

**Dodatek č. 2**  
**K Rámcové dohodě na dodávky katetrizačně implantované chlopně pro**  
**Nemocnici Na Homolce (část 4 a 5)**  
**ze dne 17. 1. 2020**

Název: **Nemocnice Na Homolce**  
IČO: 00023884  
DIČ: CZ00023884  
Sídlem: Praha 5, Motol, Roentgenova 2/37, PSČ 150 30  
Zastoupená: MUDr. Petrem Poloučkem, MBA, ředitelem  
(dále též jen jako „**kupující**“) na straně jedné

a

Obchodní společnost: **Edwards Lifesciences Czech Republic s.r.o.**  
IČO: 02004534  
DIČ: CZ02004534  
Sídlem: Pernerova 697/35, Karlín, 186 00 Praha 8  
Zapsaná: v obchodním rejstříku vedeném u Městského soudu v Praze, oddíl C, vložka 213782

Zastoupená:  
(dále též jen jako „**prodávající**“) na straně druhé

Kupující a prodávající společně dále jako „**účastníci dohody**“

Účastníci dohody se dohodli takto:

**I.**

1. Účastníci dohody uzavřeli dne 17. 1. 2020, na základě výsledků zadávacího řízení na veřejnou zakázku s názvem „**Katetrizačně implantované chlopně pro Nemocnici Na Homolce – část 4 a 5**“ uveřejněnou ve Věstníku veřejných zakázek pod ev. číslem Z2019-034142, ev. číslo zadavatele 198/VZ/2019-OVZ, **Rámcovou dohodu na dodávky katetrizačně implantované chlopně pro Nemocnici Na Homolce část 4 a 5** (dále jen „**Dohoda**“). Účastníci dohody se za účelem výměny části materiálu za nově vyvinutý materiál a v souladu s čl. IV. odst. 2 Všeobecných obchodních podmínek kupujícího, které tvoří nedílnou součást Dohody, dohodli, na následujících změnách Dohody.

**II.**

1. Účastníci dohody se dohodli na následujících změnách Dohody: ke dni účinnosti tohoto dodatku se v souladu s čl. VII. odst. 3 dohody:
  - (i) *Příloha č. 2: Specifikace plnění, Cenová tabulka*, ruší a nahrazuje novým zněním *Přílohy č. 2 Specifikace plnění, Cenová tabulka*, která tvoří nedílnou součást tohoto dodatku;
  - (ii) *Příloha č. 6: Prohlášení o shodě, prokázání označení značkou CE, je-li prohlášení vystavováno*, ruší a nahrazuje novým zněním *Přílohy č. 6: Prohlášení o shodě, prokázání označení značkou CE, je-li prohlášení vystavováno*, která tvoří nedílnou součást tohoto dodatku; a

(iii) *Příloha č. 7: Portfolio sortimentu – Část 5 Přílohy*, ruší a nahrazuje novým zněním *Přílohy č. 7: Portfolio sortimentu – Část 5*, která tvoří nedílnou součást tohoto dodatku.

2. Ostatní ujednání Dohody zůstávají beze změn a uplatní se v plném rozsahu.

### III.

1. Tento dodatek nabývá platnosti dnem podpisu posledního z účastníků dohody a účinnosti dnem jeho zveřejnění v registru smluv dle zákona č. 340/2015 Sb., o zvláštních podmínkách účinnosti některých smluv, uveřejňování těchto smluv a o registru smluv. Tento dodatek v registru smluv zveřejní kupující.
2. Tento dodatek je vyhotoven ve třech stejnopisech, z nichž jeden obdrží prodávající a dva kupující.
3. Účastníci dohody prohlašují, že si tento dodatek přečetly, porozuměly jeho obsahu a že byl uzavřen podle jejich pravé a svobodné vůle a nikoli v tísní či za nápadně nevýhodných podmínek, což stvrzují vlastnoručními podpisy.

#### Seznam příloh:

Příloha č. 2: Specifikace plnění, Cenová tabulka

Příloha č. 6: Prohlášení o shodě, prokázání označení značkou CE, je-li prohlášení vystavováno

Příloha č. 7: Portfolio sortimentu – Část 5

V Praze dne \_\_.\_\_. 2021

V Praze dne \_\_.\_\_. 2021

**Nemocnice na Homolce**  
MUDr. Petr Polouček, MBA  
ředitel

**Edwards Lifesciences Czech Republic s.r.o.**

## Portfolio sortimentu

## Část 5

Účastník: Edwards Lifesciences Czech Republic s.r.o.

Poř. číslo	VZP kód	Cena Kč VZP max za 1ks	Katalogové číslo dodavatele	Název materiálu (upřesnění rozměrů - Fr, průměr, délka)	Doplňující popis zboží	Výrobce	UDI-DI/GTIN	Jednotka	Balení = Minimální objednané množství	Nabídková cena za 1 jednotku (v Kč bez DPH)	DPH %	Třída rizika	Exspirace Ano/Ne
1	115971	497.540,00	S3UCM220	SET PRO TRANSFEM.IMPLANTACI BIO.AORT.CHLOPNĚ BOVINNÍ SAPIEN 3 ULTRA, vel. 20		ELS	(01)00690103208085	1 ks	1 ks	432.640,00 Kč	15%	III.	Ano
2	115971	497.540,00	S3UCM223	SET PRO TRANSFEM.IMPLANTACI BIO.AORT.CHLOPNĚ BOVINNÍ SAPIEN 3 ULTRA, vel. 23		ELS	(01)00690103208092	1 ks	1 ks	432.640,00 Kč	15%	III.	Ano
3	115971	497.540,00	S3UCM226	SET PRO TRANSFEM.IMPLANTACI BIO.AORT.CHLOPNĚ BOVINNÍ SAPIEN 3 ULTRA, vel. 26		ELS	(01)00690103208108	1 ks	1 ks	432.640,00 Kč	15%	III.	Ano
4	114449	497.540,00	S3TF129	SET PRO TRANSFEM.IMPLANTACI BIO.AORT.CHLOPNĚ BOVINNÍ SAPIEN 3, vel. 29		ELS	(01)07612989037521	1 ks	1 ks	432.640,00 Kč	15%	III.	Ano
5	115972	497.540,00	S3USTA120	SET PRO TRANSAPIK./TRANSAORT. IMPLANTACI BIO. AORT.CHLOPNĚ SAPIEN 3 ULTRA, vel. 20		ELS	(01)00690103199970	1 ks	1 ks	432.640,00 Kč	15%	III.	Ano
6	115972	497.540,00	S3USTA123	SET PRO TRANSAPIK./TRANSAORT. IMPLANTACI BIO. AORT.CHLOPNĚ SAPIEN 3 ULTRA, vel. 23		ELS	(01)00690103199987	1 ks	1 ks	432.640,00 Kč	15%	III.	Ano
7	115972	497.540,00	S3USTA126	SET PRO TRANSAPIK./TRANSAORT. IMPLANTACI BIO. AORT.CHLOPNĚ SAPIEN 3 ULTRA, vel. 26		ELS	(01)00690103199994	1 ks	1 ks	432.640,00 Kč	15%	III.	Ano
8	114450	497.540,00	S3TA129	SET PRO TRANSAPIK./TRANSAORT. IMPLANTACI BIO. AORT.CHLOPNĚ SAPIEN 3, vel. 29		ELS	(01)07612989037552	1 ks	1 ks	432.640,00 Kč	15%	III.	Ano
8													

Portfolio sortimentu navazuje na přílohu č. 2 ZD (Cenová tabulka). Účastník zde uvede veškeré položky, které chce zařadit do nabídky.

## Příloha č. 2 Cenová tabulka

Část	Typ	Předpokládaný odběr v ks za 4 roky	Katalogové číslo	Nabízený materiál (obchodní název)	Kód VZP	Cena v Kč VZP max za 1 ks	Základní nabídková cena				
							Cena za ks bez DPH	sazba DPH	Cena za ks vč. DPH	Celková nabídková cena bez DPH při předpokládaném počtu kusů za 4 roky	Celková nabídková cena včetně DPH při předpokládaném počtu kusů za 4 roky
Část 1	Katetrizačně implantovatelná chlopeč výhodná pro velké nebo malé anatomie - set	100							0,00	0,00	0,00
Část 2	Katetrizačně implantovatelná chlopeč pro velké nebo malé anatomie s vyšším rizikem paravalvulární regurgitace - set	100							0,00	0,00	0,00
Část 3	Katetrizačně implantovatelná chlopeč pro léčbu dysfunkce výtokového traktu pravé komory - set	8							0,00	0,00	0,00
Část 4	Katetrizačně implantovatelná chlopeč pro léčbu aortální stenózy, dysfunkce výtokového traktu pravé komory o velkém průměru a implantace do degenerovaných bioprotéz - set	72							0,00	0,00	0,00
Část 5	Katetrizačně implantovatelná chlopeč pro nemocné s komplikovaným nebo nemožným cévním přístupem a rizikem paravalvulární regurgitace - set	40	S3UCM220 S3UCM223 S3UCM226 S3TF129 S3USTA120 S3USTA123 S3USTA126 S3TA129	SET PRO TRANSFEM.IMPLANTACI BIO.AORT.CHLOPNĚ BOVINNÍ SAPIEN 3, SAPIEN 3 ULTRA, SET PRO TRANSAPIK./TRANSAORT. IMPLANTACI BIO. AORT.CHLOPNĚ SAPIEN 3, SAPIEN 3 ULTRA	115971 115971 115971 114449 115972 115972	497.540,00	432.640,00	15%	497.536,00	17.305.600,00	19.901.440,00

# EC Declaration of Conformity



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

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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*
<b>Quality Management System Certificates</b>			
3817373	2022-01-07	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. La Lima Zona Franca, Edificio Multitenant Modulos 1-3, La Lima, Cartago, Costa Rica
			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
<b>Quality Management System Certificates</b>			
3821948	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. La Lima Zona Franca, Edificio Multitenant Modulos 1-3, La Lima, Cartago, Costa Rica
			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

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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 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
			Edwards Lifesciences Costa Rica S.R.L. La Lima Zona Franca, Edificio Multitenant Modulos 1-3, La Lima, Cartago, Costa Rica
			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
EC Design-Examination Certificates			
2103732DE06 2103732DE12	2023-01-07	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
2103732DE01 2103732DE09	2023-01-07	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

\* Refer to certificates for scope of activities performed at these facilities.

# EC Declaration of Conformity



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**Notified Body:**  
(Identification No. 0344)

DEKRA Certification B.V.  
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:  
Date:

Irvine, USA  
07 May 2021

**Rand Pugmire**  
Digitally signed by Rand  
Pugmire  
Date: 2021.05.11 10:09:29  
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Rand Pugmire  
Sr. Manager, Regulatory Affairs  
Edwards Lifesciences LLC



# EC Declaration of Conformity



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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)
<b>Transcatheter Bovine Heart Valves [implant/THV] – Class III / Rules 8, 17</b>				
Edwards SAPIEN XT™ Transcatheter Heart Valve [2103732(CE01, DE06)]	9300TFX	15870	60247 (Pulmonic)	18 January 2016 <sup>[11]</sup>
Edwards SAPIEN 3™ Transcatheter Heart Valve [2103732(CE01, DE01, DE09, DE12)]	9600TFX	15870	60245 (Aortic, and Aortic Valve in Bioprosthetic Valve)  60246 (Mitral Valve in Surgical Valve)	27 January 2014 <sup>[6]</sup> 28 March 2014 <sup>[5]</sup> 16 August 2016 <sup>[10,12]</sup> 10 July 2019 <sup>[16, 17]</sup>
Edwards SAPIEN 3 Ultra™ Transcatheter Heart Valve [2103732(CE01, DE01, DE09)]	9750TFX	15870	60245 (Aortic)	13 November 2018 <sup>[2a, 10, 14]</sup>
<b>Accessories for Valve Delivery – Class I (sterile) / Rule 1</b>				
Crimper [2103732(CE01)]	9350CR	16463	16463	18 January 2016 <sup>[11]</sup>
	9600CR			27 January 2014
Qualcrimp™ Crimping Accessory [2103732(CE01)]	See NOTE <sup>[1]</sup>	15571	Not applicable	11 March 2010 <sup>[2a]</sup>
Edwards Inflation Device [2103732(CE01)]	96402	17541	17541	16 July 2019
Edwards Locking Syringe [2103732(CE01)]	96406	17541	17541	16 July 2019
<b>Predilation Catheters, Percutaneous – Class III / Rule 6</b>				
Edwards™ Transfemoral Balloon Catheter [2103732(CE01, DE01)]	9350BC16	17453	17453	9 September 2014 <sup>[10]</sup>
Edwards™ Transfemoral Balloon Catheter [2103732(CE01, DE01, DE06)]	9350BC20 9350BC23			1 February 2011 <sup>[2a]</sup> 18 January 2016 <sup>[11]</sup>
Edwards™ Transfemoral Balloon Catheter [2103732(CE01, DE01, DE06)]	9350BC25			27 April 2012 <sup>[2b]</sup> 18 January 2016 <sup>[11]</sup>
Edwards™ Transfemoral Balloon Catheter [2103732(CE01, DE01)]	9400BC25	17453	17453	13 November 2018 <sup>[2b]</sup>
<b>Systems for Percutaneous Delivery – Class IIa / Rule 6</b>				
RetroFlex® Dilator Kit [2103732(CE01)]	9100DKS	10678	58865	18 January 2016 <sup>[11]</sup>
<b>Systems for Percutaneous Delivery – Class III, Rule 6</b>				
Edwards™ Expandable Introducer Sheath Set [2103732(CE01, DE01, DE06,)]	916ES23 918ES26	10678	58865	22 February 2011 28 November 2017
	920ES29			26 September 2011 28 November 2017
Edwards™ eSheath Introducer Set [2103732(CE01, DE01, DE06, , DE12)]	9610ES14			09 January 2012 28 November 2017 10 July 2019 <sup>[16, 17]</sup>
	9610ES16			15 November 2013 28 November 2017 10 July 2019 <sup>[16, 17]</sup>

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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)
<b>Systems for Percutaneous Delivery – Class III, Rule 7</b>				
NovaFlex+™ Delivery System [2103732(CE01, DE01, DE06,)]	9355FS23 9355FS26 9355FS29	17846	60247 (Pulmonic)	18 January 2016 <sup>[11]</sup>
Edwards Commander™ Delivery System [2103732(CE01, DE01, DE12)]	9610TF20 9610TF23 9610TF26 9610TF29	17846	60245 (Aortic, , and Aortic Valve in Bioprosthetic Valve)	16 August 2016
			60246 (Mitral Valve in Surgical Valve)	27 January 2014 10 July 2019 <sup>[16, 17]</sup>
<b>Systems for Transapical Delivery – Class III / Rule 6</b>				
Edwards Certitude™ Delivery System [2103732(CE01, DE09, DE12)]	9620TA20 9620TA23 9620TA26 9620TA29	17453	60245 (Aortic, and Aortic Valve in Bioprosthetic Valve)  60246 (Mitral Valve in Surgical Valve)	16 August 2016 <sup>[12]</sup> 27 January 2014 10 July 2019 <sup>[16, 17]</sup>
	9630TA23 9630TA26	17453	60245 (Aortic)	13 November 2018 <sup>[15]</sup>
Edwards Certitude™ Introducer Sheath Set [2103732(CE01, DE09, DE12)]	9620IS18 9620IS21	10678	58865	16 August 2016 <sup>[12]</sup> 27 January 2014 10 July 2019 <sup>[16, 17]</sup>
<b>Predilation Catheters, Transapical and Transaortic – Class III / Rule 6</b>				
Ascendra® Balloon Aortic Valvuloplasty Catheter [2103732(CE01, DE09)]	9100BAVC	17453	17453	25 February 2011 <sup>[4]</sup> 30 May 2012 <sup>[5]</sup>
<b>Systems for Transapical and Transaortic Delivery – Class III / Rule 6</b>				
Edwards Certitude™ Delivery System [2103732(CE01, DE09 DE12)]	9620TA20 9620TA23 9620TA26 9620TA29	17453	60245 (Aortic and Aortic Valve in Bioprosthetic Valve)  60246 (Mitral Valve in Surgical Valve)	16 August 2016 <sup>[12]</sup> 28 March 2014 <sup>[5]</sup> 10 July 2019 <sup>[16, 17]</sup>
	9630TA23 9630TA26	17453	60245 (Aortic)	13 November 2018 <sup>[15]</sup>
Edwards Certitude™ Introducer Sheath Set [2103732(CE01, DE09, DE12)]	9620IS18 9620IS21	10678	58865	28 March 2014 <sup>[5]</sup> 10 July 2019 <sup>[16, 17]</sup>

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## NOTES:

- <sup>[1]</sup> Packaged with the NovaFlex+ delivery systems, Commander delivery systems, Ultra Delivery Systems, and Certitude delivery systems.
- <sup>[2a]</sup> Aortic, transfemoral – 23mm and 26mm systems
- <sup>[2b]</sup> Aortic, transfemoral – 29mm systems
- <sup>[4]</sup> Aortic, transapical – 29mm systems
- <sup>[5]</sup> Aortic, transapical / transaortic – 23mm, 26mm, and 29mm systems
- <sup>[6]</sup> Aortic, transfemoral/ transapical – 23mm, 26mm, and 29mm systems
- <sup>[10]</sup> Aortic, transfemoral – 20mm system
- <sup>[11]</sup> Pulmonic, transfemoral – 23mm, 26mm, and 29mm systems
- <sup>[12]</sup> Aortic, transapical/transaortic – 20mm system
- <sup>[13]</sup> Aortic, transfemoral – 20mm, 23mm, 26mm, and 29mm systems
- <sup>[14]</sup> Aortic, transapical/Transaortic – 20mm, 23mm, and 26mm systems
- <sup>[15]</sup> Aortic, transapical/Transaortic – For use with SAPIEN 3 Ultra THV 23mm and 26mm systems
- <sup>[16]</sup> Aortic/Mitral, THV-in-Surgical Valve; transfemoral, transapical, transaortic, transseptal; 20mm, 23mm, 26mm, 29mm SAPIEN 3 systems. For the Certitude Delivery System, this is only applicable to models 9620TA20, 9620TA23, 9620TA26, 9620TA29.
- <sup>[17]</sup> Aortic, THV-in-THV; transfemoral, transapical, transaortic; 20mm, 23mm, 26mm, 29mm SAPIEN 3 systems. For the Certitude Delivery System, this is only applicable to models 9620TA20, 9620TA23, 9620TA26, 9620TA29.



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## Procedure Pack Statement

Procedure pack producer: SRN: N/A (Pending Implementation of EUDAMED)  
Edwards Lifesciences LLC  
One Edwards Way  
Irvine, CA 92614, USA

Basic UDI-DI: 0690103P003CS300028,  
0690103P003CST00098,  
0690103P003CSU0009F,  
0690103P003C3U000WP,  
0690103P003NSX000EK

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 pack specified above meet 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 pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
- The operations are subjected to appropriate methods of internal monitoring, verification, and validation.

Joseph  
Mazzarella

Digitally signed by Joseph Mazzarella  
DN: cn=Joseph Mazzarella,  
email=Joseph\_Mazzarella@edwards.com  
Reason: Director THV RA, I am approving  
this document  
Date: 2021.05.20 14:16:11 -07'00'

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Joseph Mazzarella  
Director, Regulatory Affairs  
Edwards Lifesciences LLC  
One Edwards Way  
Irvine, CA 92614 USA

## Product List

Procedure Pack (Kit)		Procedure Pack Components		
Kit Reference Number	Kit	Model	Description	Quantity
9355NF23	NovaFlex+ Kit	9300TFX, 23mm	Edwards SAPIEN XT Transcatheter Heart Valve, 23mm	1
		9100DKS	RetroFlex Dilator Kit	1
		916ES23	Edwards Expandable Introducer Sheath Set (16F)	1
		9350BC20	Edwards Transfemoral Balloon Catheter, 20mm	1
		9355FS23	NovaFlex+ Delivery System, 23mm	1
		9350CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
9355NF26	NovaFlex+ Kit	9300TFX, 26mm	Edwards SAPIEN XT Transcatheter Heart Valve, 26mm	1
		9100DKS	RetroFlex Dilator Kit	1
		918ES26	Edwards Expandable Introducer Sheath Set (18F)	1
		9350BC23	Edwards Transfemoral Balloon Catheter, 23mm	1
		9355FS26	NovaFlex+ Delivery System, 26mm	1
		9350CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
9355NF29	NovaFlex+ Kit	9300TFX, 29mm	Edwards SAPIEN XT Transcatheter Heart Valve, 29mm	1
		9100DKS	RetroFlex Dilator Kit	1
		920ES29	Edwards Expandable Introducer Sheath Set (20F)	1
		9350BC25	Edwards Transfemoral Balloon Catheter, 25mm	1
		9355FS29	NovaFlex+ Delivery System, 29mm	1
		9350CR	Crimper	1
		96406	Atrion QL38 Locking Syringe, 38ml or Edwards Locking Syringe	2

Procedure Pack (Kit)		Procedure Pack Components		
Kit Reference Number	Kit	Model	Description	Quantity
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

Procedure Pack (Kit)		Procedure Pack Components		
Kit Reference Number	Kit	Model	Description	Quantity
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



Procedure Pack (Kit)		Procedure Pack Components		
Kit Reference Number	Kit	Model	Description	Quantity
		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
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

Procedure Pack (Kit)		Procedure Pack Components		
Kit Reference Number	Kit	Model	Description	Quantity
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

Procedure Pack (Kit)		Procedure Pack Components		
Kit Reference Number	Kit	Model	Description	Quantity
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

Procedure Pack (Kit)		Procedure Pack Components		
Kit Reference Number	Kit	Model	Description	Quantity
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

Procedure Pack (Kit)		Procedure Pack Components		
Kit Reference Number	Kit	Model	Description	Quantity
		9620IS18	Edwards Certitude Introducer Sheath Set, 18F	1
		9600CR	Crimper	1
		96402	Atrion QL2530 Inflation Device, 25ml or Edwards Inflation Device	2
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

Procedure Pack (Kit)		Procedure Pack Components		
Kit Reference Number	Kit	Model	Description	Quantity
		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
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

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

**Portfolio sortimentu**

Příloha č. 7 ZP - Dodávky SZM -Edwards Lifesciences

Část č. 5

Účastník: **Edwards Lifesciences, s.r.o. Czech Republic**

Portfolio sortimentu navazuje na přílohu č. 2 ZD (ceník). Účastník zde uvede veškeré položky, které chce zařadit do nabídky.

Poř. číslo	VZP kód	Cena Kč VZP max za 1ks	Katalogové číslo dodavatele	Název materiálu (upřesnění rozměrů - Fr, průměr, délka)	Výrobce	UDI-DI/GTIN	Jednotka	Minimální objednané množství = počet jednotek v balení	Nabídková cena za jednotku (v Kč bez DPH)	DPH %	Nabídková cena za jednotku (v Kč s DPH)	Třída rizika	Exspirace Ano/Ne
1	0115972	515.000,00	S3USTA120	Edwards Sapien 3 ULTRA transapikální TA - 20mm, set na TAVI	ELS	(01)00690103199970	Ks	1	432.640,00	15%	497.536,00	III	Ano
2	0115972	515.000,00	S3USTA123	Edwards Sapien 3 ULTRA transapikální TA - 23 mm, set na TAVI	ELS	(01)00690103199987	Ks	1	432.640,00	15%	497.536,00	III	Ano
3	0115972	515.000,00	S3USTA126	Edwards Sapien 3 ULTRA transapikální TA - 26mm, set na TAVI	ELS	(01)00690103199994	Ks	1	432.640,00	15%	497.536,00	III	Ano
4	0114450	497.540,00	S3TA129	Edwards Sapien 3 transapikální TA - 29 mm, set na TAVI	ELS	(01)07612989037552	Ks	1	432.640,00	15%	497.536,00	III	Ano
5	0115971	515.000,00	S3UCM220	Edwards Sapien 3 ULTRA transfemorální TF - 20 mm, set na TAVI	ELS	(01)00690103208085	Ks	1	432.640,00	15%	497.536,00	III	Ano
6	0115971	515.000,00	S3UCM223	Edwards Sapien 3 ULTRA transfemorální TF - 23 mm, set na TAVI	ELS	(01)00690103208092	Ks	1	432.640,00	15%	497.536,00	III	Ano
7	0115971	515.000,00	S3UCM226	Edwards Sapien 3 ULTRA transfemorální TF - 26 mm, set na TAVI	ELS	(01)00690103208108	Ks	1	432.640,00	15%	497.536,00	III	Ano
8	0114449	497.540,00	S3TF129	Edwards Sapien 3 transfemorální TF - 29 mm, set na TAVI	ELS	(01)07612989037521	Ks	1	432.640,00	15%	497.536,00	III	Ano
<b>Příslušenství obsažené v setu</b>													
1			9620TA20	Edwards Certitude Delivery System	ELS	(01)00690103193015	ks		**		**	III	Ano
2			9630TA23	Edwards Certitude Delivery System	ELS	(01)00690103199420	ks		**		**	III	Ano
3			9630TA26	Edwards Certitude Delivery System	ELS	(01)00690103199437	ks		**		**	III	Ano
4			9620TA29	Edwards Certitude Delivery System	ELS	(01)00690103193046	ks		**		**	III	Ano
5			9750TFX20	Transcatheter Heart Valve (Sapien 3 Ultra)	ELS	(01)00690103199727	ks		**		**	III	Ano
6			9750TFX23	Transcatheter Heart Valve (Sapien 3 Ultra)	ELS	(01)00690103199734	ks		**		**	III	Ano
7			9750TFX26	Transcatheter Heart Valve (Sapien 3 Ultra)	ELS	(01)00690103199741	ks		**		**	III	Ano
8			9600TFX29	Transcatheter Heart Valve	ELS	(01)07612989037491	ks		**		**	III	Ano
9			9620IS18	Edwards Certitude Introducer Sheath Set	ELS	(01)00690103193152	ks		**		**	III	Ano
10			9620IS21	Edwards Certitude Introducer Sheath Set	ELS	(01)00690103193169	ks		**		**	III	Ano
11			9600CR	Crimper	ELS	(01)00690103192773	ks		**		**	I	Ano
12			9100BAVC	Ascendra Balloon Aortic Valvuloplasty Catheter	ELS	(01)00690103178067	ks		**		**	III	Ano
13			9610TF20	Edwards Commander Delivery System	ELS	(01)00690103192995	ks		**		**	III	Ano
14			9610TF23	Edwards Commander Delivery System	ELS	(01)00690103190458	ks		**		**	III	Ano
15			9610TF26	Edwards Commander Delivery System	ELS	(01)00690103190465	ks		**		**	III	Ano
16			9610TF29	Edwards Commander Delivery System	ELS	(01)00690103193008	ks		**		**	III	Ano
17			9350BC25	Edwards Transfemoral Balloon Catheter	ELS	(01)00690103190717	ks		**		**	III	Ano
18			9610ES14	Edwards eSheath Introducer Set	ELS	(01)00690103191219	ks		**		**	III	Ano
19			9610ES16	Edwards eSheath Introducer Set	ELS	(01)00690103193244	ks		**		**	III	Ano
20			96402	QL2530 Inflation device	Atrion	(01)00690103210002	ks		**		**	I	Ano
21			96406	QL38 Inflation device	Atrion	(01)00690103210019	ks		**		**	I	Ano

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