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EC Certificate - Full Quality Assurance System

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

No. **CE 619063**

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

Digitally signed by Kojevnikov Dmitrii
Date: 2023.10.13 17:16:34 EEST
Reason: MoldSign Signature
Location: Moldova

In respect of:

Design, Development, and Manufacture of Sterile Cardiac Catheter Guidewires, Transcatheter Heart Valve Systems.

Those aspects of Annex II relating to securing and maintaining sterility of Transcatheter Heart Valve Loading Systems.

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 2797):

Gary E Slack

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2015-01-14** Date: **2021-04-23** Expiry Date: **2024-05-26**

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Supplementary Information to CE 619063

Issued To:

Medtronic CoreValve LLC
1851 E. Deere Avenue
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Number	Device name	Intended purpose per IFU
Class III		
---	Confida Brecker Guidewire	As per CE 622424
---	Medtronic CoreValve Evolut R System, Medtronic CoreValve Evolut PRO System Medtronic Evolut PRO+ System	As per CE 619064
Class Is		
MD 0106	Transcatheter Heart Valve Loading Systems	---

First Issued: **2015-01-14** Date: **2021-04-23** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 619063**
Date:	**2021-04-23**
Issued To:	**Medtronic CoreValve LLC** **1851 E. Deere Avenue** **Santa Ana** **California** **92705** **USA**

Subcontractor:	**Service(s) supplied**
Abbyland Pork Packing, Inc. 539 N Meridian Street, PO Box 67 Curtiss, WI 54422 USA	**Animal Tissues / Derivatives**
Admedes GmbH Rastatter Str. 15 75179 Pforzheim Germany	**Manufacture**
Banner Creek LLC 619 East Fourth, Holton, Kansas 66436 USA	**Animal Tissues / Derivatives**
Bemis Healthcare Packaging Ireland Limited Clara Co. Offaly Ireland	**Packaging**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No: **CE 619063**

Date: **2021-04-23**

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

Subcontractor:	Service(s) supplied
Calihan Pork Processors 1 South Street Peoria Illinois 61602 USA	**Animal Tissues / Derivatives**
EPflex Feinwerktechnik GmbH Im Schwöllbogen 24 72581 Dettingen/Erms Germany	**Crucial Supplier**
HA2 Medizintechnik GmbH Tschaikowskistraße 2 38820 Halberstadt Germany	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No: **CE 619063**

Date: **2021-04-23**

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

Subcontractor:	**Service(s) supplied**
Jimmy Dean Foods (D.B.A Hillshire Brands/ Tyson Foods) 2000 Biffle Rd Newburn Tennessee 38059 USA	**Animal Tissues / Derivatives**
Johnsonville Sausage, LLC (d.b.a Perry Way Foods, LLC) 1222 Perry Way Watertown Wisconsin 53094 USA	**Animal Tissues / Derivatives**
Lenzing Plastics GmbH & Co KG A-4860 Lenzing Werkstrale 2 Austria	**Crucial Supplier**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 619063**
Date:	**2021-04-23**
Issued To:	**Medtronic CoreValve LLC** **1851 E. Deere Avenue** **Santa Ana** **California** **92705** **USA**

Subcontractor:	**Service(s) supplied**
Medtronic B.V. – Medtronic EOC Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands	**EU Representative**
Medtronic Ireland Parkmore Business Park West Galway Ireland	**Manufacture**
Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California Mexico	**Manufacture**
Pine Ridge Farm (d.b.a. Kansas City Sausage, LLC) 1801 Maury St Des Moines Iowa 50317 USA	**Animal Tissues / Derivatives**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 619063**
Date:	**2021-04-23**
Issued To:	**Medtronic CoreValve LLC** **1851 E. Deere Avenue** **Santa Ana** **California** **92705** **USA**

Subcontractor:	**Service(s) supplied**
Pork King Packing 8808 Route 23 Marengo Illinois 60152 USA	**Animal Tissues / Derivatives**
Sonora Agropecuaria S.A. de C.V. (SASA) Carretera México-Nogales Km. 1778 Navojoa Sonora C.P. 85895 Mexico	**Animal Tissues / Derivatives**
SP Medical Sp.z.o.o Ul. Ceramiczna 2 98-220 Zdunska Wola Poland	**Manufacture**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No: **CE 619063**

Date: **2021-04-23**

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

Subcontractor:	**Service(s) supplied**
Swaggerty Sausage Co., Inc. 2827 Swaggerty Rd Kodak TN 37764 USA	**Animal Tissues / Derivatives**
Synergy Health Ireland Ltd (Synergy Health - AST - Ireland) IDA Business & Technology Park Tullamore Co. Offaly Ireland	**ETO Sterilization**
Teleflex Medical OEM 1295 Main Street PO Box 219 Coventry CT 06238 United States	**Crucial Supplier**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 619063**
Date:	**2021-04-23**
Issued To:	**Medtronic CoreValve LLC** **1851 E. Deere Avenue** **Santa Ana** **California** **92705** **USA**

Subcontractor:	**Service(s) supplied**
Williams Sausage Company Inc. 5132 Old Troy Hickman Rd Union City Tennessee 38261 USA	**Animal Tissues / Derivatives**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 619063**

Date: **2021-04-23**

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

Date	Reference Number	Action
14 January 2015	8271736	Transfer from another Notified Body.
29 January 2015	8209459	Transferred the Transcatheter heart valves from another Notified Body. Addition of subcontractors Medtronic Mexico, Medtronic Ireland, Teleflex, Momence Packing Co, Johnsonville Sausage, LLC, Pine Ridge Farm, Calihan Pork, Inc, Banner Creek LLC, Abbyland Pork Pack, Inc., Jimmy Dean Foods/Sara Lee Sausage, F.B. Purnell Sausage Co., Inc., Swaggerty Sausage Co., Inc., Bob Evans Farms, Inc in Xenia, OH, BOB EVANS FARMS, INC. in Hillsdale, MI, and Danish Crown AmbA.
13 October 2015	8418449	Certificate renewal.
27 July 2017	8699537	Addition of new suppliers of animal substances Williams Sausage Company Inc. and Pork King Packing. Removal of Bob Evans Farms Inc. (Xenia, OH, USA) and F.B. Purnell Sausage Co Inc. as suppliers of animal substances. Update to addresses for Johnsonville Sausage and Pine Ridge Farm also suppliers of animal substances.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 619063**

Date: **2021-04-23**

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

Date	Reference Number	Action
06 March 2019	8250502	Traceable to NB 0086. Administrative Subcontractor Service wording update for: Abbyland Pork Pack, Inc., Banner Creek LLC, BOB EVANS FARMS, INC., Calihan Pork, Inc, Danish Crown AmbA, Jimmy Dean Foods/Sara Lee Sausage, Johnsonville Sausage, LLC, Momence Packing Co, Pine Ridge Farm, Pork King Packing, Swaggerty Sausage Co., Inc. and Williams Sausage Company Inc. from "Animal Substances" to "Animal Tissues / Derivatives" Synergy Health (Isotron) from "Sterilization" to "ETO Sterilization"
12 August 2020	3145446	Certificate renewal. Addition of product table. Updates to subcontractor name and address details to align with ISO certificates: change of name from Synergy Health (Isotron) to Synergy Health Ireland Limited, Medtronic B.V. to Medtronic B.V. – Medtronic EOC, Calihan Pork, Inc. to Calihan Pork Processors, Jimmy Dean Foods/Sara Lee Sausage to Jimmy Dean Foods (D.B.A Hillshire Brands/Tyson Foods), and Steripack to Bemis Healthcare Packaging Ireland Limited; update of name and address for Admedes GmbH, Lenzing Plastics GmbH & Co KG, Abbyland Pork Packing, Inc., and Teleflex Medical OEM; update of address for Banner Creek LLC. Removal of suppliers BOB EVANS FARMS, Inc. (Hillsdale, MI, USA) and Danish Crown AmbA (Skaerbaek, 6780 Denmark).
23 April 2021	3428604	Classification correction for Transcatheter Heart Valve Loading Systems previously listed on CE 619064. Removal of subcontractor Momence Packing Co.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 619063**

Date: **2021-04-23**

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

Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Date	Reference Number	Action
29 June 2022	3623389	Addition of Sonora Agropecuaria S.A de C.V. (SASA) as a "Animal Tissues / Derivatives" subcontractor.

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29 June 2022

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

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 619063	93/42/EEC Annex II excluding Section 4	3623389	Addition of Sonora Agropecuaria S.A de C.V. (SASA) as a "Animal Tissues / Derivatives" subcontractor.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl

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10182630DOC Rev. AH

EC Declaration of Conformity

CONFORMITY

Legal Manufacturer:	Medtronic CoreValve LLC 1851 E Deere Avenue Santa Ana, CA 92705 USA
Design Facility	Medtronic CoreValve LLC 1851 E Deere Avenue Santa Ana, CA 92705 USA
Manufacturing Facilities	Medtronic Mexico S. de R.L. de CV Av. Paseo Cucaph10510 El Lago C.P. 22210 Tijuana, Baja California MEXICO Medtronic CoreValve LLC 1851 E Deere Avenue Santa Ana, CA 92705 USA (DCS and LS only) Medtronic Ireland Parkmore Business Park West Galway, Ireland
EC Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Conformity Assessment	Annex II (+ Section 4)
EC Quality Certificate	619063 (BSI)
EC Design Certificate: Name of Notified Body:	619064 BSI (Registration #2797)
Description of Device(s)	Medtronic CoreValve Evolut R System Medtronic CoreValve Evolut PRO System Medtronic Evolut PRO+ System See Attachment 1

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10182630DOC Rev. AH

Statement:

I, the undersigned, hereby declare that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 93/42/EEC including amendments issued and ISO 13485:2016, which apply to them.

This declaration is supported by the EC Quality System Certificate, 619063 issued by BSI, according to the provisions of relevant Annex (es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Place: Medtronic Ireland Date: 3rd March 2023

Name: Esther Keating
Senior Director,
Regulatory Affairs

Signature: Esther Keating

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10182630DOC Rev. AH

Attachment 1 to the EC Declaration of Conformity

Classification of the Device:

Device Name		Classification	Classification Rule
Medtronic CoreValve™ Evolut™ R System, Medtronic CoreValve™ Evolut™ PRO System, Medtronic Evolut™ PRO+ System	Transcatheter Aortic Valve	III	Annex IX Rule 8 and 17
	Delivery Catheter	III	Annex IX Rule 7

The CoreValve Evolut R system is composed of the following components:

Device Name	Model Number
CoreValve™ Evolut™ R Transcatheter Aortic Valve (TAV)	EVOLUTR-23
	EVOLUTR-26
	EVOLUTR-29
	EVOLUTR-34
EnVeo™ R Delivery Catheter System (DCS)	ENVEOR-L
	ENVEOR-N
EnVeo™ PRO Delivery Catheter System (DCS)	ENVPRO-14
	ENVPRO-16

The CoreValve Evolut PRO system is composed of the following components:

Device Name	Model Number
CoreValve™ Evolut™ PRO Transcatheter Aortic Valve (TAV)	EVOLUTPRO-23
	EVOLUTPRO-26
	EVOLUTPRO-29
EnVeo™ R Delivery Catheter System (DCS)	ENVEOR-N
EnVeo™ PRO Delivery Catheter System (DCS)	ENVPRO-16

The Evolut PRO+ system is composed of the following components:

Device Name	Model Number
Evolut™ PRO+ Transcatheter Aortic Valve (TAV)	EVPROPLUS-23
	EVPROPLUS-26
	EVPROPLUS-29
	EVPROPLUS-34
Evolut™ PRO+ Delivery Catheter System (DCS)	D-EVPROP23-29
Evolut™ PRO+ Delivery Catheter System (DCS)	D-EVPROP34

Refer to the following documents for the List of Applied Standards:
10780638DOC - Product Standards List for Evolut R and Evolut PRO Systems
10746204DOC - Product Standards List for Evolut PRO+

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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, Medtronic 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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-01-29** Date: **2021-04-22** Expiry Date: **2024-05-26**

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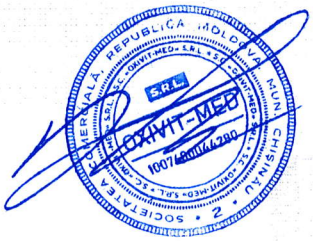
EC Design-Examination Certificate

Supplementary Information to CE 619064

Issued To:

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



Intended Purpose:
The CoreValve Evolut R/PRO/PRO+ system is indicated for patients presenting with severe native aortic valve stenosis. For patients presenting with severe native bicuspid aortic valve stenosis, the CoreValve Evolut R/PRO/PRO+ system is indicated for patients who are at intermediate or greater risk for surgical aortic valve replacement (AVR) where intermediate risk is defined as Society of Thoracic Surgeons operative risk score ≥4% or documented heart team agreement of risk for AVR due to frailty or comorbidities. For patients presenting at low risk for AVR (<4%), the system is indicated for patients ≥70 years of age with an LVEF >30%. The CoreValve Evolut R/PRO/PRO+ system is also indicated for patients with a stenosed, insufficient, or combined surgical bioprosthetic valve failure necessitating valve replacement who are at high or greater risk for surgical aortic valve replacement (AVR) where high risk is defined as Society of Thoracic Surgeons operative risk score ≥8% or documented heart team agreement of risk for AVR due to frailty or comorbidities.
Patients must present with anatomical dimensions as described in Section 1.1.

Catalogue Number	Device Name	Model, Type	Classification
EVOLUTR-23	Medtronic CoreValve Evolut R Transcatheter Aortic Valve (TAV)	Evolut R TAV, 23mm	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 (TAV)	Evolut PRO TAV, 23mm	
EVOLUTPRO-26		Evolut PRO TAV, 26mm	
EVOLUTPRO-29		Evolut PRO TAV, 29mm	
EVPROPLUS-23	Medtronic Evolut PRO+ Transcatheter Aortic Valve (TAV)	Evolut PRO+ TAV, 23mm	
EVPROPLUS-26		Evolut PRO+ TAV, 26mm	
EVPROPLUS-29		Evolut PRO+ TAV, 29mm	
EVPROPLUS-34		Evolut PRO+ TAV, 34mm	

First Issued: **2015-01-29** Date: **2021-04-22** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 619064

Issued To:

Medtronic CoreValve LLC
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92705
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Catalogue Number	Device Name	Model, Type	Classification
ENVEOR-L	EnVeo R Delivery Catheter System (DCS)	DCS for 23mm, 26mm and 29mm Evolut R TAVs	Class III
ENVEOR-N		DCS for 23mm, 26mm and 29mm Evolut PRO TAVs and 34mm Evolut R TAV	
ENVPRO-14	EnVeo PRO Delivery Catheter System (DCS)	DCS for 23mm, 26mm and 29mm Evolut R TAVs	
ENVPRO-16		DCS for 23mm, 26mm and 29mm Evolut PRO TAVs and 34mm Evolut R TAV	
D-EVPROP23-29	Evolut PRO+ Delivery Catheter System (DCS)	DCS for 23mm, 26mm and 29mm Evolut PRO+ TAVs	
D-EVPROP34		DCS for 34mm Evolut PRO+ TAV	

First Issued: **2015-01-29** Date: **2021-04-22** Expiry Date: **2024-05-26**

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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.
22 January 2020	3100459	Certificate Renewal. Reformat of device table.

First Issued: **2015-01-29** Date: **2021-04-22** Expiry Date: **2024-05-26**

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Supplementary Information to CE 619064

Issued To:

Medtronic CoreValve LLC
1851 E. Deere Avenue
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USA

Date	Reference Number	Action
18 June 2020	9788909	Extension of indications to the asymptomatic patient population and to the low risk patient population including age and LVEF limitations. Updates to indications for Valve-in-Valve and bicuspid aortic valve stenosis. IFU updates including indications, patient access criteria and rapid pacing considerations. PMCF plan updates.
19 August 2020	8861660	Packaging jar lid material change.
Current	3007758	Line extension to add the Evolut PRO+ TAVs and associated DCSs. Removal of the Loading Systems (LS) from scope due to misclassification. Device table updated. IFU and Training & Education Materials updates for all Evolut Systems to supplement existing precautionary language for Post-Implant dilatation (PID).

First Issued: **2015-01-29** Date: **2021-04-22** Expiry Date: **2024-05-26**

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Supplementary Information to CE 619064 - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

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

Date: 18 August 2021

Changes Approved:

Date	Reference Number	Action
18 August 2021	3447339	Addition of optimized PCA EO sterilization cycle.

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18 August 2021

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

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 619064	93/42/EEC Annex II Section 4	3447339	Addition of optimized PCA EtO Sterilization cycle to reduce EO concentration.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

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