ST. JUDE MEDICAL

SJM Declaration of Conformity
Portico™ and Navitor Transcatheter Heart Valve System

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC, as amended by 2007/47/EC; and EU Regulation 722/2012. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address:

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

European Representative:

St. Jude Medical Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium

Product Type:

Transcatheter Heart Valve and Delivery Systems

Product Name(s):
Model Number(s):

Product Name	Model Number
Portico™ Transcatheter Heart Valve	PRT-23
	PRT-25
	PRT-27
	PRT-29
Navitor™ Transcatheter Heart Valve	NVTR-23
	NVTR-25
	NVTR-27
	NVTR-29
FlexNav™ Delivery System	FNAV-DS-SM
	FNAV-DS-LG
Portico™ Delivery System	PRT-DS-TF-18F
	PRT-DS-TF-19F
	PRT-DS-ALT-18F
	PRT-DS-ALT-19F

Classification:

Class III per Annex IX, Rule 17, Rule 8, and Rule 6

GMDN Code(s):

60245 (Transcatheter Heart Valve)
63283 (Delivery System)

Signature:

Kara R Carter

Kara R. Carter
DVP Quality Structural Heart

24-May-2021
Issue Date:

SJM Declaration of Conformity
Portico™ and Navitor Transcatheter Heart Valve System

Original CE Mark Date:

Product Name	Date
Portico™ Transcatheter Heart Valve and Delivery System	16 November 2012
FlexNav™ Delivery System	23 December 2019
Navitor™ Transcatheter Heart Valve	10 May 2021

Design Examination Certificate No and expiration date:

Certificate No: CE 585003
Expiration Date: 2022 Nov 15

Full Quality Assurance Certificate No and expiration date:

Certificate No: CE 578287
Expiration Date: 2024 May 26

Applicable Quality System Standards:

ISO 13485:2016

Notified Body:

BSI Group The Netherlands B.V.
Say Building
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1066 EP Amsterdam
Netherlands

Notified Body Number:

2797

Manufacturing Facilities:

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Signature:

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DVP Quality Structural Heart

24-May-2021
Issue Date: