Edwards

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 Services GmbH Edisonstraße 6 85716 Unterschleißheim, Germany
Basic UDI-DI:	0690103D004PAC000S6
Product Category:	Transcatheter Valve Repair System Accessories, non-sterile and for single use only

Product / Products:

Device	Model #	Re-order #
Edwards PASCAL Transcatheter Valve Repair System – Table	10000T	10000TCE

Intended Purpose:	The Table is intended for use with the PASCAL system to provide a stable platform for the Implant System, Guide Sheath, and Stabilizer.
Classification:	Class I, Rule 1 (according to Annex VIII of the MDR)
Conformity Assessment Route:	Annex IV

Nomenclature:

Model Number	EMDN Code, Term	UMDNS Code, Term	GMDN Code, Term
10000T	**P0780**, Vascular and Cardiac Prostheses – Accessories	**15594**, Racks	**63543**, Cardiac implantation catheter table

Applicable Common Specifications:	There are no applicable common specifications for the 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:	21 June 2021

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

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

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

Edwards Lifesciences maintains a quality management system in compliance with EN ISO 134585:2016.

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

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

Julie Selstrom

Julie Selstrom
VP, Regulatory Affairs
Place and Date of Issue: Irvine, CA USA
25 August 2021

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