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:	0690103S004PAS000BC
Product category:	Transcatheter Valve Repair System
Product / Products:	Edwards PASCAL Precision Transcatheter Valve Repair System: • Implant System, Model 20000IS • PASCAL Ace Implant System, Model 20000ISM • Guide Sheath, Model 20000GS
Intended Purpose:	The PASCAL Precision System is intended to repair an insufficient mitral and/or tricuspid valve via percutaneous reconstruction through tissue approximation.

Classification:

Model Number	Classification per MDR Annex VIII
20000IS 20000ISM	Class III, Rule 8
20000GS	Class III, Rule 6

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

Nomenclature:

Model Number	EMDN Code, Term	UMDNS Code, Term	GMDN Code, Term
20000IS	**P0799,** Vascular and Cardiac Prostheses – Other	**13152,** Prostheses, Heart	**57790,** Heart Valve Clip
20000ISM			
20000GS	**P0780**, Vascular and Cardiac Prostheses - Accessories		

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: 04-AUG-2022

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) and Regulation (EU) 207/2012 (Electronic Instructions for Use of Medical Devices).

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	ISO 13485:2016 EN ISO 13485:2016
				Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020, USA	
				Edwards Lifesciences Pte Ltd 35 Changi North Crescent Singapore 499641 Singapore	
				Edwards Lifesciences LTD 10 Earhart Ave Shannon Industrial Estates Shannon, County Clare V14 P638 Ireland	
				Edwards Lifesciences LTD National Technology Park Castletroy, Limerick V94 31X5 Ireland	
3817373	07Jan2024	DEKRA Certification B.V.	Edwards Lifesciences LLC	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614, USA	MDSAP ISO 13485:2016
				Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020, USA	
				Edwards Lifesciences Pte Ltd 35 Changi North Crescent Singapore 499641 Singapore	
				Edwards Lifesciences LTD 10 Earhart Ave Shannon Industrial Estates Shannon, County Clare V14 P638 Ireland	
				Edwards Lifesciences LTD National Technology Park Castletroy, Limerick V94 31X5 Ireland	
3828128CE02	04Aug2027	DEKRA Certification B.V.	Edwards Lifesciences LLC	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614, USA	MDR 2017/745
3828128TD02					

	Procedure Code	Order Number	Devices	Model Number
PASCAL Precision Transcatheter Valve Repair System for mitral procedure	PAS2-M10	20000IS	Implant Box	
			Implant System	20000IS
			Accessory Box	
			1 x Guide Sheath	20000GS
			1 x Stabilizer	20000ST
			1 x Table	10000T
	PAS2-M5	20000ISM	Implant Box	
			Implant System	20000ISM
			Accessory Box	
			1 x Guide Sheath	20000GS
			1 x Stabilizer	20000ST
			1 x Table	10000T
PASCAL Precision Transcatheter Valve Repair System for tricuspid procedure	PAS2-T10	20000IS	Implant Box	
			Implant System	20000IS
			Accessory Box	
			1 x Guide Sheath	20000GS
			1 x Stabilizer	20000ST
			1 x Table	10000T
	PAS2-T5	20000ISM	Implant Box	
			Implant System	20000ISM
			Accessory Box	
			1 x Guide Sheath	20000GS
			1 x Stabilizer	20000ST
			1 x Table	10000T

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: 2023.04.14 15:45:56 -07'00'

Signed by:
on behalf of Edwards Lifesciences LLC
Rachel Libi
Vice President, Regulatory Affairs
Place of Issue: Irvine, CA USA

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