By Royal Charter

EC Design-Examination Certificate

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

No. **CE 585003**

Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

In respect of:

Portico™ and Navitor™ Transcatheter Aortic Heart Valve Systems

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC Annex II Section 4 and Regulation 722/2012. The design conforms to the requirements of this directive and regulation. 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: **2012-11-16** Date: **2021-05-10** Expiry Date: **2022-11-15**

...making excellence a habit™

EC Design-Examination Certificate

Supplementary Information to CE 585003

Issued To:

St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Catalogue Number	Device Name	Model Type	Associated Delivery Systems	Associated Loading Systems	Intended purpose per IFU	Classification
PRT-23	Portico™ Transcatheter Aortic valves	23mm	PRT-DS-TF-18F PRT-DS-ALT-18F FNAV-DS-SM	PRT-LS-TF/ALT-18F FNAV-LS-SM	The Portico valve is indicated for transcatheter delivery in patients with symptomatic severe native aortic stenosis, who are considered high or extreme surgical risk.	Class III Implantable
PRT-25		25mm				
PRT-27		27mm	PRT-DS-TF-19F PRT-DS-ALT-19F FNAV-DS-LG	PRT-LS-TF/ALT-19F FNAV-LS-LG		
PRT-29		29mm				

First Issued: **2012-11-16** Date: **2021-05-10** Expiry Date: **2022-11-15**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 585003

Issued To:

St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Catalogue Number	Device Name	Model Type	Access Type	Associated Valves	Associated Loading Systems	Intended purpose per IFU	Classification
PRT-DS-TF-18F	Portico™ Transcatheter Aortic delivery systems	18 Fr	Transfemoral/ subclavian/ axilliary	PRT-23 PRT-25	PRT-LS-TF/ALT-18F	The Portico Transcatheter delivery system is indicated for transfemoral or subclavian / axillary delivery of the Portico valve. The delivery system is indicated for insertion into the vessel with or without an arterial introducer sheath.	Class III
PRT-DS-ALT-18F			Subclavian/ axilliary				
PRT-DS-TF-19F		19 Fr	Transfemoral/ subclavian/ axilliary	PRT-27 PRT-29	PRT-LS-TF/ALT-19F		
PRT-DS-ALT-19F			Subclavian/ axilliary				

First Issued: **2012-11-16** Date: **2021-05-10** Expiry Date: **2022-11-15**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 585003

Issued To:

St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Catalogue Number	Device Name	Model Type	Access Type	Associated Valves	Associated Loading Systems	Intended purpose per IFU	Classification
FNAV-DS-SM	FlexNav™ delivery systems	18 Fr	Transfemoral/ subclavian/ axilliary	PRT-23 PRT-25 NVTR-23 NVTR-25	FNAV-LS-SM	The FlexNav™ delivery system is indicated for transfemoral or subclavian/axillary delivery of the Portico™ / Navitor ™ valve. The delivery system is indicated for insertion into the vessel with or without an arterial introducer sheath.	Class III
FNAV-DS-LG		19 Fr		PRT-27 PRT-29 NVTR-27 NVTR-29	FNAV-LS-LG		

First Issued: **2012-11-16** Date: **2021-05-10** Expiry Date: **2022-11-15**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 585003

Issued To:

St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Catalogue Number	Device Name	Model Type	Associated Delivery Systems	Associated Loading Systems	Intended purpose per IFU	Classification
NVTR-23	Navitor™ Transcatheter Heart valves	23mm	FNAV-DS-SM	NVTR-LS-SM	The Navitor™ valve is indicated for transcatheter delivery in patients with symptomatic severe native aortic stenosis who are considered high or extreme surgical risk.	Class III Implantable
NVRT-25		25mm				
NVTR-27		27mm	FNAV-DS-LG	NVTR-LS-LG		
NVTR-29		29mm				

First Issued: **2012-11-16** Date: **2021-05-10** Expiry Date: **2022-11-15**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 585003

Issued To:

St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Certificate History

Date	Reference Number	Action
16 November 2012	10134049	First Issue.
16 January 2013	10139233	Valve manufacturing moved to St. Jude Medical Costa Rica.
18 April 2013	10141298	Stent manufacturing moved to the St. Paul facility (177 County Road B East).
14 May 2013	10141486	Valve shelf life extended to 12 months.
11 December 2013	10143493	Line extension to include 25mm valve. Introduction of electronic IFU for the valve. Introduced reference to Regulation (EU) 722/2012.
07 April 2014	10146232	Delivery system and loading system changes: design/material modifications, shelf life extension to 12 months, introduction of electronic IFU and update of the catalogue numbers.
18 May 2015	10154403	Shelf life of delivery system and loading system extended to 2 years.

First Issued: **2012-11-16** Date: **2021-05-10** Expiry Date: **2022-11-15**

EC Design-Examination Certificate

Supplementary Information to CE 585003

Issued To:

St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Certificate History

Date	Reference Number	Action
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
14 September 2015	10157250	Valve shelf life extended to 24 months.
15 September 2015	10146798	Line extension to include 27mm and 29mm valves and 19F delivery system and loading system.
01 February 2016	10160623	Addition of Sterigenics Willowbrook, IL as a sterilizer.
15 August 2016	10163673	Final assembly and packaging of delivery and loading systems moved to the Woodridge facility (177 County Road B East, St. Paul, USA).
12 September 2016	10165209	Valve shelf life extended to 24 months for sizes 27mm and 29mm.
04 December 2016	10167255	Portico Delivery Systems (PRT-DS-TF-18F, PRT-DS-TF-19F) shelf life extended to 4 years.
16 May 2017	10171081	Portico Delivery System Nosocone design change.
9 August 2017	8692515	18Fr and 19Fr Delivery Systems Lead Screw Stop Tab design change.

First Issued: **2012-11-16** Date: **2021-05-10** Expiry Date: **2022-11-15**

EC Design-Examination Certificate

Supplementary Information to CE 585003

Issued To:

St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Certificate History

Date	Reference Number	Action
26 October 2017	8694459	Addition of Sterigenics Costa Rica as ETO sterilizer for the jar set assemblies.
15 November 2017	8795349	Certificate renewal
02 May 2018	8856717	Addition of Bierig Brothers Inc. and P&N Packaging Inc. as bovine pericardium suppliers
17 May 2018	8888839	Extension of indication for sheathless approach
07 March 2019	7780704	Traceable to NB 0086.
13 June 2019	9789389	Addition of Sterigenics US, LLC, Salt Lake City, Utah USA as a significant subcontractor for ETO Sterilization.
20 November 2019	3082687	Addition of Midwest Sterilization Corporation, Jackson, Missouri USA for ETO Sterilization in chambers 1, 2, 3, 6, and 13.

First Issued: **2012-11-16** Date: **2021-05-10** Expiry Date: **2022-11-15**

EC Design-Examination Certificate

Supplementary Information to CE 585003

Issued To:

St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Certificate History

Date	Reference Number	Action
23 December 2019	3067650	Line extension to add the ALT and the FlexNav delivery systems. Loading systems removed from scope due to misclassification. Extension of indication to subclavian/axilliary access routes. Valve shelf-life extension from 2 to 3 years. IFU updates, including especially post-implantation balloon dilatation precaution. Device table reformatted.
Current	3109323 3281064	Addition of Northern Co-operative Meat Company Ltd as Australian bovine tissue supplier. Addition of Navitor™ Transcatheter Heart Valves. Correction of Portico™ valve intended purpose to include extreme surgical risk. Reformat product tables.

First Issued: **2012-11-16** Date: **2021-05-10** Expiry Date: **2022-11-15**

...making excellence a habit.™