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, 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
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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	

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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	

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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.

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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: 29 June 2022

Changes Approved:

Date	Reference Number	Action
18 August 2021	3447339	Addition of optimized PCA EO sterilization cycle.
07 October 2021	3482195	Extension of Evolut Pro+ DCS shelf life from one year to two years.
29 June 2022	3623387	Change to Evolut PRO and PRO+; Addition of Sonora Agropecuaria S.A de C.V. (SASA) as a "Animal Tissues / Derivatives" for supply of outer wrap porcine tissue.

Inspiring trust for a more resilient world.

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 619064	93/42/EEC Annex II Section 4	3623387	Change to Evolut PRO and PRO+; Addition of Sonora Agropecuaria S.A de C.V. (SASA) as a "Animal Tissues / Derivatives" for supply of outer wrap porcine tissue.

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

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 719088 R000

Manufacturer: Medtronic, Inc.

Address:
710 Medtronic Parkway
Minneapolis
MN
55432
USA

Single Registration Number: US-MF-000019977

EU Authorised Representative: Medtronic B.V.

Address:
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2021-12-09** Date: **2022-05-30** Expiry Date: **2026-12-08**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 719088 R000

Device Schedule: Class III and Class IIb devices

Class III, Implantable	**Intended purpose**
Resolute Onyx Zotarolimus-Eluting Coronary Stent System Onyx TruCor Zotarolimus-Eluting Coronary Stent System Onyx Frontier Zotarolimus-Eluting Coronary Stent System Onyx TruStar Zotarolimus-Eluting Coronary Stent System	See MDR 719094
Resolute Integrity Zotarolimus-Eluting Coronary Stent System	See MDR 731992
Class III	**Intended purpose**
Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter	See MDR 731947

First Issued: **2021-12-09** Date: **2022-05-30** Expiry Date: **2026-12-08**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 719088 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-12-09	3084891	Issued.
2022-03-15	3625861	Amended – Change of subcontractor activity (Medtronic Ireland – Add design). Supplemented – Addition of Sprinter Legend™ Rapid Exchange Balloon Dilatation Catheter.
2022-04-08	3657388	Supplemented – Addition of Resolute Integrity Zotarolimus-Eluting Coronary Stent System. Amended – Addition of Medtronic Mexico EG as a subcontractor for manufacturing. Editorial correction to legal manufacturer's address to change Minnesota to MN.
Current	3694380	Supplemented – Addition of Onyx Frontier & Onyx TruStar Zotarolimus-Eluting Coronary Stent Systems into device schedule

First Issued: **2021-12-09** Date: **2022-05-30** Expiry Date: **2026-12-08**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 719088 R000

Date: **2022-05-30**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Medtronic Ireland Parkmore Business Park West Galway Ireland	**Design** **Manufacture**
Medtronic Mexico EG Carret. Int. Km. 1969 Guad-Nogales Km. 2 85340 Empalme Sonora Mexico	**Manufacture**
Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California Mexico	**Manufacture**
Medtronic Vascular 3576 Unocal Place Santa Rosa California 95403 USA	**Design**
ScinoPharm Taiwan, Ltd. No. 1 Nan-Ke 8th Road Shan-Hua Tainan County 74141 Taiwan (R.O.C)	**Crucial Supplier**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 719088 R000

Date: **2022-05-30**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Synergy Health Ireland Ltd IDA Business & Technology Park Tullamore Co. Offaly Ireland	**ETO Sterilization**

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EU MDR Declaration of Conformity (DoC)

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
Manufacturer SRN:	US-MF-000019977
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Authorized Representative SRN:	NL-AR-000006050
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands Notified Body number: 2797
Conformity Assessment Certificate(s):	Annex IX Ch II certificate number: MDR 719094 Annex IX Ch I & III certificate number: MDR 719088
Conformity Assessment Procedure:	Annex IX
Risk Class:	Class III
Classification Rule:	Annex VIII, Chapter 3, Rule 8 and Rule 14.

Intended Purpose:

Resolute Onyx™	The Resolute Onyx™ stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.
Onyx TruCor™	The Onyx TruCor™ stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.
Onyx Frontier™	The stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.
Onyx TruStar™	The stent is intended to improve coronary luminal diameters of either single or multiple vessels, as an adjunct to coronary interventions and to reduce restenosis. The stent is intended as a permanently implanted device.

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:	Medtronic Ireland
Name:	Sharon Fahy
Title:	Senior Regulatory Affairs Director
Signature:	Sharon Fahy
Date:	12 July 2022

Products Covered

Product Name	Medtronic Product Identifier	Basic UDI-DI
	CFN	
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX20008X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX20012X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX20015X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX20018X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX20022X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX20026X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX20030X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22508X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22512X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22515X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22518X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22522X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22526X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22530X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22534X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX22538X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25008X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25012X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25015X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25018X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25022X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25026X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25030X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25034X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX25038X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27508X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27512X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27515X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27518X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27522X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27526X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27530X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27534X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX27538X	0763000B00000156T

Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30008X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30012X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30015X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30018X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30022X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30026X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30030X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30034X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX30038X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35008X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35012X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35015X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35018X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35022X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35026X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35030X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35034X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX35038X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40008X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40012X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40015X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40018X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40022X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40026X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40030X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40034X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX40038X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX45012X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX45015X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX45018X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX45022X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX45026X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX45030X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX50012X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX50015X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX50018X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX50022X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX50026X	0763000B00000156T
Resolute Onyx™ Zotarolimus-Eluting Coronary Stent System	RONYX50030X	0763000B00000156T

Product Name	Medtronic Product Identifier	Basic UDI-DI
	CFN	
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22508X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22512X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22515X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22518X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22522X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22526X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22530X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22534X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR22538X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25008X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25012X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25015X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25018X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25022X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25026X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25030X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25034X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR25038X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR27508X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR27512X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR27515X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR27518X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR27522X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR27526X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR27530X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR27534X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR27538X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30008X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30012X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30015X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30018X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30022X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30026X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30030X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30034X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR30038X	0763000B00000156T

Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35008X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35012X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35015X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35018X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35022X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35026X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35030X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35034X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR35038X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40008X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40012X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40015X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40018X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40022X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40026X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40030X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40034X	0763000B00000156T
Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System	TRCR40038X	0763000B00000156T

Product Name	Medtronic Product Identifier	Basic UDI-DI
	CFN	
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG20008X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG20012X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG20015X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG20018X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG20022X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG20026X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG20030X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22508X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22512X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22515X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22518X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22522X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22526X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22530X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22534X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG22538X	0763000B00006588B

Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG25008X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG25012X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG25015X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG25018X	0763000B00006588B
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Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG25038X	0763000B00006588B
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Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG30008X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG30012X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG30015X	0763000B00006588B
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Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG30038X	0763000B00006588B
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Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG35015X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG35018X	0763000B00006588B
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Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG35034X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG35038X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40008X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40012X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40015X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40018X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40022X	0763000B00006588B

Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40026X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40030X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40034X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG40038X	0763000B00006588B
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Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG50026X	0763000B00006588B
Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System	ONYXNG50030X	0763000B00006588B

Product Name	Medtronic Product Identifier	Basic UDI-DI
	CFN	
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR20008X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR20012X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR20015X	0763000B00006588B
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Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR20022X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR20026X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR20030X	0763000B00006588B
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Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR22530X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR22534X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR22538X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR25008X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR25012X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR25015X	0763000B00006588B

Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR25018X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR25022X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR25026X	0763000B00006588B
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Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR27508X	0763000B00006588B
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Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR27515X	0763000B00006588B
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Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR35034X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR35038X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR40008X	0763000B00006588B
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Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR40018X	0763000B00006588B
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Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR40026X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR40030X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR40034X	0763000B00006588B

Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR40038X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR45012X	0763000B00006588B
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Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR50026X	0763000B00006588B
Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System	TSTAR50030X	0763000B00006588B

Common Specification(s)

The following common specifications were used to demonstrate conformity:

Number	Date of Issue	Title
Not Applicable		

Revision History

Revision	Date Effective	Description of Change
A	Refer to Agile MAP	Initial release of document for Resolute Onyx™
B	Refer to Agile MAP	Addition of Onyx TruCor™ Zotarolimus-Eluting Coronary Stent System information. Addition of product names to document header. Extension of Resolute Onyx™ & Onyx TruCor™ Zotarolimus-Eluting Coronary Stent Systems shelf life from 2 to 3 years.
C	Refer to Agile Map	Addition of Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System and Onyx TruStar™ Zotarolimus-Eluting Coronary Stent System information.

Revision	Date Effective	Description of Change
		Addition of product names to document header. Addition of trademark symbol (™) in product names throughout.