315 Delivery Catheter product family (Amendment # 253.100/23)
1C	June 2011	Transpose into new template FTDOP116978-13 rev 1B. Update issue date of the EC Certificates. Remove Attain 6226DEF which is no longer manufactured. Other minor typographical updates.
1D	June 2011	Correct page numbering in the footer. Correction to a Typographical error only. No impact on the DoC content.
1E	November 2011	Updated to include amendment number for the modified Attain 6216A/6218A product family. Minor documentation updates also completed to align model names and formatting with the Design Examination Cert.
1F	July 2012	Updated to include amendment number for implementation of additional sterilisation site (Sterigenics) for the C315 Delivery Catheters and to update title of signatory
1G	March 2013	Updated to add the Attain Command + SureValve and Attain Select II + SureValve product family model names and numbers and their approval details (approval date/approval number).
1H	June 2014	Updated to remove Attain Prevail as product is no longer manufactured or in distribution. Updated also to list the specific model numbers for the Attain Select™ II delivery catheter systems and to reflect re-certification approval by NSAI
1J	November 2015	Updated to include amendment number for implementation of sterilsation cycle 7 for Attain Select™ II delivery catheter systems
1K	May 2017	Updated to reflect extension to current Design Examination certificate & Full Quality Assurance certificate
1L	July 2017	Updated to reflect re-certification approval by NSAI. Revision number corrected in footer.
AA	May 2020	Updated to reflect extension to current Design Examination certificate & Full Quality Assurance certificate for file 253.100.35 under review with NSAI. Update to current template revision FTDOP116978-13 Rev. AB.
AB	August 2020	Update to include amendment number for tip material change for C315 Delivery Catheter, Attain Command + SureValve and Attain Select II + SureValve product familes (file 253.100.33, 253.100.36). Add C304-HIS product family model name, number and approval dates as per file 253.100.34.
AC	August 2020	Updated to reflect extension to current Design Examination certificate & Full Quality Assurance certificate for file 253.100.35 under review with NSAI.
AD	November 2020	Update to reflect extension to current Design Examination certificate & Full Quality Assurance certificate for file 253.100.35

		under review with NSAI.
AE	March 2021	Updated to reflect re-certification approval by NSAI (File 253.100.35). Removed Attain Command, Attain Select II, Attain 6216A/6218A models as product is no longer manufactured or in distribution, and has been removed from the EC Design Examination Certificate as per file 253.100.35. Updated to current template.

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***