EC Declaration of Conformity

Edwards

Manufacturer:	Edwards Lifesciences LLC One Edwards Way, Irvine, CA 92614, USA
European Representative:	Edwards Lifesciences Services GmbH Edisonstraße 6, 85716 Unterschleißheim, Germany
Product Category:	Systems for Heart Valve Repair and/or Replacement, and Accessories
Products:	Transfemoral, Transapical, Transaortic and Pulmonic THV Systems Model codes, Names, Types: see product list
Classification / Rule(s):	See product list (according to Annex IX of the Medical Device Directive)
Conformity Assessment Route:	Annex II
UMDNS / GMDN Nomenclature:	See product list
Applicable Standards:	The harmonized standards and other consensus 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 Essential Requirements Checklists for the products identified in this declaration.
Start of CE Marking:	See product list

We herewith declare that the distributed CE marked products specified above conform to the product(s) covered by the "CE Marking of Conformity Certificate, Medical Devices" issued and delivered by DEKRA Certification B.V., Arnhem, the Netherlands, in accordance with Annex II of the "EC-Directive", Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and with the particular requirements laid down in Annex I of Commission Regulation 722/2012 of 8 August 2012 concerning medical devices manufactured utilizing tissue of animal origin. All supporting documentation is retained at the premises of the manufacturer.

In addition, we ensure and declare that the distributed CE marked products meet the provisions of the EC-Directives that apply to them. This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive. The conformity of the full quality assurance system is described in the CE Marking of Conformity Certificate issued by DEKRA Certification B.V.

Digitally signed by Grabazei Alexandru
Date: 2021.09.09 10:16:55 EEST
Reason: MoldSign Signature
Location: Moldova

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The manufacturer has established and is maintaining a quality management system that meets the requirements of ISO 13485, as supported by the following certificates:

Certificate No.	Valid until	Holder of Certificate	Certified Locations/Facilities*
Quality Management System Certificates			
3805473	2019-03-01	Edwards Lifesciences Pte Ltd, Singapore	Edwards Lifesciences Pte Ltd 35 Changi North Crescent Singapore 499641, Singapore
Quality Management System Certificates			
3805474**	2018-12-31	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA
			Edwards Lifesciences AG Altsagenstrasse 14 6048 Horw, Switzerland
			Edwards Lifesciences Pte Ltd 35 Changi North Crescent Singapore 499641, Singapore
			Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020 USA
			Edwards Lifesciences Costa Rica S.R.L. La Lima Zona Franca Edificio Multitenant Modulos 1-3. La Lima, Cartago, Costa Rica
			Edwards Lifesciences LLC 1212 Alton Parkway Irvine, CA 92606 USA
			Edwards Lifesciences LLC 1821 Kettering Irvine, CA 92614 USA
CE Marking of Conformity Certificate			
2103732CE01	2023-01-07	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA
			Edwards Lifesciences AG Altsagenstrasse 14, 6048 Horw, Switzerland
			Edwards Lifesciences Pte Ltd 35 Changi North Crescent Singapore 499641
			Edwards Lifesciences Ltd 12050 Lone Peak Parkway Draper, UT 84020 USA
			Edwards Lifesciences Services GmbH Edisonstrasse 6 85716 Unterschleissheim, Germany
EC Design-Examination Certificates			
2103732DE01 2103732DE06 2103732DE09 2103732DE10	2023-01-07	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA
			Edwards Lifesciences AG Altsagenstrasse 14 Horw, Switzerland

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Certificate No.	Valid until	Holder of Certificate	Certified Locations/Facilities*
			Edwards Lifesciences Pte Ltd 35 Changi North Crescent Singapore 499641
			Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020 USA

* Refer to certificates for scope of activities performed at these facilities; ** Certification to ISO 13485:2003

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

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

Signed for and on behalf of manufacturer: Edwards Lifesciences LLC

Location: Irvine, USA
Date: 04 January 2018

Rand Pugmire
Manager RA Program Management, THV Regulatory Affairs
Edwards Lifesciences LLC

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Product List:

Trade Name – Classification / Rule(s) [Applicable Certificates]	Model(s)	UMDNS Code	GMDN Code	Start of CE Marking (see NOTES at end of table)
Transcatheter Bovine Heart Valves [implant/THV] – Class III / Rules 8, 17				
Edwards SAPIEN XT™ Transcatheter Heart Valve [2103732(CE01, DE06)]	9300TFX	15870	60247 (Pulmonic)	18 January 2016[11]
Edwards SAPIEN XT™ Transcatheter Heart Valve [2103732(CE01, DE01, DE09, DE10)]	9300TFX	15870	60245 (Aortic, and Aortic Valve in Surgical Valve) 60246 (Mitral Valve in Surgical Valve)	11 March 2010[2a] 22 July 2010[3] 25 February 2011[4] 27 April 2012[2b] 30 May 2012[5] 30 January 2014[7, 8, 9] 9 September 2014[10]
Edwards SAPIEN 3™ Transcatheter Heart Valve [2103732(CE01, DE01, DE09)]	9600TFX	15870	60245 (Aortic)	27 January 2014[6] 28 March 2014[5] 16 August 2016 [10,12]
Accessories for Valve Delivery – Class I (sterile) / Rule 1				
Crimper [2103732(CE01)]	9350CR	16463	16463	25 February 2011[4] 27 May 2011[2] 30 January 2014[7, 8, 9]
	9600CR			27 January 2014
Qualcrimp™ Crimping Accessory [2103732(CE01)]	See NOTE[1]	15571	Not applicable	11 March 2010[2a] 30 January 2014[9]
Predilation Catheters, Percutaneous – Class III / Rule 6				
Edwards™ Transfemoral Balloon Catheter [2103732(CE01, DE01)]	9350BC16	17453	17453	9 September 2014[10]
Edwards™ Transfemoral Balloon Catheter [2103732(CE01, DE01, DE06)]	9350BC20 9350BC23			1 February 2011[2a] 18 January 2016[11]
Edwards™ Transfemoral Balloon Catheter [2103732(CE01, DE01, DE06)]	9350BC25			27 April 2012[2b] 18 January 2016[11]
Systems for Percutaneous Delivery – Class IIa / Rule 6				
RetroFlex® Dilator Kit [2103732(CE01)]	9100DKS	10678	58865	27 September 2007[2a] 30 January 2014[9]
Systems for Percutaneous Delivery – Class III, Rule 6				
NovaFlex+™ Delivery System [2103732(CE01, DE01, DE06, DE10)]	9355FS20	17846	60245 (Aortic)	9 September 2014[10]
	9355FS23 9355FS26 9355FS29		60245 (Aortic) 60247 (Pulmonic)	27 May 2011[2a] 30 January 2014[9]
				27 April 2012[2b]
				18 January 2016[11]
Edwards™ Expandable Introducer Sheath Set [2103732(CE01, DE01, DE06, DE10)]	916ES23 918ES26	10678	58865	22 February 2011 30 January 2014[9] 28 November 2017
	920ES29			26 September 2011 28 November 2017
Edwards™ eSheath Introducer Set [2103732(CE01, DE01, DE06, DE10)]	9610ES14			09 January 2012 28 November 2017
	9610ES16			15 November 2013 28 November 2017
Systems for Percutaneous Delivery – Class III, Rule 7				
Edwards Commander™ Delivery System [2103732(CE01, DE01)]	9610TF20 9610TF23 9610TF26 9610TF29	17846	60245 (Aortic)	16 August 2016
				27 January 2014

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Product List:

Trade Name – Classification / Rule(s) [Applicable Certificates]	Model(s)	UMDNS Code	GMDN Code	Start of CE Marking (see NOTES at end of table)
Systems for Transapical Delivery – Class III / Rule 6				
Edwards Certitude™ Delivery System [2103732(CE01, DE09)]	9620TA20 9620TA23 9620TA26 9620TA29	17453	60245 (Aortic)	16 August 2016[12] 27January 2014
Edwards Certitude™ Introducer Sheath Set [2103732(CE01, DE09)]	9620IS18 9620IS21	10678	58865	16 August 2016 [12] 27January 2014
Predilation Catheters, Transapical and Transaortic – Class III / Rule 6				
Ascendra® Balloon Aortic Valvuloplasty Catheter [2103732(CE01, DE09)]	9100BAVC	17453	17453	25 February 2011[4] 30 May 2012[5]
Systems for Transapical and Transaortic Delivery – Class III / Rule 6				
Ascendra+™ Delivery System [2103732(CE01, DE09, DE10)]	9355AS23 9355AS26	17453	60245 (Aortic) 60246 (Mitral Valve in Surgical Valve)	30 May 2012[5] 30 January 2014[7, 8]
	9355AS29			30 May 2012[5]
Edwards Certitude™ Delivery System [2103732(CE01, DE09)]	9620TA20 9620TA23 9620TA26 9620TA29	17453	60245 (Aortic)	16 August 2016[12] 28 March 2014[5]
Ascendra+™ Introducer Sheath Set [2103732(CE01, DE09, DE10)]	9350IS23 9350IS26	10678	58865	30 May 2012[5] 30 January 2014[7, 8]
	9350IS29			30 May 2012[5]
Edwards Certitude™ Introducer Sheath Set [2103732(CE01, DE09)]	9620IS18 9620IS21			28 March 2014[5]

NOTES:

[1] Packaged with the NovaFlex+ delivery systems, Commander delivery systems, and Certitude delivery systems.
[2a] Aortic, transfemoral – 23mm and 26mm systems
[2b] Aortic, transfemoral – 29mm systems
[3] Aortic, transapical – 23mm and 26mm systems
[4] Aortic, transapical – 29mm systems
[5] Aortic, transapical / transaortic – 23mm, 26mm, and 29mm systems
[6] Aortic, transfemoral/ transapical – 23mm, 26mm, and 29mm systems
[7] Aortic, THV-in-Surgical Valve, transaortic – 23mm and 26mm systems
[8] Aortic/Mitral, THV-in-Surgical Valve, transapical – 23mm and 26mm systems
[9] Aortic, THV-in-Surgical Valve, transfemoral – 23mm and 26mm systems
[10] Aortic, transfemoral – 20mm system
[11] Pulmonic, transfemoral – 23mm, 26mm, and 29mm systems
[12] Aortic, transapical/transaortic – 20mm system