

**OBSAH PONUKY (súpis dokumentov):**

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8. *Sortiment ponúkaného tovaru* - pre časť č. 4 - Príloha č. 7 SP
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13. *ŠUKL* – pre časť č. 4 – Potvrdenie ŠUKL (P 7361A)
14. *Prospektový materiál* – pre časť č. 4
15. *Rozhodnutie o zaradení* - pre časť č. 4 (S04798-2024-OKCHZPDP-14396)

V Bratislave, dňa 18.2.2026

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Ing. Silvia Augustinová, konateľ

Názov predmetu zákazky:  
**Chlopňové protézy a srdcové chlopne**

## IDENTIFIKAČNÉ ÚDAJE UCHÁDZAČA

Obchodné meno/Názov uchádzača: **Operatíva, medicínska spoločnosť s.r.o.**  
Sídlo/Miesto podnikania: Donská 61, 841 06 Bratislava  
IČO: 35757329  
DIČ: 2020253730

### Kontaktná osoba uchádzača - počas procesu VO

Meno a priezvisko: **Mgr. Nicole Rigová**  
Telefónne číslo: +421 905 500 511  
E-mail: [rigova@operativa.sk](mailto:rigova@operativa.sk)

### Kontaktná osoba uchádzača - pre elektronickú aukciu

Meno a priezvisko: **Mgr. Ivana Csabiová**  
Telefónne číslo: +421 2 654 56 111  
E-mail: [obstaravanie@operativa.sk](mailto:obstaravanie@operativa.sk)

V: Bratislave  
Dňa: 18.2.2026

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Ing. Silvia Augustinová  
konateľ

Poznámka:

- povinné údaje vyplní uchádzač

## Príloha č. 2 SP

Vyhlasenie uchádzača vo verejnom obstarávaní

Názov predmetu zákazky:

**Chlopňové protézy a srdcové chlopne**

### VYHLÁSENIE UCHÁDZAČA VO VEREJNOM OBSTARÁVANÍ

Obchodné meno/Názov uchádzača: **Operatíva, medicínska spoločnosť**

Sídlo/Miesto podnikania: Donská 61, 841 06 Bratislava

IČO: 35757329

DIČ: 2020253730

Týmto vyhlasujem, že ako uchádzač vo verejnom obstarávaní na uvedený predmet zákazky:

- súhlasím s podmienkami určenými verejným obstarávateľom v tomto verejnom obstarávaní uvedené v Oznámení o vyhlásení verejného obstarávania a v súťažných podkladoch,
- som dôkladne oboznámený s celým obsahom súťažných podkladov a s celým obsahom všetkých ostatných dokumentov poskytnutých verejným obstarávateľom,
- prehlasujem, že všetky doklady, dokumenty, vyhlásenia a údaje uvedené v ponuke a predložené s ponukou sú pravdivé a úplné,
- poskytnem verejnému obstarávateľovi za úhradu plnenie požadovaného predmetu zákazky pri dodržaní podmienok stanovených v súťažných podkladoch a podmienok uvedených v mojom predloženej návrhu záväzných zmluvných podmienok na uvedený predmet zákazky, vrátane príloh,
- nie som členom skupiny dodávateľov, ktorá ako iný uchádzač predkladá ponuku.

V: Bratislave

Dňa: 18.2.2026

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Ing. Silvia Augustinová  
konateľ

Poznámka:

- povinné údaje vyplní uchádzač

### Príloha č. 3 SP

Vyhlásenie uchádzača o súhlase s obsahom návrhu zmluvných podmienok

Názov predmetu zákazky:

**Chlopňové protézy a srdcové chlopne**

## VYHLÁSENIE UCHÁDZAČA O SÚHLASE S OBSAHOM NÁVRHU ZMLUVNÝCH PODMIENOK

Obchodné meno/Názov uchádzača: **Operatíva, medicínska spoločnosť s.r.o.**

Sídlo/Miesto podnikania: Donská 61, 841 06 Bratislava

IČO: 35757329

DIČ: 2020253730

Uchádzač vo verejnom obstarávaní na uvedený predmet zákazky týmto vyhlasuje, že s návrhom zmluvných podmienok uvedených v časti D. Záväzné zmluvné podmienky súťažných podkladov bez výhrad **SÚHLASÍ**.

**Prehľad časti/častí predmetu zákazky**, na ktoré uchádzač predkladá vyhlásenie o súhlase s obsahom návrhu zmluvy (uchádzač uvedie samostatne pre každú časť predmetu zákazky jej číslo a názov):

Časť č.	Názov príslušnej časti predmetu zákazky
Časť č.4	Biologické srdcové chlopne

V: Bratislave

Dňa: 18.2.2026

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Poznámka:

- povinné údaje vyplní uchádzač

## Príloha č. 4 k SP

Vyhlasenie uchádzača ku konfliktom záujmov

Názov predmetu zákazky:

**Chlopňové protézy a srdcové chlopne**

### UYHLÁSENIE UCHÁDZAČA KU KONFLIKTOM ZÁUJMOV

Obchodné meno/Názov uchádzača: **Operatíva, medicínska spoločnosť s.r.o.**

Sídlo/Miesto podnikania: Donská 61, 841 06 Bratislava

IČO: 35757329

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Týmto vyhlasujem, že ako uchádzač vo verejnom obstarávaní na uvedený predmet zákazky:

- som nevyvíjal a nebudem vyvíjať voči žiadnej osobe na strane verejného obstarávateľa ktorá je alebo by mohla byť zainteresovaná v zmysle ustanovení § 23 ods. 3 zákona č. 343/2015 Z. z. o verejnom obstarávaní a o zmene a doplnení niektorých zákonov v znení neskorších predpisov („zainteresovaná osoba“) akékoľvek aktivity, ktoré vy mohli viesť k zvýhodneniu nášho postavenia vo verejnom obstarávaní,
- som neposkytol a neposkytnem akékoľvek, čo i len potenciálne zainteresovanej osobe priamo alebo nepriamo akúkoľvek finančnú alebo vecnú výhodu ako motiváciu alebo odmenu súvisiacu s týmto verejným obstarávaním,
- budem bezodkladne informovať verejného obstarávateľa o akékoľvek situácii, ktorá je považovaná za konflikt záujmov alebo ktorá by mohla viesť ku konfliktu záujmov kedykoľvek v priebehu procesu verejného obstarávania.

V: **Bratislave**

Dňa: **18.2.2026**

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Ing. Silvia Augustinová  
konateľ

Poznámka:

- povinné údaje vyplní uchádzač

Názov predmetu zákazky:  
**Chlopňové protézy a srdcové chlopne**

### Špecifikácia predmetu zákazky

#### časť 4. - Biologické srdcové chlopne

Požadované minimálne technické vlastnosti, parametre a hodnoty predmetu zákazky		Uchádzač uvedie informácie, či ním ponúkaný produkt spĺňa, resp. nespĺňa verejným obstarávateľom definované požiadavky na predmet zákazky (v prípade, ak ponúkaný produkt nespĺňa definované požiadavky uvedie ekvivalentnú hodnotu ním ponúkaného produktu)	
		spĺňa/nespĺňa	hodnota ponúkaného produktu
<i>Položka č. 1 - Biologické srdcové chlopne pre aortálne a mitrálne ústie</i>			
1.1	biologická stentovaná chlopňa	spĺňa	
1.2	prasačí xenotransplantát	spĺňa	
1.3	trikompozitný dizajn s ochranou cípov proti abrázii a zabezpečenie optimálnej koaptácie a hemodynamiky	spĺňa	
1.4	výtokový okraj chlopne s pripevneným prúžkom z hovädzieho perikardiálneho tkaniva	spĺňa	
1.5	šijacia manžeta obsahuje tri značky na stehy na upresnenie umiestnenia chlopne	spĺňa	
1.6	supraanulárna	spĺňa	
1.6.1	* pre aortálny anulus veľkostí 21-29 mm	spĺňa	
1.6.2	* pre mitrálny anulus veľkostí 25 -33 mm	spĺňa	
1.7	nízkotlaková fixácia tkaniva	spĺňa	
1.8	flexibilný Flex fit stent s nízkym profilom a vrúbkovaným tvarom	spĺňa	
1.9	účinná antikalcifikačná úprava Linx, cipy chlopne a perikardiálny prúžok fixované priečnymi vazbami v glutaraldehydovom roztoku	spĺňa	
1.10	nízka štruktúrálna deteriorácia chlopne	spĺňa	
1.11	ultrakrátke premývanie	spĺňa	
1.12	RTG kontrastná	spĺňa	
1.13	MRI kompatibilná	spĺňa	
<i>Položka č. 2 - Biologické srdcové chlopne pre aortálne ústie</i>			
<b>Variant A)</b>			
A.1.1	biologická stentovaná chlopňa	spĺňa	
A.1.2	prasačí xenotransplantát	spĺňa	
A.1.3	trikompozitný dizajn s ochranou cípov proti abrázii a zabezpečenie optimálnej koaptácie a hemodynamiky	spĺňa	
A.1.4	supraanulárna, pre anulus veľkostí 19-29 mm	spĺňa	
A.1.5	nízkotlaková fixácia tkaniva	spĺňa	
A.1.6	flexibilný Flex fit stent s nízkym profilom a vrúbkovaným tvarom	spĺňa	
A.1.7	účinná antikalcifikačná úprava Linx, cipy a perikardiálny prúžok fixované priečnymi vazbami v glutaraldehydovom roztoku	spĺňa	
A.1.8	nízka štruktúrálna deteriorácia chlopne	spĺňa	
A.1.9	ultrakrátke premývanie	spĺňa	
A.1.10	výtokový okraj chlopne s pripevneným prúžkom z hovädzieho perikardiálneho tkaniva	spĺňa	
A.1.11	šijacia manžeta obsahuje tri značky na stehy na upresnenie umiestnenia chlopne	spĺňa	

<b>Variant B)</b>			
B.1.1	biologická stentovaná chlopňa	spĺňa	
B.1.2	prasačí xenotransplantát	spĺňa	
B.1.3	trikompozitný dizajn s ochranou cípov proti abrázii a zabezpečenie optimálnej koaptácie a hemodynamiky	spĺňa	
B.1.4	supraannulárna implantácia chlopne aj šijacej manžety, pre aortálny anulus veľkostí 19-27 mm	spĺňa	
B.1.5	flexibilný Flex fit stent s nízkym profilom a vrúbkovaným tvarom	spĺňa	
B.1.6	výtokový okraj chlopne s pripevneným prúžkom z hovadzieho perikardiálneho tkaniva	spĺňa	
B.1.7	šijacia manžeta obsahuje tri značky na stehy na upresnenie umiestnenia chlopne	spĺňa	
B.1.8	účinná antikalcifikačná úprava Linx, cipy a perikardiálny prúžok fixované priečnymi väzbami v glutaraldehydovom roztoku	spĺňa	
B.1.9	nízka štruktúrálna deteriorácia chlopne	spĺňa	
B.1.10	ultratrátke premývanie	spĺňa	
B.1.11	RTG kontrastná	spĺňa	
B.1.12	MRI kompatibilná	spĺňa	

Týmto potvrdzujem, že všetky uvedené informácie sú pravdivé.

Obchodné meno/Názov uchádzača:

**Operativa, medicínska spoločnosť s.r.o.**

Sídlo/Miesto podnikania:

Donská 61, 841 06 Bratislava

IČO:

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2020253730

V: Bratislave

Dňa: 18.2.2026

.....  
Ing. Silvia Augustínová  
konateľ

Poznámka:

- povinné údaje vyplní uchádzač

**Príloha č. 6 SP**

Kalkulácia ceny a návrh na plnenie kritéria na vyhodnotenie ponúk

Názov predmetu zákazky:

**Chlopňové protézy a srdcové chlopne****KALKULÁCIA CENY A NÁVRH NA PLNENIE KRITÉRIA NA VYHODNOTENIE PONÚK****časť 4. - Biologické srdcové chlopne**

Por. č.	Názov položky	Mer. jed. (MJ)	Predpokladané množstvo MJ počas trvania zmluvy (36 mesiacov)	Jednotková cena za MJ v EUR				Celková cena za predpokladané množstvo MJ v EUR		
				bez DPH	sadzba DPH v %	suma DPH	s DPH	bez DPH	DPH v EUR	s DPH
1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.
1.	Biologické srdcové chlopne pre aortálne a mitrálne ústie	ks	200	3 267,00	5%	163,35	3 430,35	653 400,00	32 670,00	686 070,00
2.	Biologické srdcové chlopne pre aortálne ústie - <b>Variant A)</b>	ks	200	3 267,00	5%	163,35	3 430,35	653 400,00	32 670,00	686 070,00
	Biologické srdcové chlopne pre aortálne ústie - <b>Variant B)</b>	ks	200	3 267,00	5%	163,35	3 430,35	653 400,00	32 670,00	686 070,00
<b>SPOLU za časť č. 4 predmetu zákazky:</b>								<b>1 960 200,00</b>		<b>2 058 210,00</b>

Týmto potvrdzujem, že všetky uvedené informácie sú pravdivé.

Obchodné meno/Názov uchádzača:

**Operatíva, medicínska spoločnosť s.r.o.**

Sídlo/Miesto podnikania:

Donská 61, 841 06 Bratislava

IČO:

35757329

DIČ:

2020253730

V: Bratislava

Dňa: 18.2.2026

Ing. Silvia Augustinová  
konateľ

Poznámka:

 - povinné údaje vyplní uchádzač

Názov predmetu zákazky:

Chlopňové protézy a srdcové chlopne

Sortiment ponúkaného tovaru

časť 4. - Biologické srdcové chlopne

Položka č. 1 - Biologické srdcové chlopne pre aortálne a mitrálne ústie

Por. č.	Obchodný názov ponúkaného produktu	Výrobca ponúkaného produktu	Katalógové číslo	ŠUKL	Kategorizačný kód	Produkt zaradený v aktuálne platnom Zozname kategorizovaných SZM áno / nie	Merná jednotka (MJ)	Jednotková cena za MJ v EUR			Predpokladané množstvo MJ počas trvania zmluvy (36 mesiacov)
								bez DPH	sadzba DPH v %	s DPH	
1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.
1.	Epic Plus aortálna	Abbott	E200-21A	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	200
2.	Epic Plus aortálna	Abbott	E200-23A	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	
3.	Epic Plus aortálna	Abbott	E200-25A	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	
4.	Epic Plus aortálna	Abbott	E200-27A	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	
5.	Epic Plus aortálna	Abbott	E200-29A	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	
6.	Epic Plus mitrálna	Abbott	E200-25M	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	
7.	Epic Plus mitrálna	Abbott	E200-27M	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	
8.	Epic Plus mitrálna	Abbott	E200-29M	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	
9.	Epic Plus mitrálna	Abbott	E200-31M	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	
10.	Epic Plus mitrálna	Abbott	E200-33M	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	

Položka č. 2 - Biologické srdcové chlopne pre aortálne ústie - Variant A)

Por. č.	Obchodný názov ponúkaného produktu	Výrobca ponúkaného produktu	Katalógové číslo	ŠUKL	Kategorizačný kód	Produkt zaradený v aktuálne platnom Zozname kategorizovaných SZM áno / nie	Merná jednotka (MJ)	Jednotková cena za MJ v EUR			Predpokladané množstvo MJ počas trvania zmluvy (36 mesiacov)
								bez DPH	sadzba DPH v %	s DPH	
1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.
1.	Epic Plus Supra	Abbott	ESP200-19	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	200
2.	Epic Plus Supra	Abbott	ESP200-21	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	
3.	Epic Plus Supra	Abbott	ESP200-23	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	
4.	Epic Plus Supra	Abbott	ESP200-25	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	
5.	Epic Plus Supra	Abbott	ESP200-27	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	
6.	Epic Plus Supra	Abbott	ESP200-29	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	

**Položka č. 2 - Biologické srdcové chlopne pre aortálne ústie - Variant B)**

Por. č.	Obchodný názov ponúkaného produktu	Výrobca ponúkaného produktu	Katalógové číslo	SUKL	Kategorizačný kód	Produkt zaradený v aktuálne platnom Zozname kategorizovaných ŠZM áno / nie	Merná jednotka (MJ)	Jednotková cena za MJ v EUR			Predpokladané množstvo MJ počas trvania zmluvy (36 mesiacov)
								bez DPH	sadzba DPH v %	s DPH	
1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.
1.	Epic Max	Abbott	EMAX-19	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	200
2.	Epic Max	Abbott	EMAX-21	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	
3.	Epic Max	Abbott	EMAX-23	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	
4.	Epic Max	Abbott	EMAX-25	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	
5.	Epic Max	Abbott	EMAX-27	P 7361A	X05831	áno	ks	3 267,00	5%	3 430,35	

Týmto potvrdzujem, že všetky uvedené informácie sú pravdivé.

Obchodné meno/Názov uchádzača: **Operatíva, medicínska spoločnosť s.r.o.**  
 Sídlo/Miesto podnikania: Donská 61, 841 06 Bratislava  
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V: Bratislave  
 Dňa: 18.2.2026

Poznámka:  
 - povinné údaje vyplní uchádzač

.....  
 Ing. Silvia Augustinová  
 konateľ

**EU MDR Declaration of Conformity**

**Epic™ Plus Stented Tissue Valves, Epic™ Plus Heart Valve Sizer Set, Epic™ Plus Holder Handles (Aortic/Mitral)**

<b>Manufacturer's Name:</b>	Abbott Medical	
<b>Manufacturer's Single Registration Number (SRN):</b>	US-MF-000018613	
<b>Manufacturer's Address:</b>	<p><b>Abbott Medical</b> 177 County Road B East St. Paul, MN 55117 USA</p> <p><b>St. Jude Medical Brasil Ltda.</b> Rua Professor José Vieira de Mendonça, 1301 Bairro Engenho Nogueira Belo Horizonte Minas Gerais, BR 31.310-260</p>	
<b>Authorized Representative's Name, Address, and Single Registration Number (SRN):</b>	<p>Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium</p>	
<b>Product Trade Name(s):</b>	<p>Epic™ Plus Stented Tissue Valves Epic™ Plus Supra Stented Tissue Valve Epic™ Plus Heart Valve Sizer Set Epic™ Plus Holder Handle (Aortic) Epic™ Plus Holder Handle (Mitral)</p>	
<b>Model Number(s):</b>	<b>Device Name</b>	<b>Model Number</b>
	<b>Valves</b>	
	Epic™ Plus Stented Tissue Valves - Aortic	E200-21A
		E200-23A
		E200-25A
		E200-27A
		E200-29A
	Epic™ Plus Stented Tissue Valves - Mitral	E200-25M
		E200-27M
		E200-29M
		E200-31M
		E200-33M
	Epic™ Plus Supra Stented Tissue Valves	ESP200-19
		ESP200-21
		ESP200-23
		ESP200-25
		ESP200-27
	ESP200-29	
	<b>Accessories</b>	
	Epic™ Plus Heart Valve Sizer Set	E2000
	Epic™ Plus Holder Handle (Aortic)	E2000-HA
	Epic™ Plus Holder Handle (Mitral)	E2000-HM

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## EU MDR Declaration of Conformity

### Epic™ Plus Stented Tissue Valves, Epic™ Plus Heart Valve Sizer Set, Epic™ Plus Holder Handles (Aortic/Mitral)

<b>Intended Purpose:</b>	<b>Valves:</b>  The Epic™ Plus and Epic™ Plus Supra Valves are intended to replace native aortic or mitral heart valves or previously implanted mitral or aortic prosthetic valves.  <b>Sizer Set:</b>  The E2000 sizer sets are intended to aid in the selection of the appropriate Epic™ Plus Tissue Valve size.  <b>Holder Handles (Aortic / Mitral):</b>  The Holder Handle is intended to facilitate valve handling during the tissue heart valve implant procedure.
<b>Risk Classification and Rule:</b>	<b>Valve</b> Class III, Rule 8 per MDR, Annex VIII  <b>Sizer Set / Holder Handle</b> Class III, Rule 6 per MDR, Annex VII
<b>EMDN Code(s):</b>	Epic Plus Tissue Heart Valves - Aortic and Epic Plus Supra Tissue Heart Valves <b>P0703010101</b> Stented Aortic Biological Valves for Surgical Implant – Valve Tissue of Animal Origin:  Epic Plus Tissue Heart Valves - Mitral <b>P0703010102</b> Stented Mitral Biological Valves for Surgical Implant – Valve Tissue of Animal Origin:  Epic Plus Sizer Set <b>P07038001</b> – Heart Valve Implant Sizers:  Epic Plus Holder Handles (Aortic and Mitral) <b>P07038099</b> – Heart Valve Accessories – Other:
<b>GMDN Code(s):</b>	60242 (Aortic valve models) 60244 (Mitral valve models)

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**EU MDR Declaration of Conformity**

**Epic™ Plus Stented Tissue Valves, Epic™ Plus Heart Valve Sizer Set, Epic™ Plus Holder Handles (Aortic/Mitral)**

Basic UDI-DI:	Epic Plus Device	Basic UDI-DI	Basic UDI-DI Description
	Epic™ Plus Stented Tissue Valves - Aortic	5415067SHV1001PD	Surgical Heart Valve Products Tissue Heart Valves
	Epic™ Plus Stented Tissue Valves - Mitral	5415067SHV1001PD	
	Epic™ Plus Supra Stented Tissue Valves	5415067SHV1001PD	
	Epic™ Plus Heart Valve Sizer Set	5415067SHV9000R3	Surgical Heart Valve Products Epic Plus Sizers and Accessories
	Epic™ Plus Holder Handle (Aortic)	5415067SHV9006RF	
	Epic™ Plus Holder Handle (Mitral)	5415067SHV9006RF	

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**EU MDR Declaration of Conformity****Epic™ Plus Stented Tissue Valves, Epic™ Plus Heart Valve Sizer Set, Epic™ Plus Holder Handles (Aortic/Mitral)**

This declaration of conformity is issued under the sole responsibility of the manufacturer.

I, the undersigned, for and on behalf of Abbott Medical, hereby declare that the medical device(s) specified above conform(s) with the applicable *General Safety & Performance Requirements* listed in Annex I and all relevant provisions of Regulation (EU) 2017/745.

Directive 2006/42/EC on Machinery and Directive 89/686/EEC (and the superseding Regulation (EU) 2016/425) on Personal Protective Equipment do not apply.

**Common Specifications Utilized** No applicable common specifications.

**Notified Body:**

BSI Group The Netherlands B.V.  
NB #: 2797  
Say Building  
John M. Keynesplein 9  
1066 EP Amsterdam  
The Netherlands

**Conformity Assessment Procedure:**

Conformity assessment for Epic Plus Valves and Accessories are based on a quality management system and assessment of the technical documentation as per Annex IX.

**Supporting Certificate(s):**

- EU Quality Management System Certificate: MDR 750915
- Technical Documentation Assessment Certificate Number: MDR 773424

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**EU MDR Declaration of Conformity**

**Epic™ Plus Stented Tissue Valves, Epic™ Plus Heart Valve Sizer Set, Epic™ Plus Holder Handles (Aortic/Mitral)**

**This signature section is applicable to all declarations of conformity, including to other European Union legislation, if applicable:**

Prepared By:   
Josh Clarin, Assoc. Director Regulatory Affairs

Date: 23 Jan 2024

Authorized Signatory:   
Christopher Gallivan, DVP, Quality Structural Heart, Quality PRRC (Person Responsible for Regulatory Compliance)

Date: 24 Jan 2024

Place of Issue: St. Paul, Minnesota, USA

Issue Date: 24 Jan 2024

### EU MDR Declaration of Conformity

## Epic™ Plus Stented Tissue Valves, Epic™ Plus Heart Valve Sizer Set, Epic™ Plus Holder Handles (Aortic/Mitral)

### Declaration of Conformity Product List

Model No.	Product Trade Name	Basic UDI-DI
E200-21A	Epic™ Plus Stented Tissue Valves - Aortic	5415067SHV1001PD
E200-23A		
E200-25A		
E200-27A		
E200-29A		
E200-25M	Epic™ Plus Stented Tissue Valves - Mitral	5415067SHV1001PD
E200-27M		
E200-29M		
E200-31M		
E200-33M		
ESP200-19	Epic™ Plus Supra Stented Tissue Valves	5415067SHV1001PD
ESP200-21		
ESP200-23		
ESP200-25		
ESP200-25		
ESP200-27		
ESP200-29		
E2000	Epic™ Plus Heart Valve Sizer Set	5415067SHV9000R3
E2000-HA	Epic™ Plus Holder Handle (Aortic)	5415067SHV9006RF
E2000-HM	Epic™ Plus Holder Handle (Mitral)	5415067SHV9006RF

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# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 773424 R000

**Manufacturer:** Abbott Medical

**Address:**

177 County Road B East  
St. Paul  
Minnesota  
55117  
USA

**Single Registration Number:** US-MF-000018613

**EU Authorised Representative:** Abbott Medical

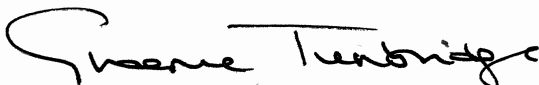
**Address:**

The Corporate Village  
Da Vincilaan 11 Box F1  
1935  
Zaventem  
Belgium

**Scope:** See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II and Regulation (EU) 722/2012, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-12-22**

Current Issue Date: **2023-12-22**

Starting Validity Date: **2023-12-22**

Expiry Date: **2028-12-21**

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# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 773424 R000

**Device Schedule:**

**Risk Classification:** Class III Implantable

**Type (per EU 2017/2185):** MDN 1101

**Basic UDI-DI:** 5415067SHV1001PD

Device Name	Valve Size (mm)	Epic Plus Aortic	Epic Plus Supra	Epic Plus Mitral	Intended Purpose (as per the IFU)
Epic™ Plus Stented Tissue Valves	19	N/A	ESP200-19	N/A	The Epic™ Plus Valve and Epic™ Plus Supra Valve are intended to replace native mitral or aortic heart valves or previously implanted mitral or aortic prosthetic valves.
	21	E200-21A	ESP200-21	N/A	
	23	E200-23A	ESP200-23	N/A	
	25	E200-25A	ESP200-25	E200-25M	
	27	E200-27A	ESP200-27	E200-27M	
	29	E200-29A	ESP200-29	E200-29M	
	31	N/A	N/A	E200-31M	
	33	N/A	N/A	E200-33M	

**Additional Information:** The Epic™ Plus Stented Tissue Valves are part of the Epic Plus™ Tissue Heart Valve System.

First Issue Date: **2023-12-22**

Current Issue Date: **2023-12-22**

Starting Validity Date: **2023-12-22**

Expiry Date: **2028-12-21**

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# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 773424 R000

**Risk Classification:** Class III

**Type (per EU 2017/2185):** MDN 1208

**Basic UDI-DI:** See table below.

Device Name	Model	Basic UDI-DI	Intended Purpose (as per the IFU)
Epic™ Plus Heart Valve Sizer Set	E2000	5415067SHV9000R3	The E2000 sizer sets are intended to aid in the selection of the appropriate Epic™ Plus Tissue Valve size.
Epic™ Plus Holder Handle (Aortic)	E2000-HA	5415067SHV9006RF	The Holder Handle is intended to facilitate valve handling during the tissue heart valve implant procedure.
Epic™ Plus Holder Handle (Mitral)	E2000-HM		

**Additional Information:** The Epic Plus™ Sizers and Accessories are part of the Epic Plus™ Tissue Heart Valve System.

First Issue Date: **2023-12-22**

Current Issue Date: **2023-12-22**

Starting Validity Date: **2023-12-22**

Expiry Date: **2028-12-21**

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# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 773424 R000

### Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
Current	3702357	Issued



First Issue Date: **2023-12-22**

Current Issue Date: **2023-12-22**

Starting Validity Date: **2023-12-22**

Expiry Date: **2028-12-21**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.

### EU MDR Declaration of Conformity

## Epic™ Max Stented Tissue Valves, Epic™ Max Heart Valve Sizer Set, Epic™ Max Holder Handle

<b>Manufacturer's Name:</b>	Abbott Medical	
<b>Manufacturer's Single Registration Number (SRN):</b>	US-MF-000018613	
<b>Manufacturer's Address:</b>	177 County Road B East St. Paul, MN 55117 USA	
<b>Authorized Representative's Name, Address, and Single Registration Number (SRN):</b>	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium  <b>SRN:</b> BE-AR-000008744	
<b>Product Trade Name(s):</b>	Epic™ Max Stented Tissue Valves Epic™ Max Heart Valve Sizer Set Epic™ Max Holder Handle	
<b>Model Number(s):</b>	<b>Model No.</b>	<b>Product Trade Name</b>
	EMAX-19	Epic™ Max Stented Tissue Valves
	EMAX-21	
	EMAX-23	
	EMAX-25	
	EMAX-27	
	EMAX-1000	Epic™ Max Heart Valve Sizer Set
	E2000-HA	Epic™ Max Holder Handle
<b>Intended Purpose:</b>	<p><b>Valve</b> The Epic Max valve is intended to replace native aortic heart valves or previously implanted aortic prosthetic valves.</p> <p><b>Sizer Set</b> The EMAX-1000 sizer sets are intended to aid in the selection of the appropriate Epic™ Max Tissue Valve size.</p> <p><b>Holder Handle</b> The Holder Handle is intended to facilitate valve handling during the tissue heart valve implant procedure.</p>	

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### EU MDR Declaration of Conformity

## Epic™ Max Stented Tissue Valves, Epic™ Max Heart Valve Sizer Set, Epic™ Max Holder Handle

<b>Risk Classification and Rule:</b>	<b>Valve</b> Class III, Rule 8 per MDR, Annex VIII  <b>Sizer Set / Holder Handle</b> Class III, Rule 6 per MDR, Annex VIII		
<b>EMDN Code(s):</b>	<b>Device</b>	<b>Code</b>	<b>Description</b>
	Epic Max Stented Tissue Valves	P070301010101	Tissue Heart Valve
	Epic Max Heart Valve Sizer Set	P07038001	Heart Valve Implant Sizers
	Epic Max Holder Handle	P07038099	Heart Valve Accessories – Other
<b>GMDN Code(s):</b>	<b>Device</b>	<b>Code</b>	<b>Description</b>
	Epic Max Stented Tissue Valves	60242	Aortic Heart Valve
<b>Basic UDI-DI:</b>	<b>Device</b>	<b>Basic UDI-DI</b>	
	Epic Max Stented Tissue Valves	5415067SHV1101PJ	
	Epic Max Heart Valve Sizer Set	5415067SHV9004RB	
	Epic Max Holder Handle	5415067SHV9006RF	

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**EU MDR Declaration of Conformity****Epic™ Max Stented Tissue Valves, Epic™ Max Heart Valve Sizer Set, Epic™ Max Holder Handle**

This declaration of conformity is issued under the sole responsibility of the manufacturer.

I, the undersigned, for and on behalf of Abbott Medical, hereby declare that the medical device(s) specified above conform(s) with the applicable *General Safety & Performance Requirements* listed in Annex I and all relevant provisions of Regulation (EU) 2017/745.

Directive 2006/42/EC on Machinery and Directive 89/686/EEC (and the superseding Regulation (EU) 2016/425) on Personal Protective Equipment do not apply.

**Common Specifications Utilized** No applicable common specifications.

**Notified Body:**

BSI Group The Netherlands B.V.  
NB #: 2797  
Say Building  
John M. Keynesplein 9  
1066 EP Amsterdam  
The Netherlands

**Conformity Assessment Procedure:**


Conformity assessment for Epic Max Valves and Accessories are based on a quality management system and assessment of the technical documentation as per Annex IX.


**Supporting Certificate(s):**

- EU Quality Management System Certificate: MDR 750915
- Technical Documentation Assessment Certificate Number: MDR 781775

**EU MDR Declaration of Conformity****Epic™ Max Stented Tissue Valves, Epic™ Max Heart Valve Sizer Set, Epic™ Max Holder Handle**

**This signature section is applicable to all declarations of conformity, including to other European Union legislation, if applicable:**

Prepared By:  Date: 23 Jan 2024  
Josh Clarin, Assoc. Director Regulatory Affairs

Authorized Signatory:  Date: 24-Jan-2024  
Christopher Gallivan, DVP, Quality Structural Heart, Quality PRRC (Person Responsible for Regulatory Compliance)

Place of Issue: St. Paul, Minnesota, USA Issue Date: 24-Jan-2024

**EU MDR Declaration of Conformity****Epic™ Max Stented Tissue Valves, Epic™ Max Heart Valve Sizer Set, Epic™ Max Holder Handle****Declaration of Conformity Product List**

<b>Model No.</b>	<b>Product Trade Name</b>	<b>Basic UDI-DI</b>
EMAX-19	Epic™ Max Stented Tissue Valves	5415067SHV1101PJ
EMAX-21		
EMAX-23		
EMAX-25		
EMAX-27		
EMAX-1000	Epic™ Max Heart Valve Sizer Set	5415067SHV9004RB
E2000-HA	Epic™ Max Holder Handle	5415067SHV9006RF

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# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 781775 R000

**Manufacturer:** Abbott Medical

**Address:**

177 County Road B East  
St. Paul  
Minnesota  
55117  
USA

**Single Registration Number:** US-MF-000018613

**EU Authorised Representative:** Abbott Medical

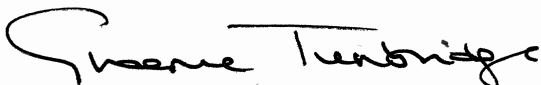
**Address:**

The Corporate Village  
Da Vincilaan 11 Box F1  
1935 Zaventem  
Belgium

**Scope:** See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II and Regulation (EU) 722/2012, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-12-22**

Current Issue Date: **2023-12-22**

Starting Validity Date: **2023-12-22**

Expiry Date: **2028-12-21**

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# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 781775 R000

### Device Schedule:

**Risk Classification:** Class III Implantable

**Type** (Codes as per (EU) 2017/2185): MDN 1101

**Basic UDI-DI:** 5415067SHV1101PJ

Device Name	Model	Valve Size (mm)	Intended purpose (as per the IFU)
Epic™ Max Stented Tissue Valves	EMAX-19	19	The Epic Max valve is intended to replace native aortic heart valves or previously implanted aortic prosthetic valves.
	EMAX-21	21	
	EMAX-23	23	
	EMAX-25	25	
	EMAX-27	27	

**Risk Classification:** Class III

**Type** (Codes as per (EU) 2017/2185): MDN 1208

**Basic UDI-DI:** see table below.

Device Name	Model	Basic UDI-DI	Intended purpose (as per the IFU)
Epic™ Max Heart Valve Sizer Set	EMAX-1000	5415067SHV9004 RB	The EMAX-1000 sizer sets are intended to aid in the selection of the appropriate Epic™ Max Tissue Valve size.
Epic™ Max Holder Handle	E2000-HA	5415067SHV9006 RF	The Holder Handle is intended to facilitate valve handling during the tissue heart valve implant procedure.

First Issue Date: **2023-12-22**

Current Issue Date: **2023-12-22**

Starting Validity Date: **2023-12-22**

Expiry Date: **2028-12-21**

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# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 781775 R000

### Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
Current	3804852	Issued



First Issue Date: **2023-12-22**

Current Issue Date: **2023-12-22**

Starting Validity Date: **2023-12-22**

Expiry Date: **2028-12-21**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 750915 R000

**Manufacturer:** Abbott Medical

**Address:**

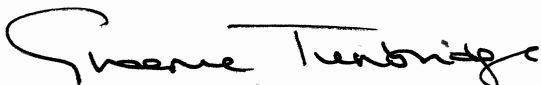
177 County Road B East  
St. Paul  
Minnesota  
55117  
USA

**Single Registration Number:** US-MF-000018613

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-04-21**

Current Issue Date: **2023-12-22**

Starting Validity Date: **2023-12-22**

Expiry Date: **2027-04-20**

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# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 750915 R000

**EU Authorised Representative:** Abbott Medical

**Address:**

The Corporate Village  
Da Vincilaan 11 Box F1  
1935 Zaventem  
Belgium

**EU Authorised Representative:** Abbott Vascular International BVBA

**Address:**

Park Lane, Culliganlaan 2B  
1831 Diegem  
Belgium



First Issue Date: **2022-04-21**

Current Issue Date: **2023-12-22**

Starting Validity Date: **2023-12-22**

Expiry Date: **2027-04-20**

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# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 750915 R000

### Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
Amplatzer™ Talisman™ PFO Occlusion System	See MDR 751010
Navitor™ Transcatheter Aortic Valve	See MDR 751017
Amplatzer™ Amulet™ Left Atrial Appendage Occluder	See MDR 751008
Portico™ Transcatheter Aortic Valve	See MDR 751019
MitraClip G4 System	See MDR 751009
Amplatzer™ Duct Occluder	See MDR 777151
Amplatzer™ Duct Occluder II	See MDR 777152
Amplatzer™ Piccolo™ Occluder	
Masters Series HP™ Valved Graft with Gelweave Valsalva™ technology (VAVGJ)	See MDR 772712
Masters Series™ Aortic Valved Graft with Hemashield™ Graft Technology (CAVGJ)	See MDR 772713
Tendyne Transcatheter Mitral Valve System	See MDR 772768
TriClip™ G4 System	See MDR 777146
Master Series™ Mechanical Heart Valves	See MDR 775965
Amplatzer™ Multifenestrated Septal Occluder – “Cribriform”	See MDR 777149
Amplatzer™ Septal Occluder	
Epic™ Max Stented Tissue Valves	See MDR 781775
Epic™ Plus Stented Tissue Valves	See MDR 773424
Class III	Intended purpose
FlexNav™ Delivery System	See MDR 751005
Amplatzer™ Amulet™ Delivery Sheath	See MDR 750953
Amplatzer™ Steerable Delivery Sheath	
Amplatzer™ Trevisio™ Intravascular Delivery System	
Amplatzer™ TorqVue™ Delivery System	
Amplatzer™ TorqVue™ Exchange System	
Amplatzer™ TorqVue™ 2 Delivery Sheath	
Amplatzer™ TorqVue™ LP Catheter and Delivery System	
Amplatzer™ Sizing Balloon II	See MDR 777443
Epic™ Max Heart Valve Sizer Set and Holder Handle	See MDR 781775
Epic™ Plus Heart Valve Sizer Set and Holder Handles	See MDR 773424
Class IIb, Implantable	Intended purpose
Amplatzer™ Vascular Plug, Amplatzer™ Vascular Plug II, Amplatzer™ Vascular Plug 4	See MDR 767903

First Issue Date: **2022-04-21**

Current Issue Date: **2023-12-22**

Starting Validity Date: **2023-12-22**

Expiry Date: **2027-04-20**

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# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 750915 R000

### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Transcatheter Aortic Heart Valve Loading System	Class Is
Tendyne Loading System	Class Is
Tendyne Stand Components	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	



First Issue Date: **2022-04-21**

Current Issue Date: **2023-12-22**

Starting Validity Date: **2023-12-22**

Expiry Date: **2027-04-20**

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# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 750915 R000

### Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-04-21	3447260	Issued
2022-08-16	3682747	Amended – Addition of subcontractors. Addition of service for subcontractor: Microbiology service. Removal of services for subcontractor: Labelling and packaging. Supplemented - Addition of Navitor™ Transcatheter Aortic Valve, FlexNav™ Delivery System, Amplatzer™ Amulet™ Left Atrial Appendage Occluder, and Transcatheter Heart Valve Loading System.
2022-09-29	3677048	Amended – Addition of subcontractor.
2022-11-11	3795938	Supplemented – Addition of Portico™ Transcatheter Aortic Valve. Amended – Administrative update to previous entries Reference Number 3682747 and Reference Number 3677048.
2022-11-29	3766365	Supplemented – Addition of MitraClip G4 System, Amplatzer™ Steerable Delivery Sheath, and Amplatzer™ Vascular Plug, Amplatzer™ Vascular Plug II, Amplatzer™ Vascular Plug 4. Amended – Addition of subcontractor.
2023-02-21	3854349	Supplemented – Addition of Amplatzer™ TorqVue™ Delivery System, Amplatzer™ TorqVue™ Exchange System, Amplatzer™ Trevisio™ Intravascular Delivery System
2023-03-20	3873040	Supplemented – Addition of Amplatzer™ TorqVue™ 2 Delivery Sheath.
2023-05-17	3894086	Supplemented – Addition of Amplatzer™ Amulet™ Delivery Sheath, Amplatzer™ Duct Occluder, Amplatzer™ Duct Occluder II, and Amplatzer™ Piccolo™ Occluder.
2023-06-14	3869869	Supplemented – Addition of Masters HP™ Valved Graft with Gelweave Valsalva™ technology (VAVGJ) and Masters Series™ Aortic Valved Graft with Hemashield™ Technology (CAVGJ).

First Issue Date: **2022-04-21**

Current Issue Date: **2023-12-22**

Starting Validity Date: **2023-12-22**

Expiry Date: **2027-04-20**

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# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 750915 R000

Date	Reference Number	Action
2023-08-25	30002038	Amended – Minor update to clarify the device name from “Transcatheter Heart Valve Loading System” to “Transcatheter Aortic Heart Valve Loading System”. Supplemented – Addition of TriClip™ G4 System, Tendyne Transcatheter Mitral Valve System, Master Series™ Mechanical Heart Valves, Tendyne Loading System and Tendyne Stand Components.
2023-11-15	30007555	Supplemented – Addition of Amplatzer™ Multifenestrated Septal Occluder – “Cribriform” and Amplatzer™ Sizing Balloon II to device schedule. Amended – Administrative correction of device names in device schedule for Masters Series HP™ Valved Graft with Gelweave Valsalva™ Technology (VAVGJ) and Masters Series™ Aortic Valved Graft with Hemashield™ Graft Technology (CAVGJ)
2023-12-07	30057065	Amended – Minor formatting update to consolidate devices with same MDR TDA certificate number into the same column of the device schedule. Supplemented – Addition of Amplatzer™ Septal Occluder and Amplatzer™ TorqVue™ LP Catheter and Delivery System.
Current	30072385	Supplemented – Addition of Epic™ Max Stented Tissue Valves, Epic™ Plus Stented Tissue Valves, Epic™ Max Heart Valve Sizer Set and Holder Handle, and Epic™ Plus Heart Valve Sizer Set and Holder Handles.

First Issue Date: **2022-04-21**

Current Issue Date: **2023-12-22**

Starting Validity Date: **2023-12-22**

Expiry Date: **2027-04-20**

...making excellence a habit.™

Skúšobnú verziu novej webovej stránky nájdete na [beta.sukl.sk \(https://beta.sukl.sk\)](https://beta.sukl.sk). Všetky aktuality, informácie a kompletný obsah sú zatiaľ prioritne dostupné na **pôvodnej verzii webu**.



(<https://www.sukl.sk/>)

# DETAIL ZDRAVOTNÍCKEJ POMÔCKY



## Chlopňa srdcová bioprotetická prasacia stentovaná EPIC Max / Plus / Plus Supra

<b>Kód:</b>	P 7361A
<b>Názov:</b>	Chlopňa srdcová bioprotetická prasacia stentovaná EPIC Max / Plus / Plus Supra
<b>Doplňok:</b>	s príslušenstvom, rôzne veľkosti
<b>Trieda ZP:</b>	III
<b>Výrobca skratka:</b>	ABT
<b>Výrobca:</b>	Abbott Medical 177 County Road B East 55117 St. Paul, MN Spojené štáty americké
<b>Splnomocnenec:</b>	Abbott Medical The Corporate Village, Da Vincilaan 11, Box F1 1935 Zaventem Belgicko



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Táto slovenská verzia stránky : [https://www.sukl.sk/hlavna-stranka/slovenska-verzia/pomocne-stranky/detail-zdravotnickej-pomocky?page\\_id=1377](https://www.sukl.sk/hlavna-stranka/slovenska-verzia/pomocne-stranky/detail-zdravotnickej-pomocky?page_id=1377)



EPIC™ PLUS  
STENTED TISSUE VALVES

# VALUE ANALYSIS INFORMATION KIT



Information contained herein for **DISTRIBUTION outside of the U.S. ONLY.**  
Always check the regulatory status of the device in your region.



Dear Healthcare Provider,

**ABBOTT STRUCTURAL HEART IS PLEASED TO ANNOUNCE THE APPROVAL OF THE EPIC™ PLUS STENTED TISSUE VALVES.**

The Epic™ Plus valve continues the product family's history of excellence. The Epic Plus mitral and aortic valves provide the same trusted durability and performance — plus significant enhancements to radiopacity and implantability to facilitate future interventions.

These enhancements further streamline mitral valve implantation, improve visibility under fluoroscopy with an easy-to-expand radiopaque band, while maintaining the triple composite porcine leaflet design and low stent post height to avoid left ventricular outflow tract (LVOT) and coronary obstruction.

These features continue to uphold the Epic legacy of proven performance across patient populations.

- The Epic Mitral displayed excellent durability in the Leipzig study, with 93.8% and 96.3% freedom from SVD at ten years for the mitral and aortic position, respectively<sup>1</sup>
- The Epic Mitral experience from Rennes shows excellent performance in younger patients, with 10-year freedom from SVD of 87.7% for the age ≤59 subgroup<sup>2</sup>
- The U.S Real-World experience with over 25,000 patients demonstrated outstanding durability
  - 91.4% and 94.6% freedom from valve reintervention at ten years for the mitral and aortic position respectively<sup>3,4</sup>
  - >95% freedom from valve reintervention three years post valve-in-valve for both mitral and aortic positions<sup>5</sup>

Attached you will find additional documentation and information about the Epic Plus valve. We are pleased to have the opportunity to partner with you to rebuild healthier hearts.

Sincerely,

References

1. Lehmann S. et al. Porcine xenograft for aortic, mitral, and double valve replacement: long-term results of 2544 consecutive patients. *Eur J Cardiothorac Surg.* 2016;49:1150-1156.
2. Anselmi A, Aymami M, Tomasi J et al. Durability of Mitral Valve Replacement with a 3rd Generation Bioprosthesis. *The Annals of Thoracic Surgery* (2021), doi:<https://doi.org/10.1016/j.athoracsur.2021.03.097>.
3. Rodriguez, E. et. al. (2022, January). Ten-year Outcomes of a Contemporary Generation Low-profile Porcine Mitral Bioprosthesis in a Medicare Population. Poster presented at the 2022 STS Annual Meeting, Virtual.
4. Wiechmann, RJ. et. al. Ten-year Outcomes of Surgical Aortic Valve Replacement with a Contemporary Supra Annular Porcine Valve in a Medicare Population. *JTCVS Open.* 2022, <https://doi.org/10.1016/j.xjon.2022.08.002>.
5. H. Kenith Fang, et al. Three-year Outcomes of Valve-in-valve intervention within the Epic™ Supra and Epic™ Mitral Valves in a Medicare Population. TVT Conference 2022; Chicago, USA; June 9, 2022.



**Abbott**

# EPIC™ PLUS MITRAL

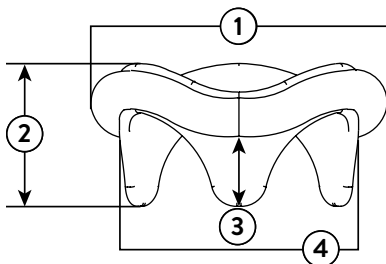
## STENTED TISSUE VALVE



### MODEL SPECIFICATIONS

Catalog Number	Tissue Annulus Diameter (mm)	Aortic/Ventricular Protrusion (mm)	Total Height (mm)	Cuff Outer Diameter (mm)	Stent Internal Diameter <sup>1</sup> (mm)
E200-25M	25	9	16	33	22.6
E200-27M	27	9	17	35	24.5
E200-29M	29	10	19	37	26.3
E200-31M	31	10	20	39	28.4
E200-33M	33	11	20	41	30.3

<sup>1</sup>Stent Internal Diameter does not account for the tissue/fabric covering the stent which may vary in thickness between approximately 1 to 2 mm.



- 1. Cuff outer diameter
- 2. Total height
- 3. Ventricular protrusion
- 4. Tissue annulus diameter

### PACKAGE LABELING



- Valve Position
- Valve Size
- Line Art
- Product Barcode
- Valve Expiration
- Valve Model

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# EPIC™ PLUS SUPRA & AORTIC

## STENTED TISSUE VALVES

### MODEL SPECIFICATIONS

#### AORTIC HEART VALVES, EPIC™ PLUS SUPRA

Catalog Number	Tissue Annulus Diameter (mm)	Aortic/Ventricular Protrusion (mm)	Total Height (mm)	Cuff Outer Diameter (mm)	Stent Internal Diameter <sup>1</sup> (mm)
ESP200-19	19	11	14	25	18.7
ESP200-21	21	11	15	28	20.8
ESP200-23	23	13	16	29	22.6
ESP200-25	25	13	17	31	24.5
ESP200-27	27	14	19	33	26.3
ESP200-29*	29	15	20	35	28.4

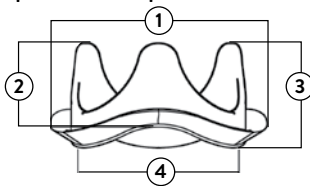
#### AORTIC HEART VALVES, EPIC™ PLUS

Catalog Number	Tissue Annulus Diameter (mm)	Aortic/Ventricular Protrusion (mm)	Total Height (mm)	Cuff Outer Diameter (mm)	Stent Internal Diameter <sup>1</sup> (mm)
E200-21A	21	9	14	25	18.7
E200-23A	23	9	15	27	20.8
E200-25A	25	10	16	29	22.6
E200-27A	27	11	17	31	24.5
E200-29A	29	12	19	33	26.3

<sup>1</sup>Stent Internal Diameter does not account for the tissue/fabric covering the stent which may vary in thickness between approximately 1 to 2 mm.

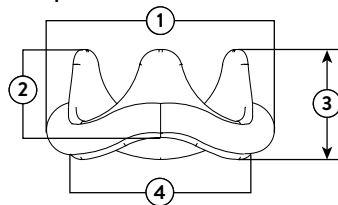
\*This size may not be available in your region.

#### Epic™ Plus Supra Aortic Valve



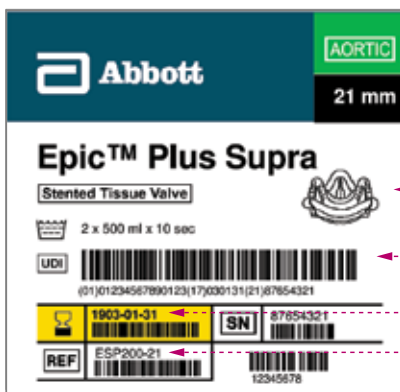
1. Cuff outer diameter
2. Aortic protrusion
3. Total height
4. Tissue annulus diameter

#### Epic™ Plus Aortic Valve



1. Cuff outer diameter
2. Aortic protrusion
3. Total height
4. Tissue annulus diameter

### PACKAGE LABELING



- ← AORTIC Valve Position
- ← 21 mm Valve Size
- ← Line Art
- ← Product Barcode
- ← Valve Expiration
- ← Valve Model

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Abbott Structural Heart  
3200 Lakeside Dr.  
Santa Clara, CA, 95054 USA  
T: +1 408 845 3200

To whom it may concern:

Re: Technical Information for Epic™ Plus / Epic™ Plus Supra Stented Tissue Valve



## MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the Epic™ Plus heart valves are MR Conditional. A patient with one of these devices can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0 Tesla (3.0T)
- Maximum spatial gradient field of 19T/m (1900 G/cm)
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 2°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends radially up to 0.6 cm from the device when imaged with a gradient echo pulse sequence in a 1.5T MR system.

## NICKEL

**The Epic™ Plus and Epic™ Plus Supra stented tissue valves contain nickel.** Each valve has a radiopaque marker that contains 316 stainless steel and thus contains nickel. This component is contained entirely within the valve and would be implanted.

Additionally, portions of the valve holder handles and sizers are made from metallic alloys containing nickel. These valve accessories may have temporary contact with patient tissue during the implantation procedure.

## LATEX FREE

The materials used in the manufacture of Epic™ Plus and Epic™ Plus Supra valves do not contain any latex.

If you have any questions, please contact Abbott Customer Service at 1-800-544-1664 (option 2) or email [SHCustomerService@abbott.com](mailto:SHCustomerService@abbott.com).



## EPIC™ PLUS STENTED TISSUE VALVES BARCODE PRODUCT CATALOG

Description	Brand Name	Product	Orderable Unit of Measure	Quantity	Barcode (GTIN)
Epic Plus Aortic, 21mm	Epic™	E200-21A	EA	1	 (01) 05415067033017
Epic Plus Aortic, 23mm	Epic™	E200-23A	EA	1	 (01) 05415067033024
Epic Plus Aortic, 25mm	Epic™	E200-25A	EA	1	 (01) 05415067033031
Epic Plus Mitral, 25mm	Epic™	E200-25M	EA	1	 (01) 05415067033048
Epic Plus Aortic, 27mm	Epic™	E200-27A	EA	1	 (01) 05415067033055
Epic Plus Mitral, 27mm	Epic™	E200-27M	EA	1	 (01) 05415067033062
Epic Plus Aortic, 29mm	Epic™	E200-29A	EA	1	 (01) 05415067033079
Epic Plus Mitral, 29mm	Epic™	E200-29M	EA	1	 (01) 05415067033086
Epic Plus Mitral, 31mm	Epic™	E200-31M	EA	1	 (01) 05415067033093
Epic Plus Mitral, 33mm	Epic™	E200-33M	EA	1	 (01) 05415067033109
Epic Plus Supra, 19mm	Epic™	ESP200-19	EA	1	 (01) 05415067033116
Epic Plus Supra, 21mm	Epic™	ESP200-21	EA	1	 (01) 05415067033123
Epic Plus Supra, 23mm	Epic™	ESP200-23	EA	1	 (01) 05415067033130
Epic Plus Supra, 25mm	Epic™	ESP200-25	EA	1	 (01) 05415067033147
Epic Plus Supra, 27mm	Epic™	ESP200-27	EA	1	 (01) 05415067033154
Epic Plus Supra, 29mm*	Epic™	ESP200-29	EA	1	 (01) 05415067033161

\*This size may not be available in your region.

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[www.structuralheart.abbott](http://www.structuralheart.abbott)

<sup>™</sup> Indicates a trademark of the Abbott group of companies.

<sup>‡</sup> Indicates a third-party trademark, which is property of its respective owner.

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Epic™ Max  
Aortic Stented Tissue Valve

OPTIMIZE OUTCOMES.  
**REDEFINE POSSIBILITIES.**



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# TODAY

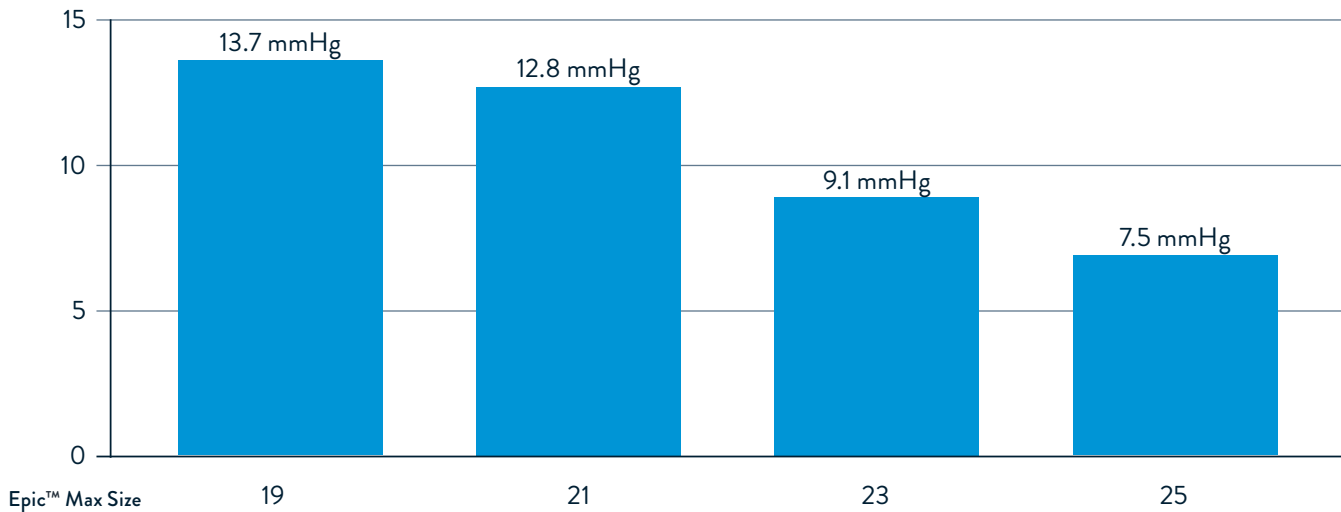
BENEFITS EXPERIENCED BY BOTH PATIENTS AND SURGEONS.

## UNPARALLELED HEMODYNAMICS\*

Maximizing the internal orifice provides large effective orifice areas (EOAs) and low gradients to reduce the burden on the heart and contribute to better patient outcomes.

### Estimated Epic™ Max Mean Pressure Gradients at 1 year (mmHg)<sup>1</sup>

Mean pressure gradient predicted based on matched stent ID for Biocor/Epic™ valves



## IMPLANT WITH EASE

The Epic™ Max design was engineered to allow maximum flexibility and easy passage through all anatomies.

The adaptive cuff is designed to prevent paravalvular leaks by sealing in all planes and minimizes parachuting resistance when delivering the valve onto the annulus.



\*Compared to previous Epic Platform iterations.

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# TOMORROW

BUILT ON THE EPIC™ PLATFORM THAT HAS STOOD THE TEST OF TIME.

## PROVEN LONG-TERM DURABILITY

The Epic™ platform has demonstrated proven outcomes across large patient populations and maximum durability by design.

## STABLE GRADIENTS

The Epic valve family has demonstrated stable gradients through all intermediate time points in its multi-center FDA Post Approval study data.<sup>4</sup> This leaflet behavior is advantaged because increasing gradients are a known indicator for Structural Valve Deterioration (SVD) in tissue heart valves.

## REDUCED STROKE RISK

- Porcine leaflets have less leaflet calcification at the time of reintervention.<sup>4</sup>
- At the time of reintervention, porcine valves have reduced intra-operative stroke and greater 30-day freedom from stroke compared to bovine pericardial valves.<sup>5</sup>

## 10-YEAR DURABILITY



**Epic™ Supra Valve**  
Freedom From All-Cause  
Reintervention<sup>2</sup>



**Epic™ Supra Valve**  
Freedom from SVD  
(Structural Valve Degeneration)  
All patient age<sup>3</sup>

# THE ROAD AHEAD

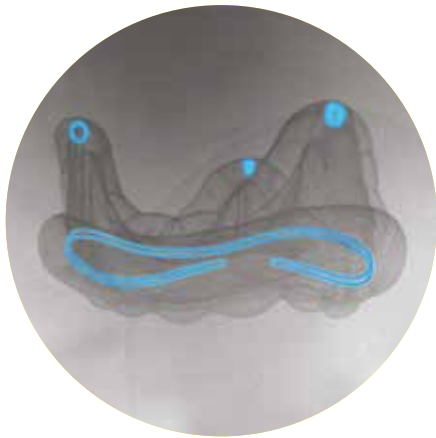
LAY THE FOUNDATION FOR THE NEXT INTERVENTION.

## DESIGNED TO REDEFINE POSSIBILITIES

A larger stent internal diameter expands future treatment options for patients by facilitating ViV\* procedures with a wide range of Transcatheter Aortic Valve Implantation prostheses.



For illustrative purposes only. TAVI frame used is not meant to depict any specific valve.



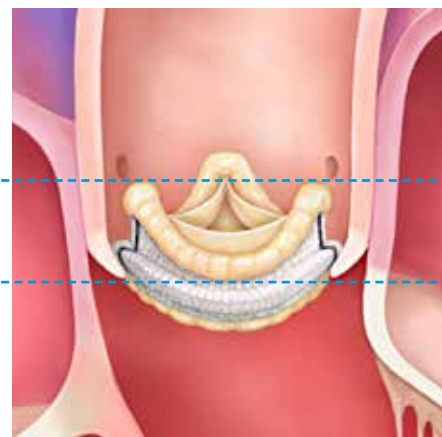
## FUTURE-READY VALVE-IN-VALUE\* FEATURES

The Epic™ Platform was engineered for future ViV:

- Non-curtaining leaflets
- Low profile
- Internally mounted leaflets
- Radiopacity at the stent posts and annulus
- Fractures at 8 atm of pressure<sup>7</sup>

## MITIGATE OBSTRUCTION RISK

Low aortic protrusion and non-curtaining Epic™ leaflets mitigate the risk of coronary obstruction and sinus jailing.



\*The safety and effectiveness of valve-in-valve procedures in an Epic™ Max valve has not been established.

# MAXIMIZE TODAY, TOMORROW AND **THE ROAD AHEAD.**

INTRODUCING THE EPIC™ MAX, OUR LATEST SOLUTION FOR OPTIMIZING KEY CLINICAL OUTCOMES AND THE POSSIBILITIES FOR PATIENT LIFETIME MANAGEMENT.

Epic™ Max is designed to redefine the future of aortic valve lifetime management by providing unparalleled hemodynamics\* while maintaining the Epic Platform's ease of implant, proven durability, and features designed for future intervention.



\*Compared to previous Epic Platform iterations.

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## REFERENCES

1. [a] Biocor IFU [b] Maitland, Andrew, Gregory M. Hirsch, and Edward A. Pascoe. "Hemodynamic Performance of the St. Jude Medical Epic™ Supra Aortic Stented Valve." *Journal of Heart Valve disease* 20.3 (2011): 327. [c] Epic Plus IFU
2. Wiechmann, RJ. et. al. Ten-year Outcomes of Surgical Aortic Valve Replacement with a Contemporary Supra Annular Porcine Valve in a Medicare Population. *JTCVS Open*. 2022, <https://doi.org/10.1016/j.xjon.2022.08.002>.
3. Jawad, Khalil, Sven Lehmann, Alex Koziarz, Maja Dieterlen, Stefan Feder, Martin Misfeld, Jens Garbade, Vivek Rao, and Michael Borger. "Midterm results after St Jude Medical Epic porcine xenograft for aortic, mitral, and double valve replacement." *Journal of Cardiac Surgery* 35, no. 8 (2020): 1769-1777.
4. Biocor IFU
5. Keshishi, Melanie, et al. "Comparison of Modes of Failure and Clinical Outcomes Between Explanted Porcine and Bovine Pericardial Bioprosthetic Valves." *Cardiovascular Pathology* (2023): 107516.
6. Bernard, J. et al. (2023, May). Mechanisms of Failure of a Mitral Valve Porcine Xenograft Prosthesis and Comparison of Outcomes According to Reintervention Approach. Poster presented at the AATS Mitral Conclave, New York.
7. Allen, KB., Adnan, CK., Cohen, DJ., et al. Bioprosthetic valve fracture to facilitate transcatheter valve-in-valve implantation. *Ann Thorac Surg*. 2017;104:1501-1508.

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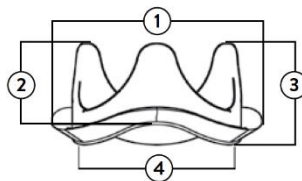
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# EPIC™ MAX VALVE

PRODUCT	CATALOG NUMBER	TISSUE ANNULUS DIAMETER (mm)	AORTIC PROTRUSION (mm)	TOTAL HEIGHT (mm)	CUFF OUTER DIAMETER (mm)	STENT INTERNAL DIAMETER <sup>1</sup> (mm)
Epic Max	EMAX-19	19	11	15	27.5	20.8
Epic Max	EMAX-21	21	13	16	29.0	22.6
Epic Max	EMAX-23	23	13	17	31.0	24.5
Epic Max	EMAX-25	25	14	19	33.0	26.3
Epic Max	EMAX-27	27	15	20	35.5	28.4
Epic Max Sizer Set	EMAX-1000					

Epic™ Max Valve



1. Cuff outer diameter
2. Aortic protrusion
3. Total height
4. Tissue annulus diameter

<sup>1</sup> Stent Internal Diameter does not account for the tissue/fabric covering the stent which may vary in thickness between approximately 1 to 2 mm.  
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# MINISTERSTVO ZDRAVOTNÍCTVA SLOVENSKEJ REPUBLIKY

Bratislava 15. 10. 2024

Číslo: S04798-2024-OKCHZPDP-14396

## ROZHODNUTIE

Ministerstvo zdravotníctva Slovenskej republiky (ďalej len "ministerstvo") ako príslušný orgán podľa § 50 zákona č. 363/2011 Z. z. o rozsahu a podmienkach úhrady liekov, zdravotníckych pomôcok a dietetických potravín na základe verejného zdravotného poistenia a o zmene a doplnení niektorých zákonov (ďalej len "zákon") rozhodlo v konaní s týmito účastníkmi konania

**Všeobecná zdravotná poisťovňa, a. s., Panónska cesta 2, 851 04 Bratislava,**  
**DÓVERA zdravotná poisťovňa, a. s., Einsteinova 25, 851 01 Bratislava,**  
**Union zdravotná poisťovňa, a. s., Karadžičova 10, 814 53 Bratislava,**  
**Abbott Medical, 177 County Road B East, St. Paul, MN-55117, USA**

t a k t o :

1. zdravotnícka pomôcka *Chlopňa srdcová bioprotetická prasacia stentovaná EPIC Max/Plus/Plus Supra; s príslušenstvom, rôzne veľkosti* sa podľa § 50 ods. 1 zákona zaraďuje do zoznamu kategorizovaných špeciálnych zdravotníckych materiálov s kódom X05831,
2. úradne určená cena zdravotníckej pomôcky sa určuje vo výške 2 970,00 eur,
3. maximálna cena zdravotníckej pomôcky, za ktorú môže byť dodávaná poskytovateľovi zdravotnej starostlivosti, sa určuje vo výške 3 593,70 eur,
4. na zdravotnícku pomôcku sa vzťahujú všetky charakteristiky právoplatne určené pre podskupinu zdravotníckych pomôcok, do ktorej táto zdravotnícka pomôcka patrí; charakteristikami podskupiny zdravotníckych pomôcok sú preskripčné obmedzenie, indikačné obmedzenie, množstvový limit, finančný limit a obmedzenie úhrady zdravotnej poisťovne na jej predchádzajúci súhlas.

Neoddeliteľnou súčasťou tohto rozhodnutia je príloha, v ktorej sú uvedené podrobnosti o zaradení zdravotníckej pomôcky v zozname kategorizovaných špeciálnych zdravotníckych materiálov.

## O d ô v o d n e n i e

Ministerstvu bola doručená žiadosť výrobcu zdravotníckej pomôcky Abbott Medical, 177 County Road B East, St. Paul, MN-55117, USA o zaradenie zdravotníckej pomôcky *Chlopňa srdcová bioprotetická prasacia stentovaná EPIC Max/Plus/Plus Supra; s príslušenstvom, rôzne veľkosti* do zoznamu kategorizovaných špeciálnych zdravotníckych materiálov a úradné určenie ceny zdravotníckej pomôcky (ďalej len "žiadosť").

Ministerstvo žiadosť spolu s prílohami odborne posúdilo a došlo k záveru, že zdravotnícka pomôcka spĺňa kritériá kategorizácie špeciálnych zdravotníckych materiálov podľa § 43 zákona.

Na základe hore uvedeného ministerstvo rozhodlo tak, ako je uvedené vo výroku tohto rozhodnutia.

Poučenie:

Proti tomuto rozhodnutiu možno podľa § 82 ods. 1 zákona podať námietky na Ministerstvo zdravotníctva Slovenskej republiky do siedmich dní od doručenia rozhodnutia. Rozhodnutie nie je preskúmateľné súdom, pokiaľ nebol vyčerpaný riadny opravný prostriedok.

Podľa § 82 ods. 4 a 5 zákona ten, kto podáva námietky, je povinný zložiť na účet ministerstva kauciu v sume 3 000 eur. Kaucia musí byť pripísaná na účet ministerstva najneskôr v nasledujúci pracovný deň po poslednom dni lehoty na podanie námietok, inak sa konanie o námietkach zastaví. Ministerstvo kauciu vráti, ak minister námietkam čo aj len čiastočne vyhovel.

Kamil Šaško  
minister zdravotníctva

*Toto rozhodnutie sa považuje za doručené všetkým účastníkom konania dňom nasledujúcim po dni jeho zverejnenia na webovom sídle ministerstva. Elektronický portál Kategorizácia (<http://kategorizacia.mzsr.sk>) je súčasťou webového sídla ministerstva.*

**Príloha k rozhodnutiu č. S04798-2024-OKCHZPDP-14396**

*Podrobnosti o zaradení zdravotníckej pomôcky v zozname kategorizovaných špeciálnych zdravotníckych materiálov*

**Podskupina špeciálnych zdravotníckych materiálov**

Názov	Doplňok názvu	Preskripčné obmedzenie	ÚZP2	Jednotka ÚZP2
<i>XB6.2 BIOLOGICKÁ CHLOPŇOVÁ PROTÉZA STENTOVÁ</i>	-	<i>KCH</i>	3 593,70 €	<i>ks</i>

**Zaradenie zdravotníckej pomôcky v zozname kategorizovaných špeciálnych zdravotníckych materiálov**

Kód MZ SR	Kód ŠÚKL	Názov	Doplňok názvu
<i>X05831</i>	<i>P7361A</i>	<i>Chlopňa srdcová bioprotetická prasacia stentovaná EPIC Max/Plus/Plus Supra</i>	<i>s príslušenstvom, rôzne veľkosti</i>

Výrobca	Štát	MJD	MCV	DPH	AKC	ÚZP	DOP	DOP %
<i>ABT</i>	<i>US</i>	<i>ks</i>	<i>2 970,00 €</i>	<i>10,00 %</i>	<i>3 593,70 €</i>	<i>3 593,70 €</i>	<i>0,0000 €</i>	<i>0,0000 %</i>

**Vysvetlivky:** **ÚZP2** – Maximálna výška úhrady zdravotnej poisťovne za zdravotnícku pomôcku zaradenú v tejto podskupine špeciálnych zdravotníckych materiálov, **Kód MZ SR** – Kód zdravotníckej pomôcky pridelený Ministerstvom zdravotníctva Slovenskej republiky, **Kód ŠÚKL** – Kód zdravotníckej pomôcky pridelený Štátnym ústavom pre kontrolu liečiv, **Výrobca** – Skratka výrobcu zdravotníckej pomôcky, **Štát** - Skratka štátu, v ktorom má sídlo výrobca zdravotníckej pomôcky, **MJD** - Merná jednotka (napr. kus, balenie, set, pár a pod.), **MCV** - Úradne určená cena zdravotníckej pomôcky (bez dane z pridanej hodnoty), **DPH** - Sadzba dane z pridanej hodnoty, **AKC** – Maximálna cena zdravotníckej pomôcky, za ktorú môže byť dodávaná poskytovateľovi zdravotnej starostlivosti (vrátane dane z pridanej hodnoty), **ÚZP** – Maximálna výška úhrady zdravotnej poisťovne za zdravotnícku pomôcku, **DOP** – Maximálna výška doplatku poistenca za zdravotnícku pomôcku, **DOP%** – Podiel maximálnej výšky doplatku poistenca za zdravotnícku pomôcku a maximálnej ceny zdravotníckej pomôcky, za ktorú môže byť dodávaná poskytovateľovi zdravotnej starostlivosti, vyjadrený v percentách, **Preskripčné obmedzenie** – Skratka špecializačného odboru. Ak je v slúpci „preskripčné obmedzenie“ uvedená skratka „ZP“, úhrada zdravotníckej pomôcky na základe verejného zdravotného poistenia je podmienená predchádzajúcim súhlasom zdravotnej poisťovne.