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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**



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<br><br>**Device Name:** Evolut FX System<br>**Type:** P070301030101 Stented biological aortic valves for percutaneous implant – valve tissue of animal origin<br>**Model:**<br>- Evolut FX 23mm Transcatheter Aortic Valve (EVOLUTFX-23)<br>- Evolut FX 26mm Transcatheter Aortic Valve (EVOLUTFX -26)<br>- Evolut FX 29mm Transcatheter Aortic Valve (EVOLUTFX -29)<br>- Evolut FX 34mm Transcatheter Aortic Valve (EVOLUTFX -34)<br>- Evolut FX 23-29mm Delivery Catheter System (D-EVOLUTFX-2329)<br>- Evolut FX 34mm Delivery Catheter System (D-EVOLUTFX-34)<br>- Evolut FX 23-29mm Loading System (L-EVOLUTFX-2329)<br>- Evolut FX 34mm Loading System (L-EVOLUTFX-34) | *Intended Purpose:*<br>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**



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
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2185-6

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**



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



2184-5

**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**



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



2184-5

# EU MDR Declaration of Conformity (DoC)

| | |
|---|---|
| **Manufacturer:** | Medtronic CoreValve, LLC<br>1851 E Deere Ave<br>Santa Ana, CA 92705 |
| **Manufacturer SRN:** | US-MF-000019985 |
| **Manufacturing Site/s:**<br>**(Transcatheter Aortic Valve)** | Medtronic Mexico S. de R.L. de CV.<br>Av. Paseo Cucapah 10510 El Lago CP22210<br>Tijuana, Baja California,<br>Mexico |
| **Manufacturing Site/s:**<br>**(Delivery System & Loading System)** | Medtronic Ireland<br>Parkmore Business Park West,<br>Galway, Ireland |
| **Authorized Representative:** | Medtronic B.V.<br>Earl Bakkenstraat 10<br>6422 PJ Heerlen<br>The Netherlands |
| **Authorized Representative SRN:** | NL-AR-000006050 |
| **Notified Body:** | DEKRA Certification B.V.<br>Meander 1051<br>6825 MJ Arnhem<br>The Netherlands<br><br>NB Number: 0344 |
| **Conformity Assessment Certificate(s):** | MDR EU Quality Management System Certificate 2266996CE02<br>MDR EU Technical Documentation Assessment Certificate 2266996TD02 |
| **Conformity Assessment Procedure:** | Annex IX |
| **Risk Class:** | Evolut FX System – Class III |

**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 |
|---|---|
| | |
| | |
| | |
| | |

**Place:** Santa Rosa, CA

**Name:** Declan Dineen

**Title:** Vice President, Regulatory Affairs Structural Heart

**Signature:**

**Date:** Sept. 21, 2023

# 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<br>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 | | |

# Common Specification(s)

**Not Applicable**

The following common specifications were used to demonstrate conformity:

| Number | Date of Issue | Title |
|---|---|---|
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# Revision History

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