Number: 3828128TD06

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

Manufacturer:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States of America
SRN ID.: US-MF-000007139

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2103732CN

Authorized Representative: Edwards Lifesciences GmbH, Parkring 30, 85748 Garching bei München, Germany

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Principal Certification Manager

First Issued: **06 August 2024** Date: **06 August 2024** Expiry date**: 06 August 2029**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 3828128TD06

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

This certificate covers the following device(s):

Class III	
Basic UDI-DI: 0690103D003AAP000ND **Device Name:** Edwards Alterra Adaptive Prestent System **Type:** P07038004 Heart Valve Reconstruction Implants **Model:** 29AP4045	**Intended Purpose:** The bioprosthesis with prestent is intended for use in patients requiring pulmonary heart valve replacement. The delivery systems and accessories are intended to facilitate placement of the bioprosthesis and prestent via the transfemoral access approach.
Basic UDI-DI: 0690103D003PDS000W6 **Device Name:** Edwards SAPIEN 3 Pulmonic Delivery System **Type:** P07038002 Cardiac Valve Transcatheter Implant Accessories **Model:** 9630PL29	**Intended Purpose:** The delivery system and accessories are intended to facilitate the placement of the bioprosthesis via the transfemoral access approach.

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	06 August 2024	2103732CN361	First issued

First Issued: **06 August 2024** Date: **06 August 2024** Expiry date**: 06 August 2029**

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