Number: 3828128TD01

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.A. McKenzie
Principal Certification Manager

First Issued: **01 August 2022** Date: **13 April 2023** Expiry date**: 01 August 2027**

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: 3828128TD01

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) / groups of device(s):

Class III	
Basic UDI-DI: 0690103D003SAP000VP **Name:** Edwards SAPIEN 3 Transcatheter Heart Valve **Models:** 9600TFX20, 9600TFX23, 9600TFX26, 9600TFX29 **Types:** P070301030201 (Stented Biological Aortic Valves For Percutaneous Implant - Non-Valve Tissue Of Animal Origin) P070301030202 (Stented Biological Mitral Valves For Percutaneous Implant - Non-Valve Tissue Of Animal Origin) P070301030203 (Stented Biological Pulmonary Valves For Percutaneous Implant - Non-Valve Tissue Of Animal Origin)	***Intended Purpose**:* The bioprosthesis is intended for use in patients requiring heart valve replacement.
Basic UDI-DI: 0690103D003SAP000VP **Name:** Edwards SAPIEN 3 Ultra Transcatheter Heart Valve **Models:** 9750TFX20, 9750TFX23, 9750TFX26 **Types:** P070301030201 (Stented Biological Aortic Valves For Percutaneous Implant - Non-Valve Tissue Of Animal Origin) P070301030202 (Stented Biological Mitral Valves For Percutaneous Implant - Non-Valve Tissue Of Animal Origin)	***Intended Purpose:*** The bioprosthesis is intended for use in patients requiring heart valve replacement.
Basic UDI-DI: 0690103D003COM000TC **Name:** Edwards Commander Delivery System **Models**: 9610TF20, 9610TF23, 9610TF26, 9610TF29 **Type:** P07038002 (Cardiac Valve Transcatheter Implant Accessories)	***Intended Purpose:*** The delivery system and accessories are intended to facilitate the placement of the bioprosthesis via the transfemoral, transeptal, subclavian/axillary access approaches.
Basic UDI-DI: 0690103D003S3E000NT **Name:** Edwards eSheath Introducer Set **Models:** 9610ES14, 9610ES16 **Type:** C0502 (Cardiovascular Introducer Sheaths, Valved)	***Intended Purpose:*** The product is intended to be used to gain access to the vasculature.

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Number: 3828128TD01

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) / groups of device(s):

Class III	
Basic UDI-DI: 0690103D003CER000QZ **Name:** Edwards Certitude Delivery System **Models:** 9620TA20 9620TA23 9620TA26 9620TA29 9630TA23 9630TA26 **Type:** P07028002 – Cardiac Valve Transcatheter Implant Accessories	***Intended Purpose:*** The introducer sheath set, delivery system and accessories are intended to facilitate the placement of the SAPIEN 3 and SAPIEN 3 Ultra bioprostheses via the transapical and transaortic access approaches.
Basic UDI-DI: 0690103D003CIS000SL **Name:** Edwards Certitude Introducer Sheath Set **Models:** 9620IS18, 9620IS21 **Type:** C0502 Cardiovascular Introducing Sheath-Valvulated	***Intended Purpose:*** The introducer sheath set, delivery system and accessories are intended to facilitate the placement of the SAPIEN 3 and SAPIEN 3 Ultra bioprostheses via the transapical and transaortic access approaches.

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	01 August 2022	2103732CN314	First issued
1	04 September 2022	2103732CN319	intended purpose correction
2	21 November 2022	2103732CN320	Line extension - Edwards Certitude Delivery System and Certitude Introducer Sheath Set
3	13 April 2023	2103732CN327	EU AER Name and Address Change

First Issued: **01 August 2022** Date: **13 April 2023** Expiry date**: 01 August 2027**

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

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Edwards

Declaration of Conformity

Manufacturer:	Edwards Lifesciences LLC One Edwards Way, Irvine, CA 92614, USA
European Representative:	Edwards Lifesciences GmbH Parkring 30, 85748 Garching bei München, Germany
Product Category:	Systems for Heart Valve Repair and/or Replacement, and Accessories
Products:	Transfemoral, Transapical, Transaortic and Pulmonic THV System Kits – See product list

We herewith declare that the procedure packs specified above meet the provisions of Article 12 of Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices or meets the requirements of Article 22, Sections 1,2 and 5 of the REGULATION (EU) 2017/745:

- We have verified the mutual compatibility of the devices in accordance with the manufacturers' instructions and have carried out operations in accordance with these instructions;
- We have packaged the procedure packs and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
- The operations are subjected to appropriate methods of internal control and inspection.

Date Signed: 17 April 2023
(*Valid for three years from date signed)*

Momchil Blagoev

Digitally signed by Momchil Blagoev
DN: cn=Momchil Blagoev, email=Momchil_Blagoev@Edwards.com
Reason: I am approving this document
Date: 2023.04.17 15:05:01 -07'00'

Momchil Blagoev
Vice President, Regulatory Affairs
Edwards Lifesciences LLC

Declaration of Conformity

Product List

Kit		Kit Components		
Kit Model	**Kit**	**Model**	**Description**	**Quantity**
MDD Codes				
S3TF120	Edwards SAPIEN 3 – Edwards Commander Kit	9600TFX, 20mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 20mm	1
		9610ES14	Edwards eSheath Introducer Set (14F)	1
		9350BC16	Edwards Transfemoral Balloon Catheter,16mm	1
		9610TF20	Edwards Commander Delivery System, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3TF123	Edwards SAPIEN 3 – Edwards Commander Kit	9600TFX, 23mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 23mm	1
		9610ES14	Edwards eSheath Introducer Set (14F)	1
		9350BC20	Edwards Transfemoral Balloon Catheter,20mm	1
		9610TF23	Edwards Commander Delivery System, 23mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3TF126	Edwards SAPIEN 3 – Edwards Commander Kit	9600TFX, 26mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 26mm	1
		9610ES14	Edwards eSheath Introducer Set (14F)	1
		9350BC23	Edwards Transfemoral Balloon Catheter, 23mm	1
		9610TF26	Edwards Commander Delivery System 26mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3TF129	Edwards SAPIEN 3 – Edwards Commander Kit	9600TFX, 29mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 29mm	1
		9610ES16	Edwards eSheath Introducer Set (16F)	1
		9350BC25	Edwards Transfemoral Balloon Catheter, 25mm	1
		9610TF29	Edwards Commander Delivery System, 29mm	1
		9600CR	Crimper	1
		96406	Atrion QL38 Locking Syringe, 38ml or Edwards Locking Syringe	2
S3FTF123	Edwards SAPIEN 3 – Edwards Commander Kit [France]	9600TFX, 23mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 23mm	1
		9610ES14	Edwards eSheath Introducer Set (14F)	1
		9350BC20	Edwards Transfemoral Balloon Catheter,20mm	1
		9610TF23	Edwards Commander Delivery System, 23mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3FTF126	Edwards SAPIEN 3 – Edwards Commander Kit [France]	9600TFX, 26mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 26mm	1
		9610ES14	Edwards eSheath Introducer Set (14F)	1
		9350BC23	Edwards Transfemoral Balloon Catheter, 23mm	1
		9610TF26	Edwards Commander Delivery System 26mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2

Declaration of Conformity

Kit		Kit Components		
Kit Model	**Kit**	**Model**	**Description**	**Quantity**
S3FTF129	Edwards SAPIEN 3 – Edwards Commander Kit [France]	9600TFX, 29mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 29mm	1
		9610ES16	Edwards eSheath Introducer Set (16F)	1
		9350BC25	Edwards Transfemoral Balloon Catheter, 25mm	1
		9610TF29	Edwards Commander Delivery System, 29mm	1
		9600CR	Crimper	1
		96406	Atrion QL38 Locking Syringe, 38ml or Edwards Locking Syringe	2
S3MTF123	Edwards SAPIEN 3 – Edwards Commander Kit [Iberia]	9600TFX, 23mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 23mm	1
		9610ES14	Edwards eSheath Introducer Set (14F)	1
		9610TF23	Edwards Commander Delivery System, 23mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3MTF126	Edwards SAPIEN 3 – Edwards Commander Kit [Iberia]	9600TFX, 26mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 26mm	1
		9610ES14	Edwards eSheath Introducer Set (14F)	1
		9610TF26	Edwards Commander Delivery System 26mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3MTF129	Edwards SAPIEN 3 – Edwards Commander Kit [Iberia]	9600TFX, 29mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 29mm	1
		9610ES16	Edwards eSheath Introducer Set (16F)	1
		9610TF29	Edwards Commander Delivery System, 29mm	1
		9600CR	Crimper	1
		96406	Atrion QL38 Locking Syringe, 38ml or Edwards Inflation Device	2
S3TA120	Edwards SAPIEN 3 – Edwards Certitude Kit	9600TFX, 20mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 20mm	1
		9620TA20	Edwards Certitude Delivery System, 20mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3TA123	Edwards SAPIEN 3 – Edwards Certitude Kit	9600TFX, 23mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 23mm	1
		9620TA23	Edwards Certitude Delivery System, 23mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9100BAVC	Ascendra Balloon Aortic Valvuloplasty Catheter, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3TA126	Edwards SAPIEN 3 – Edwards Certitude Kit	9600TFX, 26mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 26mm	1
		9620TA26	Edwards Certitude Delivery System, 26mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9100BAVC	Ascendra Balloon Aortic Valvuloplasty Catheter, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2

Declaration of Conformity

Kit		Kit Components		
Kit Model	**Kit**	**Model**	**Description**	**Quantity**
S3TA129	Edwards SAPIEN 3 – Edwards Certitude Kit	9600TFX, 29mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 29mm	1
		9620TA29	Edwards Certitude Delivery System, 29mm	1
		9620IS21	Edwards Certitude Introducer Sheath Set, 21F	1
		9100BAVC	Ascendra Balloon Aortic Valvuloplasty Catheter, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
		96406	Atrion QL38 Locking Syringe Device, 38ml or Edwards Locking Syringe	1
S3FTA123	Edwards SAPIEN 3 – Edwards Certitude Kit [France]	9600TFX, 23mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 23mm	1
		9620TA23	Edwards Certitude Delivery System, 23mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9100BAVC	Ascendra Balloon Aortic Valvuloplasty Catheter, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3FTA126	Edwards SAPIEN 3 – Edwards Certitude Kit [France]	9600TFX, 26mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 26mm	1
		9620TA26	Edwards Certitude Delivery System, 26mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9100BAVC	Ascendra Balloon Aortic Valvuloplasty Catheter, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3FTA129	Edwards SAPIEN 3 – Edwards Certitude Kit [France]	9600TFX, 29mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 29mm	1
		9620TA29	Edwards Certitude Delivery System, 29mm	1
		9620IS21	Edwards Certitude Introducer Sheath Set, 21F	1
		9100BAVC	Ascendra Balloon Aortic Valvuloplasty Catheter, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
		96406	Atrion QL38 Locking Syringe Device, 38ml or Edwards Locking Syringe	1
S3MTA123	Edwards SAPIEN 3 – Edwards Certitude Kit [Iberia]	9600TFX, 23mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 23mm	1
		9620TA23	Edwards Certitude Delivery System, 23mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3MTA126	Edwards SAPIEN 3 – Edwards Certitude Kit [Iberia]	9600TFX, 26mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 26mm	1
		9620TA26	Edwards Certitude Delivery System, 26mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2

Edwards

Declaration of Conformity

Kit		Kit Components		
Kit Model	**Kit**	**Model**	**Description**	**Quantity**
S3MTA129	Edwards SAPIEN 3 – Edwards Certitude Kit [Iberia]	9600TFX, 29mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 29mm	1
		9620TA29	Edwards Certitude Delivery System, 29mm	1
		9620IS21	Edwards Certitude Introducer Sheath Set, 21F	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
		96406	Atrion QL38 Locking Syringe Device, 38ml or Edwards Locking Syringe	1
S3USTA120	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System	9750TFX, 20mm	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve, 20mm	1
		9620TA20	Edwards Certitude Delivery System, 20mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
S3USTA123	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System	9750TFX, 23mm	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve, 23mm	1
		9630TA23	Edwards Certitude Delivery System, 23mm	1
		9620IS21	Edwards Certitude Introducer Sheath Set, 21F	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
S3USTA126	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System	9750TFX, 26mm	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve, 26mm	1
		9630TA26	Edwards Certitude Delivery System, 26mm	1
		9620IS21	Edwards Certitude Introducer Sheath Set, 21F	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
S3UCM220	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System	9750TFX, 20mm	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve, 20mm	1
		9610TF20	Edwards Commander Delivery System, 20mm	1
		9610ES14	Edwards eSheath Introducer Set	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
S3UCM223	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System	9750TFX, 23mm	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve, 23mm	1
		9610TF23	Edwards Commander Delivery System, 23mm	1
		9610ES14	Edwards eSheath Introducer Set	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1

Declaration of Conformity

Kit		Kit Components		
Kit Model	**Kit**	**Model**	**Description**	**Quantity**
S3UCM226	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System	9750TFX, 26mm	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve, 26mm	1
		9610TF26	Edwards Commander Delivery System, 26mm	1
		9610ES14	Edwards eSheath Introducer Set	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
MDR Codes – Transfemoral Procedural Pack Basic-UDI: 0690103P003SXT000HF				
S3TF320	Edwards SAPIEN 3 – Edwards Commander Kit	9600TFX, 20mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 20mm	1
		9610ES14	Edwards eSheath Introducer Set (14F)	1
		9610TF20	Edwards Commander Delivery System, 20mm	1
		9600CR	Edwards Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
S3TF323	Edwards SAPIEN 3 – Edwards Commander Kit	9600TFX, 23mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 23mm	1
		9610ES14	Edwards eSheath Introducer Set (14F)	1
		9610TF23	Edwards Commander Delivery System, 23mm	1
		9600CR	Edwards Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
S3TF326	Edwards SAPIEN 3 – Edwards Commander Kit	9600TFX, 26mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 26mm	1
		9610ES14	Edwards eSheath Introducer Set (14F)	1
		9610TF26	Edwards Commander Delivery System, 26mm	1
		9600CR	Edwards Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
S3TF329	Edwards SAPIEN 3 – Edwards Commander Kit	9600TFX, 29mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 29mm	1
		9610ES16	Edwards eSheath Introducer Set (16F)	1
		9610TF29	Edwards Commander Delivery System, 26mm	1
		9600CR	Edwards Crimper	1
		96406	Atrion QL38 Locking Syringe, 38ml or Edwards Locking Syringe	1
S3UCM320	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System [France]	9750TFX, 20mm	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve, 20mm	1
		9610TF20	Edwards Commander Delivery System, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
S3UCM323	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System [France]	9750TFX, 23mm	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve, 23mm	1
		9610TF23	Edwards Commander Delivery System, 23mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1

Declaration of Conformity

Kit		Kit Components		
Kit Model	**Kit**	**Model**	**Description**	**Quantity**
S3UCM326	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System [France]	9750TFX, 26mm	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve, 26mm	1
		9610TF26	Edwards Commander Delivery System, 26mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
S3UCM220	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System	9750TFX, 20mm	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve, 20mm	1
		9610TF20	Edwards Commander Delivery System, 20mm	1
		9610ES14	Edwards eSheath Introducer Set	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
S3UCM223	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System	9750TFX, 23mm	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve, 23mm	1
		9610TF23	Edwards Commander Delivery System, 23mm	1
		9610ES14	Edwards eSheath Introducer Set	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
S3UCM226	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System	9750TFX, 26mm	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve, 26mm	1
		9610TF26	Edwards Commander Delivery System, 26mm	1
		9610ES14	Edwards eSheath Introducer Set	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
MDR Codes – Transfemoral Procedural Pack Basic-UDI: 0690103P003CS300028				
S3TF120	Edwards SAPIEN 3 – Edwards Commander Kit	9600TFX, 20mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 20mm	1
		9610ES14	Edwards eSheath Introducer Set (14F)	1
		9350BC16	Edwards Transfemoral Balloon Catheter,16mm	1
		9610TF20	Edwards Commander Delivery System, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3TF123	Edwards SAPIEN 3 – Edwards Commander Kit	9600TFX, 23mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 23mm	1
		9610ES14	Edwards eSheath Introducer Set (14F)	1
		9350BC20	Edwards Transfemoral Balloon Catheter,20mm	1
		9610TF23	Edwards Commander Delivery System, 23mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3TF126	Edwards SAPIEN 3 – Edwards Commander Kit	9600TFX, 26mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 26mm	1
		9610ES14	Edwards eSheath Introducer Set (14F)	1
		9350BC23	Edwards Transfemoral Balloon Catheter, 23mm	1
		9610TF26	Edwards Commander Delivery System 26mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2

Edwards

Declaration of Conformity

Kit		Kit Components		
Kit Model	**Kit**	**Model**	**Description**	**Quantity**
S3TF129	Edwards SAPIEN 3 – Edwards Commander Kit	9600TFX, 29mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 29mm	1
		9610ES16	Edwards eSheath Introducer Set (16F)	1
		9350BC25	Edwards Transfemoral Balloon Catheter, 25mm	1
		9610TF29	Edwards Commander Delivery System, 29mm	1
		9600CR	Crimper	1
		96406	Atrion QL38 Locking Syringe, 38ml or Edwards Locking Syringe	2
S3FTF123	Edwards SAPIEN 3 – Edwards Commander Kit [France]	9600TFX, 23mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 23mm	1
		9610ES14	Edwards eSheath Introducer Set (14F)	1
		9350BC20	Edwards Transfemoral Balloon Catheter,20mm	1
		9610TF23	Edwards Commander Delivery System, 23mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3FTF126	Edwards SAPIEN 3 – Edwards Commander Kit [France]	9600TFX, 26mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 26mm	1
		9610ES14	Edwards eSheath Introducer Set (14F)	1
		9350BC23	Edwards Transfemoral Balloon Catheter, 23mm	1
		9610TF26	Edwards Commander Delivery System 26mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3FTF129	Edwards SAPIEN 3 – Edwards Commander Kit [France]	9600TFX, 29mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 29mm	1
		9610ES16	Edwards eSheath Introducer Set (16F)	1
		9350BC25	Edwards Transfemoral Balloon Catheter, 25mm	1
		9610TF29	Edwards Commander Delivery System, 29mm	1
		9600CR	Crimper	1
		96406	Atrion QL38 Locking Syringe, 38ml or Edwards Locking Syringe	2
MDR Codes – S3 Transapical/Transaortic Procedural Pack Basic-UDI: 0690103P003CST00098				
S3TA320	Edwards SAPIEN 3 – Edwards Certitude Kit	9600TFX, 20mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 20mm	1
		9620TA20	Edwards Certitude Delivery System, 20mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9600CR	Edwards Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
S3TA323	Edwards SAPIEN 3 – Edwards Certitude Kit	9600TFX, 23mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 23mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9620TA23	Edwards Certitude Delivery System, 23mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
S3TA326	Edwards SAPIEN 3 – Edwards Certitude Kit	9600TFX, 26mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 26mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9620TA26	Edwards Certitude Delivery System, 26mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1

Declaration of Conformity

Kit		Kit Components		
Kit Model	**Kit**	**Model**	**Description**	**Quantity**
S3TA329	Edwards SAPIEN 3 – Edwards Certitude Kit	9600TFX, 29mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 29mm	1
		9620IS21	Edwards Certitude Introducer Sheath Set, 21F	1
		9620TA29	Edwards Certitude Delivery System, 29mm	1
		9600CR	Crimper	1
		96406	Atrion QL38 Locking Syringe, 38ml or Edwards Locking Syringe	1
S3TA120	Edwards SAPIEN 3 – Edwards Certitude Kit	9600TFX, 20mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 20mm	1
		9620TA20	Edwards Certitude Delivery System, 20mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3TA123	Edwards SAPIEN 3 – Edwards Certitude Kit	9600TFX, 23mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 23mm	1
		9620TA23	Edwards Certitude Delivery System, 23mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9100BAVC	Ascendra Balloon Aortic Valvuloplasty Catheter, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3TA126	Edwards SAPIEN 3 – Edwards Certitude Kit	9600TFX, 26mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 26mm	1
		9620TA26	Edwards Certitude Delivery System, 26mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9100BAVC	Ascendra Balloon Aortic Valvuloplasty Catheter, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3TA129	Edwards SAPIEN 3 – Edwards Certitude Kit	9600TFX, 29mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 29mm	1
		9620TA29	Edwards Certitude Delivery System, 29mm	1
		9620IS21	Edwards Certitude Introducer Sheath Set, 21F	1
		9100BAVC	Ascendra Balloon Aortic Valvuloplasty Catheter, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
		96406	Atrion QL38 Locking Syringe Device, 38ml or Edwards Locking Syringe	1
S3FTA123	Edwards SAPIEN 3 – Edwards Certitude Kit [France]	9600TFX, 23mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 23mm	1
		9620TA23	Edwards Certitude Delivery System, 23mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9100BAVC	Ascendra Balloon Aortic Valvuloplasty Catheter, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
S3FTA126	Edwards SAPIEN 3 – Edwards Certitude Kit [France]	9600TFX, 26mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 26mm	1
		9620TA26	Edwards Certitude Delivery System, 26mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9100BAVC	Ascendra Balloon Aortic Valvuloplasty Catheter, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2

Declaration of Conformity

Kit		Kit Components		
Kit Model	**Kit**	**Model**	**Description**	**Quantity**
S3FTA129	Edwards SAPIEN 3 – Edwards Certitude Kit [France]	9600TFX, 29mm	Edwards SAPIEN 3 Transcatheter Heart Valve, 29mm	1
		9620TA29	Edwards Certitude Delivery System, 29mm	1
		9620IS21	Edwards Certitude Introducer Sheath Set, 21F	1
		9100BAVC	Ascendra Balloon Aortic Valvuloplasty Catheter, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
		96406	Atrion QL38 Locking Syringe Device, 38ml or Edwards Locking Syringe	1
MDR Codes – S3U Transapical/Transaortic Procedural Pack Basic-UDI: 0690103P003C3U000WP				
S3USTA120	Edwards SAPIEN 3 Ultra – Edwards Certitude Kit	9750TFX, 20mm	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve, 20mm	1
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9620TA20	Edwards Certitude Delivery System, 20mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
S3USTA123	Edwards SAPIEN 3 Ultra – Edwards Certitude Kit	9750TFX, 23mm	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve, 23mm	1
		9620IS21	Edwards Certitude Introducer Sheath Set, 21F	1
		9630TA23	Edwards Certitude Delivery System, 23mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1
S3USTA126	Edwards SAPIEN 3 Ultra – Edwards Certitude Kit	9750TFX, 26mm	Edwards SAPIEN 3 Ultra Transcatheter Heart Valve, 26mm	1
		9620IS21	Edwards Certitude Introducer Sheath Set, 21F	1
		9630TA26	Edwards Certitude Delivery System, 26mm	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	1

Edwards

EU Declaration of Conformity

Manufacturer:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614, USA SRN: US-MF-000007139
European Authorized Representative:	Edwards Lifesciences GmbH Parkring 30 85748 Garching bei München, Germany SRN: DE-AR-000006184
Basic UDI-DI:	See product list for UDI-DI information
Product category:	Systems for Heart Valve Repair and/or Replacement, and Accessories
Product / Products:	Model codes, Names, Types: see product list
Intended Purpose:	The bioprosthesis is intended for use in patients requiring heart valve replacement. The delivery system and accessories are intended to facilitate the placement of the bioprosthesis via the transfemoral, transseptal, subclavian/axillary access approaches. The eSheath is intended to be used to gain access to the vasculature.
Classification:	See product list (According to Annex VIII)
Conformity Assessment Route:	See product list for conformity assessment route

Nomenclature:	See product list for UMDNS/EMDN information
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 for the products identified in this declaration.
Start of CE Marking:	See product list for CE Marking dates.

The device(s) covered in this DoC, as listed in the product list below, are in conformity with Regulation (EU) 2017/745 and Regulation (EU) 722/2012.

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

Notified Body:	DEKRA Certification B.V.
(Identification No. 0344)	Arnhem, The Netherlands

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

These regulations are supported by the following certificates:

Certificate No. Standards	Valid until	Holder of Certificate	Certified Locations/Facilities
Quality Management System Certificates			
DEKRA Certificate 3817373 MDSAP ISO 13485:2016	2024-01-07	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA
			Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020 USA
			Edwards Lifesciences Pte Ltd 35 Changi North Crescent Singapore 499641, Singapore
			Edwards Lifesciences Costa Rica S.R.L. Zona Franca La Lima de la entrada de Pequeño Mundo 100 mts oeste y 200 mts sur, Finca 31 y 32, Guadalupe Cartago, Costa Rica

Certificate No. Standards	Valid until	Holder of Certificate	Certified Locations/Facilities
			Edwards Lifesciences LTD 10 Earhart Ave Shannon Industrial Estates Shannon, Country Clare V14 P638 , Ireland
			Edwards Lifesciences Ireland National Technology Park Castletroy Limerick , Ireland V9431X5
Quality Management System Certificates			
DEKRA Certificate 3821948 ISO 13485:2016 EN ISO 13485:2016	2024-01-07	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA
			Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020 USA
			Edwards Lifesciences Pte Ltd 35 Changi North Crescent Singapore 499641, Singapore
			Edwards Lifesciences Costa Rica S.R.L. Zona Franca La Lima de la entrada de Pequeño Mundo 100 mts oeste y 200 mts sur, Finca 31 y 32, Guadalupe Cartago, Costa Rica
			Edwards Lifesciences LTD 10 Earhart Ave Shannon Industrial Estates Shannon, Country Clare V14 P638 , Ireland
			Edwards Lifesciences Ireland National Technology Park Castletroy Limerick , Ireland V9431X5
TUV Certificate QS6 039555 0195 Rev. 02 MDSAP ISO 13485:2016	2025-09-12	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences State Road 402 N, Kn1.4, Industrial Park Anasco PR 00610
TUV Certificate Q5 039555 0207 Rev.00 EN ISO 13485:2016	2023-06-06	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences State Road 402 N, Kn1.4, Industrial Park Anasco PR 00610
EU Quality Management Certificate			
3828128CE01	2027-08-01	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA

Certificate No. Standards	Valid until	Holder of Certificate	Certified Locations/Facilities
			Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020 USA
			Edwards Lifesciences Pte Ltd 35 Changi North Crescent Singapore 499641, Singapore
			Edwards Lifesciences Costa Rica S.R.L. Zona Franca La Lima de la entrada de Pequeño Mundo 100 mts oeste y 200 mts sur, Finca 31 y 32, Guadalupe Cartago, Costa Rica
			Edwards Lifesciences State Road 402 N, Kn1.4, Industrial Park Anasco PR 00610
			Edwards Lifesciences LTD 10 Earhart Ave Shannon Industrial Estates Shannon, Country Clare V14 P638 , Ireland
			Edwards Lifesciences Ireland National Technology Park Castletroy Limerick , Ireland V9431X5
EU Technical Documentation Assessment Certificate			
3828128TD01	2027-08-01	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA
			Edwards Lifesciences Pte Ltd 35 Changi North Crescent Singapore 499641
			Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020 USA
			Edwards Lifesciences Costa Rica S.R.L. Zona Franca La Lima de la entrada de Pequeño Mundo 100 mts oeste y 200 mts sur, Finca 31 y 32, Guadalupe Cartago, Costa Rica

Certificate No. Standards	Valid until	Holder of Certificate	Certified Locations/Facilities
			Edwards Lifesciences State Road 402 N, Kn1.4, Industrial Park Anasco PR 00610
			Edwards Lifesciences LTD 10 Earhart Ave Shannon Industrial Estates Shannon, Country Clare V14 P638 , Ireland
			Edwards Lifesciences Ireland National Technology Park Castletroy Limerick , Ireland V9431X5

Edwards Lifesciences maintains a quality management system in compliance with EN ISO 13485:2016.

This declaration of conformity is issued under the sole responsibility of Edwards Lifesciences LLC.

Issued by the Manufacturer:

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

Signed for and on behalf of Manufacturer:

Rand Pugmire April 25, 2023

Rand Pugmire
Director, THV Regulatory Affairs
Issued: April 25, 2023

Product List

Device Name/ Sizes	Model Number(s)	Reorder Number(s)	Assessment Route	Classification	Basic UDI-DI Code	UMDNS Code	EMDN Code	Start of CE Marking
Edwards SAPIEN 3 Transcatheter Heart Valve Sizes 20, 23, 26 and 29mm	9600TFX20 9600TFX23 9600TFX26 9600TFX29	9600TFX20 9600TFX23 9600TFX26 9600TFX29	Annex IX, Rules 8 and 18	Class III per Annex VIII	0690103D003SAP000VP	15870	P070301030201, Stented Biological Aortic Valves For Percutaneous Implant - Non-Valve Tissue Of Animal Origin P070301030202, Stented Biological Mitral Valves For Percutaneous Implant - Non-Valve Tissue Of Animal Origin P070301030203, Stented Biological Pulmonary Valves For Percutaneous Implant - Non-Valve Tissue Of Animal Origin	September 30th, 2022
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve Sizes 20, 23 and 26	9750TFX20 9750TFX23 9750TFX26	9750TFX20 9750TFX23 9750TFX26	Annex IX, Rules 8 and 18	Class III per Annex VIII	0690103D003SAP000VP	15870	P070301030201, Stented Biological Aortic Valves For Percutaneous Implant - Non-Valve Tissue Of Animal Origin P070301030202, Stented Biological Mitral Valves For Percutaneous Implant - Non-Valve Tissue Of Animal Origin	September 30th, 2022

Device Name/ Sizes	Model Number(s)	Reorder Number(s)	Assessment Route	Classification	Basic UDI-DI Code	UMDNS Code	EMDN Code	Start of CE Marking
Edwards Commander Delivery System Sizes 20, 23, 26 and 29mm	9610TF20 9610TF23 9610TF26 9610TF29	9610TF20 9610TF23 9610TF26 9610TF29	Annex IX, Rule 7	Class III per Annex VIII	0690103D003COM000TC	17846	P07038002, Cardiac Valve Transcatheter Implant Accessories	September 30th, 2022
	9610TF20 9610TF23 9610TF26	9610TF20U 9610TF23U 9610TF26U	Annex IX, Rule 7	Class III per Annex VIII	0690103D003COM000TC	17846	P07038002, Cardiac Valve Transcatheter Implant Accessories	September 30th, 2022
Edwards eSheath Introducer Set Sizes 14F and 16F	9610ES14 9610ES16	9610ES14 9610ES16	Annex IX, Rule 7	Class III per Annex VIII	0690103D003S3E000NT	10678	C0502, Cardiovascular Introducer Sheaths, Valved	September 30th, 2022
Edwards Certitude Delivery System Sizes 20, 23, 26 and 29mm	9620TA20 9620TA23 9620TA26 9620TA29 9630TA23 9630TA26	9620TA20 9620TA23 9620TA26 9620TA29 9630TA23 9630TA26	Annex IX, Rule 6	Class III per Annex VIII	0690103D003CER000QZ	17846	P07038002, Cardiac Valve Transcatheter Implant Accessories	February 6th, 2023
Edwards Certitude Introducer Sheath Set Sizes 18F and 21F	9620IS18 9620IS21	9620IS18 9620IS21	Annex IX, Rule 6	Class III per Annex VIII	0690103D003CIS000SL	10678	C0502, Cardiovascular Introducer Sheaths, Valved	February 6th, 2023
Edwards Crimper	9600CR	9600CR	Annex IX, Rule 1	Class I (Sterile) per Annex VIII	0690103D003CRI000TH	16463	P07038002, Cardiac Valve Transcatheter Implant Accessories	September 30th, 2022
Edwards Inflation Device	96402	96402	Annex IX, Rule 1	Class I (Sterile) per Annex VIII	0690103D003IND000TG	17451	A020199, Syringes, Single-Use-Other	September 30th, 2022
Edwards Locking Syringe	96406	96406	Annex IX, Rule 1	Class I (Sterile) per Annex VIII	0690103D003IND000TG	17451	A020199, Syringes, Single-Use-Other	September 30th, 2022

Edwards Lifesciences SA
Attn: Daniel Lippis
Route de L'Etraz 70
1260 Nyon
Switzerland

Date: 26th April 2023

Re: Authorization to appoint sub-distributor

Dear Mr. Lippis,

I refer to the distribution agreement between Edwards Lifesciences SA ("Edwards") and Cardiotech SRL ("**Distributor**"), originally commencing on 1st October 2021 ("the Agreement").

Pursuant to Section 2.2 "Resellers" of the Agreement, Distributor requests Edwards consent, with effect from 1st October 2021 to appoint a sub-distributor, namely, FCPC DataControl SRL ("**Sub-Distributor**"), with its principal place of business at MD – 2001, R. Moldova, mun. Chisinau, str Melestiu 20, to perform for and on behalf of Distributor the rights granted in the Agreement to Distributor, i.e to re-sell the Products listed in Exhibit A of the Agreement in Moldavia (the "**Territory**").

Distributor and Sub-Distributor understand and agree that Edwards' consent shall remain valid subject to the following conditions:

- Sub-Distributor shall comply with all national, EU and/or US-applicable laws, rules and regulations including those dealing with anti-fraud, anti-bribery, and anti-corruption, including, but not limited to the Foreign Corrupt Practices Act and the UK Bribery Act and comply with the ethical standards adopted by MedTech Europe - trade association representing the medical technology industries in Europe with the MedTech Europe Code of Business Practice and/or the Guide for Medical Technology Sales & Marketing Intermediaries.;

- Sub-Distributor will not make any payments to or for the benefit of any government official, health care professional or of any customer for the purpose of obtaining business or obtaining any concession, or for any other improper purpose, and that it will strictly abide with any applicable national, EU or US laws and regulations related to foreign commerce, including, but not limited to, the Foreign Corrupt Practices Act, the UK Bribery Act, and anti-boycott legislation;

- Distributor shall immediately inform EDWARDS in writing of any information obtained or discovered during the term of the Agreement, relating to the Sub-Distributor' possible violations of the above conditions;

- Distributor will train all appropriate Sub-Distributor's employees providing services on behalf of Edwards regarding Edwards' policies and procedures for Interactions with Health Care Professionals and any anti-fraud, anti-bribery and anti-corruption laws.

Distributor understands and agrees that it shall remain fully responsible for the actions or omission of Sub-Distributor.

Sub-Distributor consents in writing to be bound by the terms of the Agreement and to use its best efforts to perform the duties assumed by Sub-Distributor.

Edwards' consent remains valid as long as (i) compliance with the above conditions is met and (ii) the Agreement is in force. Notwithstanding the foregoing, Edwards may at any time and for any reason revoke its consent upon written notice to Distributor.

With this letter, Distributor and Sub-Distributor seek Edwards' consent and ask that Edwards signs a copy of this letter to acknowledge and agree to this request. Once signed, Edwards shall return one original back to Distributor and one original to Sub-Distributor.

Cardiotech SRL

By: ……

Title: ……

Date: ……

Edwards Lifesciences SA

By: ……

Title: ……

Date: ……

FCPC DataControl SRL

By: ……

Title: ……

Date: ……

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: FCPC DataControl S.R.L., cu sediul în or. Chișinău, str. N. Testemițanu 17/6, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1) Transfemoral, Transapical, Transaortic and Pulmonic THV System Kits – Sapien 3

S3TF120
S3TF123
S3TF126
S3TF129
S3FTF123
S3FTF126
S3FTF129
S3MTF123
S3MTF126
S3MTF129
S3TA120
S3TA123
S3TA126
S3TA129
S3FTA123
S3FTA126
S3FTA129
S3MTA123
S3MTA126
S3MTA129
S3USTA120
S3USTA123
S3USTA126
S3UCM220
S3UCM223
S3UCM226
S3TF320
S3TF323
S3TF326
S3TF329
S3UCM320
S3UCM323
S3UCM326
S3UCM220
S3UCM223
S3UCM226
S3TF120
S3TF123
S3TF126
S3TF129
S3FTF123
S3FTF126
S3FTF129
S3TA320
S3TA323
S3TA326
S3TA329
S3TA120
S3TA123
S3TA126
S3TA129
S3FTA123
S3FTA126
S3FTA129
S3USTA123
S3USTA126
S3USTA120

Se anexează următoarele acte:
1) Declarație de Conformitate, din 17.04.2023;
2) EU Quality Management System Certificate no. 3828128CE01 din 13.04.2023.
3) EU Technical Documentation Assessment Certificate no. 3828128TD01 din 13.04.2023.
4) Actul prin care producătorul își desemnează reprezentantul

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____

Grabazei Alexandru, director general. *Data* 12.10.2023

Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 1 din 12.10.2023

Solicitantul FCPC DataControl S.R.L., cu sediul în or. Chișinău, str. N. Testemițanu 17/6, tel./fax: 022-273712, e-mail: contact@datacontrol.md
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

1) Transfemoral, Transapical, Transaortic and Pulmonic THV System Kits – Sapien 3

S3TF120	S3FTA126	S3UCM320	S3TA326
S3TF123	S3FTA129	S3UCM323	S3TA329
S3TF126	S3MTA123	S3UCM326	S3TA120
S3TF129	S3MTA126	S3UCM220	S3TA123
S3FTF123	S3MTA129	S3UCM223	S3TA126
S3FTF126	S3USTA120	S3UCM226	S3TA129
S3FTF129	S3USTA123	S3TF120	S3FTA123
S3MTF123	S3USTA126	S3TF123	S3FTA126
S3MTF126	S3UCM220	S3TF126	S3FTA129
S3MTF129	S3UCM223	S3TF129	S3USTA123
S3TA120	S3UCM226	S3FTF123	S3USTA126
S3TA123	S3TF320	S3FTF126	S3USTA120
S3TA126	S3TF323	S3FTF129	
S3TA129	S3TF326	S3TA320	
S3FTA123	S3TF329	S3TA323	

Se anexează următoarele acte:
1) Declarație de Conformitate, din 17.04.2023;
2) EU Quality Management System Certificate no. 3828128CE01 din 13.04.2023.
3) EU Technical Documentation Assessment Certificate no. 3828128TD01 din 13.04.2023.
4) Actul prin care producătorul își desemnează reprezentantul

Data 12.10.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepţionarea dosarului	
Semnătura persoanei responsabile	

Number: 3828128CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I 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

Additional certificate: 3828128TD01
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.A. McKenzie
Principal Certification Manager

First Issued: **01 August 2022** Date: **13 April 2023** Expiry date**: 01 August 2027**

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: 3828128CE01

EU Quality Management System Certificate

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

This certificate covers the following device(s) / groups of device(s):

NBOG Code MDN1203, Class Is **Sterilization method:** Ethylene oxide
Crimper, model 9600CR

NBOG Code MDN1208, Class Is **Sterilization method:** Ethylene oxide
Edwards Inflation Device, model 96402 Edwards Locking Syringe, model 96406

NBOG Code MDN1101, Class III
Edwards SAPIEN 3 Transcatheter Heart Valve Edwards SAPIEN 3 Ultra Transcatheter Heart Valve Edwards Commander Delivery System Edwards eSheath Introducer Set Edwards Certitude Delivery System Edwards Certitude Introducer Set

Conditions for or limitations to the validity of this certificate:

- For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions

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	01-August-2022	2103732CN314	First issue
1	21 November 2022	2103732CN320	Line extension - Edwards Certitude Delivery System and Certitude Introducer Sheath Set
2	13 April 2023	2103732CN327	EU AER Name and Address Change

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