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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 (Implantable Class IIb Devices and Class III Devices)

No. G12 039709 1456 Rev. 05

Manufacturer:

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

SRN Manufacturer - US-MF-000019977

Authorized Representative:

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. All applicable requirements of the Testing, 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:G12 039709 1456 Rev. 05

Report No.:	72195120
Preceding Certificate No.:	G12 039709 1456 Rev. 04
Valid from:	2025-04-14
Valid until:	2027-11-27
Date of Initial Issuance:	2022-11-28

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-04-14

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No. G12 039709 1456 Rev. 05

Classification: Class III
Device Group: P070301 - BIOLOGICAL CARDIAC VALVES
Intended Purpose: -

Classification: Class III
Device Group: P070302 - MECHANICAL HEART VALVES
Intended Purpose: -

Classification: Class III
Device Group: P070303 - HEART VALVE TUBES
Intended Purpose: -

Classification: Class III
Device Group: P070380 - HEART VALVES - ACCESSORIES
Intended Purpose: -

Classification: Class III
Device Group: C020299 - CARDIAC TEMPORARY STIMULATION DEVICES (WITH OR WITHOUT ACTIVE SUBSTANCES) - OTHER
Intended Purpose: -

Classification: Class III
Device Group: P070304 - HEART VALVE RINGS
Intended Purpose: -

Classification: Class III
Device Group: C019012 - AORTIC PUNCHES AND AORTOTOMY SYSTEMS
Intended Purpose: -

The validity of this certificate depends on conditions and/or is limited to the following: -

Revision History:

Rev.	Dated	Report	Description
00	2022-11-28	72179409	-
01	2023-06-23	72187593	Supplemented: Device(s)/group of device(s) added
02	2023-09-11	72192891, 72192892	Renewal of certificate
03	2023-12-11	72194254	Supplemented: Device(s)/group of

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TÜV SÜD
Product Service

EU Quality Management System Certificate (MDR)

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

No. G12 039709 1456 Rev. 05

			device(s) added
04	2025-01-23	72195120	Supplemented: Device(s)/group of device(s) added
05	2025-04-14	72195120	Supplemented: Device(s)/group of device(s) added

EU MDR Declaration of Conformity (DoC)

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
Manufacturer SRN:	US-MF-000019977
Manufacturing Site(s):	Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California Mexico
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Authorized Representative SRN:	NL-AR-000006050
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65, 80339 Munich, Germany (0123)
Conformity Assessment Certificate(s):	G70 039709 1496 G12 039709 1456
Conformity Assessment Procedure:	Annex IX
Risk Class:	Class III
Classification Rule:	Refer to the Products Covered table below
Intended Purpose:	Refer to the Products Covered table below

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: Santa Ana, CA, Cardiac Surgery

Name: Zach Larsen

Title: Regulatory Affairs Manager

Signature: 

Date: 13 Aug 2024

Products Covered

Product Name	Medtronic Product Identifier Model # (with variants-if applicable)	Basic UDI-DI	Risk Class/ Rule	Intended Purpose	EMDN / GMDN Codes
SimuPlus™ Flexible Annuloplasty Ring	Model: 7700FR Variants: 7700FR26 7700FR28 7700FR30 7700FR32 7700FR34 7700FR36 7700FR38 7700FR40 7700FR42	0763000B00015017G	Class III Rule 8	The intended purpose of the SimuPlus flexible annuloplasty ring is to restore unidirectional blood flow through the mitral annulus by repairing a diseased or damage mitral valve.	P07030401/ 66338
SimuPlus™ Flexible Annuloplasty Band	Model: 7700FB Variants: 7700FB26 7700FB28 7700FB30 7700FB32 7700FB34 7700FB36 7700FB38 7700FB40 7700FB42	0763000B00014988L	Class III Rule 8	The intended purpose of the SimuPlus flexible annuloplasty band is to restore unidirectional blood flow through the mitral annulus and/or tricuspid annulus by repairing a diseased or damaged mitral or tricuspid valve.	P07030401/ 66338
SimuForm™ Semi-Rigid Annuloplasty Ring	Model: 7800RR Variants: 7800RR24 7800RR26 7800RR28 7800RR30 7800RR32 7800RR34 7800RR36 7800RR38 7800RR40	0763000B00014978J	Class III Rule 8	The intended purpose of the SimuForm semi-rigid annuloplasty ring is to restore unidirectional blood flow through the mitral annulus by repairing a diseased or damage mitral valve.	P07030401/ 66338
SimuPlus Polysulfone Sizers	Model: 7700PS Variants: 7700PS	0763000B00015027J	Class III Rule 6	The intended purpose of the SimuPlus sizer set (Models 7700PS and 7700FS) is to facilitate the sizing and implantation of a	P07038001/ 47684
SimuPlus Silicone Sizers	Model: 7700FS Variants: 7700FS	0763000B00014998N	Class III Rule 6		P07038001/ 47684

Product Name	Medtronic Product Identifier Model # (with variants-if applicable)	Basic UDI-DI	Risk Class/ Rule	Intended Purpose	EMDN / GMDN Codes
				SimuPlus annuloplasty ring or band.	
SimuForm Polysulfone Sizers	Model: 7800PS Variants: 7800PS	0763000B00015007E	Class III Rule 6	The intended purpose of the SimuForm sizer set, Models 7800PS, is to facilitate the sizing and implantation of a SimuForm annuloplasty ring.	P07038001/ 47684

Common Specification(s)

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title
Not applicable	Not applicable	Not applicable

Revision History

Revision	Date Effective	Description of Change
A	Refer to Agile	Initial release of document

EU MDR Declaration of Conformity (DoC)

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
Manufacturer SRN:	US-MF-000019977
Manufacturing Site(s):	Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California Mexico Medtronic Heart Valves Division 1851 E. Deere Ave Santa Ana, CA 92705 USA
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Authorized Representative SRN:	NL-AR-000006050
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65, 80339 Munich, Germany (0123)
Conformity Assessment Certificate(s):	TD Assessment (Ring, Sizers): G70 039709 1494 MDR QMS (Ring, Sizers): G12 039709 1456
Conformity Assessment Procedure:	Refer to the Products Covered table below
Risk Class:	Refer to the Products Covered table below
Classification Rule:	Refer to the Products Covered table below
Intended Purpose:	Refer to the Products Covered table below

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: Santa Ana, CA, Cardiac Surgery

Name: Zach Larsen

Title: Regulatory Affairs Manager

Signature: 

Date: 11 April 2025

Products Covered

Product Name	Medtronic Product Identifier Model # (with variants-if applicable)	Basic UDI-DI	Conformity Assessment Route	Risk Class	Classification Rule	Intended Purpose
Contour 3D™ annuloplasty ring	Model: 690R Variants: 690R26 690R28 690R30 690R32 690R34 690R36	0763000B000150570	Annex IX	Class III	Annex VIII, Chapter 3, Rule 8	The intended purpose of the Contour 3D annuloplasty ring is to restore unidirectional blood flow through the tricuspid annulus by repairing a diseased or damaged tricuspid valve.
Contour 3D™ Sizer Set	Model: 7690S Variants: 7690S	0763000B000150675	Annex IX	Class III	Annex VIII, Chapter 3, Rule 6	The intended purpose of the Contour 3D sizer set, 7690S, is to facilitate the sizing and implantation of a Contour 3D annuloplasty ring.

Common Specification(s)

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title
Not Applicable	Not Applicable	Not Applicable

Revision History

Revision	Date Effective	Description of Change
A	Refer to Agile	Initial release of document