By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 619064**

Issued To: **Medtronic CoreValve LLC**
1851 E. Deere Avenue
Santa Ana
California
92705
USA

In respect of:

Medtronic CoreValve™ Evolut™ R System, Medtronic CoreValve™ Evolut™ PRO System

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-01-29** Date: **2020-01-22** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 619064

Issued To:

Medtronic CoreValve LLC
1851 E. Deere Avenue
Santa Ana
California
92705
USA

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
EVOLUTR-23	Medtronic CoreValve Evolut R Transcatheter Aortic Valve (TAV)	Evolut R TAV, 23mm	The Evolut R and Evolut PRO systems are indicated for patients with symptomatic native aortic valve stenosis or a stenosed, insufficient, or combined surgical bioprosthetic valve failure necessitating valve replacement. The system is indicated for patients who are at high or greater risk for surgical aortic valve replacement OR are ≥75 years of age and at intermediate risk for surgical AVR (Society of Thoracic Surgeons operative risk score ≥4% or with an estimated hospital mortality ≥4% as assessed by the heart team).	Class III Implantable
EVOLUTR-26		Evolut R TAV, 26mm		
EVOLUTR-29		Evolut R TAV, 29mm		
EVOLUTR-34		Evolut R TAV, 34mm		
EVOLUTPRO-23	Medtronic CoreValve Evolut PRO Transcatheter Aortic Valve	Evolut PRO TAV, 23mm		
EVOLUTPRO-26		Evolut PRO TAV, 26mm		
EVOLUTPRO-29		Evolut PRO TAV, 29mm		
ENVEOR-L	EnVeo R Delivery Catheter System (DCS)	DCS for 23mm, 26mm, 29mm Evolut R TAVs		Class III
ENVEOR-N		DCS for 23mm, 26mm, 29mm Evolut PRO TAVs and 34mm Evolut R TAV		
LS-ENVEOR-23	EnVeo R Loading System (LS)	LS for 23mm Evolut R TAV		
LS-ENVEOR-2629		LS for 26mm, 29mm Evolut R TAVs		
LS-ENVEOR-34		LS for 34mm Evolut R TAV		

First Issued: **2015-01-29** Date: **2020-01-22** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 619064

Issued To:

Medtronic CoreValve LLC
1851 E. Deere Avenue
Santa Ana
California
92705
USA

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
LS-MDT2-23	EnVeo R Loading System (LS)	LS for 23mm Evolut PRO TAV	The Evolut R and Evolut PRO systems are indicated for patients with symptomatic native aortic valve stenosis or a stenosed, insufficient, or combined surgical bioprosthetic valve failure necessitating valve replacement. The system is indicated for patients who are at high or greater risk for surgical aortic valve replacement OR are ≥75 years of age and at intermediate risk for surgical AVR (Society of Thoracic Surgeons operative risk score ≥4% or with an estimated hospital mortality ≥4% as assessed by the heart team).	Class III
LS-MDT2-2629		LS for 26mm, 29mm Evolut PRO TAVs		
ENVPRO-14	EnVeo PRO Delivery Catheter System	DCS for 23mm, 26mm, 29mm Evolut R TAVs		
ENVPRO-16		DCS for 23mm, 26mm, 29mm Evolut PRO TAVs and 34mm Evolut R TAV		
L-ENVPRO-14	EnVeo PRO Loading System	LS for 23mm, 26mm, 29mm Evolut R TAVs		
L-ENVPRO-16		LS for 26mm, 29mm Evolut PRO TAVs and 34mm Evolut R TAV		
L-ENVPRO-1623		LS for 23mm Evolut PRO TAV		

First Issued: **2015-01-29** Date: **2020-01-22** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 619064

Issued To:

Medtronic CoreValve LLC
1851 E. Deere Avenue
Santa Ana
California
92705
USA

Certificate History

Date	Reference Number	Action
29 January 2015	10150860	Transfer from another Notified Body (size 23, EVOLUTR).
30 January 2015	10150861	New issue for the sizes 26 and 29, EVOLUTR.
06 October 2015	10157079	Dupont Tyvek Change.
01 August 2016	10161293	Expansion of indication for use to cover intermediate risk population.
01 December 2016	10166384	IFU & physician training plan updates for the Evolut R delivery system.
13 January 2017	10167774	Line extension to include the size 34, Evolut R.
24 April 2017	10169206	Material and manufacturing process change for the ENVEOR-L and ENVEOR-N.
27 July 2017	10169895	Line extension to include the Evolut PRO system (23mm, 26mm and 29mm).
15 March 2018	8294624	Manufacturing specification change for the tissue splits on the leaflet free-margin.
02 May 2018	8797519	Addition of the EnVeo PRO delivery and loading systems (ENVPRO-14, ENVPRO-16, L-ENVPRO-14, L-ENVPRO-16 and L-ENVPRO-1623).
06 March 2019	8250502	Traceable to NB 0086.
Current	3100459	Certificate Renewal. Reformat of device table.

First Issued: **2015-01-29** Date: **2020-01-22** Expiry Date: **2024-05-26**

...making excellence a habit.™

Digitally signed by DAIVA MACIJAUSKIENĖ
Date: 2020.04.14 12:01:03 +03'00'

BSI
CE SERTIFIKATAS - Pilnas Kokybės Atitikties Užtikrinimas

Direktyva 93/42 / EEB dėl medicinos prietaisų, II priedo 4 skirsnis

Nr. CE 619064

Kam išduota:
„Medtronic CoreValve LLC“
1851 m. E. Deere prospektas
Santa Ana
Kalifornija
92705
JAV

Apimami produktai:
„Medtronic CoreValve ™ Evolut ™ R“ sistema, „Medtronic CoreValve ™ Evolut ™ PRO“ sistema

BSI atliko aukščiau nurodytų produktų kokybės sistemos patikrinimą pagal Tarybos direktyvą 93/42 / EEB, II priedo 4 skirsnį. Kokybės užtikrinimo Sistema atitinka direktyvos reikalavimus. Šių produktų pardavimui reikalingas papildomas II priedas, išskyrus 4 skirsnio pažymėjimą.

BSI vardu ir minėtos direktyvos notifikuotoji įstaiga (notifikuotosios įstaigos numeris 2797):

Gary E Slack, vyresnysis viceprezidentas medicinos prietaisams

Pirmoji sertifikavimo data: 2004 m. rugpjūčio 24 d.
Šio sertifikato data: 2019 m. rugpjūčio 22 d.
Galioja iki: 2024 m. gegužės 26 d.