EU Declaration of Conformity

Manufacturer:	SRN: US-MF-000007139 Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614, USA
European Authorized Representative:	SRN: DE-AR-000006184 Edwards Lifesciences GmbH Parkring 30 85748 Garching bei München Germany
Basic UDI-DI:	0690103D004PAC000S6
Product category:	Transcatheter Valve Repair System - Accessory
Product / Products:	Edwards PASCAL Precision Transcatheter Valve Repair System: • Stabilizer Rail System, Model 20000ST
Intended Purpose:	The Stabilizer Rail System is intended to aid with positioning and stabilization of the PASCAL Precision System during implantation procedures.

Classification:

Model Number	Classification per MDR Annex VIII
20000ST	Class Is, Rule 1

Conformity Assessment Route: Annex IX of Regulation (EU) 2017/745 (MDR)

Nomenclature:

Model Number	EMDN Code, Term	UMDNS Code, Term	GMDN Code, Term
20000ST	**P0780,** Vascular and Cardiac Prostheses – Accessories	**15594,** Racks	**63542,** Cardiac Implantation Catheter Holder

Applicable Common Specifications: There are no applicable common specifications for these devices. The standards used (specified by numbers, titles, editions and/or dates of issue) in relation to which conformity is declared, as well as the identification of internal data confirming compliance are provided in the General Safety and Performance Requirements Checklist (GSPR) for the products identified in this declaration.

Start of CE Marking: 01-SEP-2023

We herewith declare that the device(s) covered in this Declaration of Conformity (DoC) are in conformity with Regulation (EU) 2017/745 (Medical Device Regulation).

All supporting documentation is retained at the premises of the manufacturer.

Notified Body: DEKRA Certification B.V.
Meander 1051
6825 MJ Arnhem
The Netherlands
Identification Number 0344

The manufacturer has established and is maintaining a quality management system which meets the requirements of the common specifications and/or international standards.

These regulations are supported by the following certificates:

Certificate Number	Valid until	Issued by	Holder of Certificate	Facility(ies)	Regulation/ Standard for which the Certificate is Issued
3821948	07Jan2024	DEKRA Certification B.V.	Edwards Lifesciences LLC	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614, USA Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020, USA Edwards Lifesciences LTD 10 Earhart Ave Shannon Industrial Estates Shannon, County Clare V14 P638 Ireland	ISO 13485:2016 EN ISO 13485:2016
3817373	07Jan2024	DEKRA Certification B.V.	Edwards Lifesciences LLC	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614, USA Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020, USA Edwards Lifesciences LTD 10 Earhart Ave Shannon Industrial Estates Shannon, County Clare V14 P638 Ireland	MDSAP ISO 13485:2016
3828128CE02	04Aug2027	DEKRA Certification B.V.	Edwards Lifesciences LLC	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614, USA	MDR 2017/745

Edwards Lifesciences maintains a quality management system in compliance with EN ISO13485:2016.

This Declaration of Conformity is issued under the sole responsibility of Edwards LifesciencesLLC.

Signed for and on behalf of Manufacturer: *Edwards Lifesciences LLC*

Rachel Libi

Digitally signed by Rachel Libi
DN: cn=Rachel Libi, email=Rachel_Libi@edwards.com
Reason: I am approving this document
Date: 2023.09.01 12:02:33 -07'00'

Signed by:
on behalf of Edwards Lifesciences LLC
Rachel Libi
Vice President, Regulatory Affairs
Place and Date of Issue: Irvine, CA USA
01-SEP-2023

This is a supporting document for DOC-0090114, *EU MDR Technical Documentation Requirements.*