

Number: 2266996TD02

EU Technical Documentation Assessment Certificate

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

Manufacturer:

Medtronic CoreValve LLC

1851 E. Deere Avenue

92705

Santa Ana, California

United States

SRN ID.: US-MF-000019985

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:

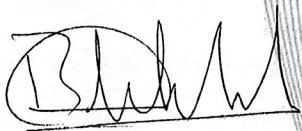
0344

Supplement to certificate: 2259338CN

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.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Principal Certification Manager



First Issued: 19 September 2023 Date: 19 September 2023 Expiry date: 1 September 2028

© Integral publication of this certificate and adjoining reports is allowed

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: 2266996TD02

EU Technical Documentation Assessment Certificate

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

This certificate covers the following device(s):

Class III	
Basic UDI-DI: 0763000B00011727K Device Name: Evolut FX System Type: P070301030101 Stented biological aortic valves for percutaneous implant – valve tissue of animal origin Model: - Evolut FX 23mm Transcatheter Aortic Valve (EVOLUTFX-23) - Evolut FX 26mm Transcatheter Aortic Valve (EVOLUTFX -26) - Evolut FX 29mm Transcatheter Aortic Valve (EVOLUTFX -29) - Evolut FX 34mm Transcatheter Aortic Valve (EVOLUTFX -34) - Evolut FX 23-29mm Delivery Catheter System (D-EVOLUTFX-2329) - Evolut FX 34mm Delivery Catheter System (D-EVOLUTFX-34) - Evolut FX 23-29mm Loading System (L-EVOLUTFX-2329) - Evolut FX 34mm Loading System (L-EVOLUTFX-34)	Intended Purpose: The intended purpose of the Evolut FX system is to replace the function of a stenosed native or failed surgical aortic valve without the need for open heart surgery.

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	19-09-2023	2259338CN03	First issue

First Issued: 19 September 2023 Date: 19 September 2023 Expiry date: 1 September 2028

© Integral publication of this certificate and adjoining reports is allowed

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: 2266996CE02

EU Quality Management System Certificate

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

Manufacturer:

Medtronic CoreValve LLC

1851 E. Deere Avenue

92705

Santa Ana, California

United States

SRN ID.: US-MF-000019985

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

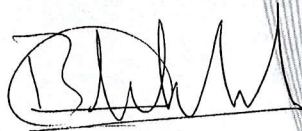
Supplement to certificate: 2259338CN

Additional certificate: 2266996TD02

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.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Principal Certification Manager



First Issued: 19 September 2023

Date: 19 September 2023

Expiry date: 1 September 2028

© Integral publication of this certificate and adjoining reports is allowed

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: 2266996CE02

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):

Class III

Device Name: Evolut FX System

Conditions for or limitations to the validity of this certificate:

- N/A

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	19-09-2023	2259338CN03	First issue



First Issued: 19 September 2023 Date: 19 September 2023 Expiry date: 1 September 2028

© Integral publication of this certificate and adjoining reports is allowed

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 CoreValve, LLC
1851 E Deere Ave
Santa Ana, CA 92705

Manufacturer SRN: US-MF-000019985

Manufacturing Site/s:
(Transcatheter Aortic Valve) Medtronic Mexico S. de R.L. de CV.
Av. Paseo Cucapah 10510 El Lago CP22210
Tijuana, Baja California,
Mexico

Manufacturing Site/s:
(Delivery System & Loading System) Medtronic Ireland
Parkmore Business Park West,
Galway, Ireland

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
The Netherlands

NB Number: 0344

Conformity Assessment Certificate(s): MDR EU Quality Management System Certificate 2266996CE02/
MDR EU Technical Documentation Assessment Certificate 2266996TD02

Conformity Assessment Procedure: Annex IX

Risk Class: Evolut FX System – Class III



EU MDR Declaration of Conformity

D00853521

Revision A

Page 2 of 5

Form

Medtronic

Classification Rule:

Evolut FX System:

Evolut FX Transcatheter Aortic Valve - Annex VIII Section 5.4, Rule 8; Section 7.5, Rule 18

Evolut FX Delivery Catheter System - Annex VIII Section 5.3, Rule 7

Evolut FX Loading System - Annex VIII Section 4.1, Rule 1

Per MDCG 2021-24, classification is determined by the intended use of the system; therefore, classification of the system selected is at the level of the highest classified component. Accordingly, the Evolut FX system (TAV, DCS, and LS) is classified as a Class III medical device.

Intended Purpose:

The intended purpose of the Evolut FX system is to replace the function of a stenosed native or failed surgical aortic valve without the need for open heart surgery.

Statement:

We, Medtronic CoreValve, LLC., 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):

Not applicable

Union Legislation	Applicable Declaration of Conformity Document Number



EU MDR Declaration of Conformity

Form

D00853521

Revision A

Page 3 of 5

Medtronic

Place: Santa Rosa, CA

Name: Declan Dineen

Title: Vice President, Regulatory Affairs Structural Heart

Signature:



Date: Sept. 21, 2023



This document is electronically controlled

Medtronic Controlled Information
CONFIDENTIAL

D00009859 Revision D

EU MDR Declaration of Conformity

Form

D00853521

Revision A

Page 4 of 5

Medtronic

Products Covered

Trade Name	Product Name	Medtronic Product Identifier	Basic UDI-DI	Optional: Additional nomenclature identifier (e.g. EMDN, GMDN)
		CFN		
Medtronic Evolut FX System	Medtronic Evolut FX Transcatheter Aortic Valve, 23 mm	EVOLUTFX-23	0763000B00011727K	GMDN: 60245 EMDN: P070301030101
	Medtronic Evolut FX Transcatheter Aortic Valve, 26 mm	EVOLUTFX-26		
	Medtronic Evolut FX Transcatheter Aortic Valve, 29 mm	EVOLUTFX-29		
	Medtronic Evolut FX Transcatheter Aortic Valve, 34 mm	EVOLUTFX-34		
	Medtronic Evolut FX Delivery Catheter System, 23-29 mm	D-EVOLUTFX-2329		
	Medtronic Evolut FX Delivery Catheter System, 34 mm	D-EVOLUTFX-34		
	Medtronic Evolut FX Loading System, 23-29 mm	L-EVOLUTFX-2329		
	Medtronic Evolut FX Loading System, 34mm	L-EVOLUTFX-34		



EU MDR Declaration of Conformity

Form

Medtronic

D00853521

Revision A

Page 5 of 5

Common Specification(s)

Not Applicable

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title

Revision History

Revision	Date Effective	Description of Change
A	21 September 2023	Initial release of document

This document is electronically controlled

Medtronic Controlled Information
CONFIDENTIAL

D00009859 Revision D



