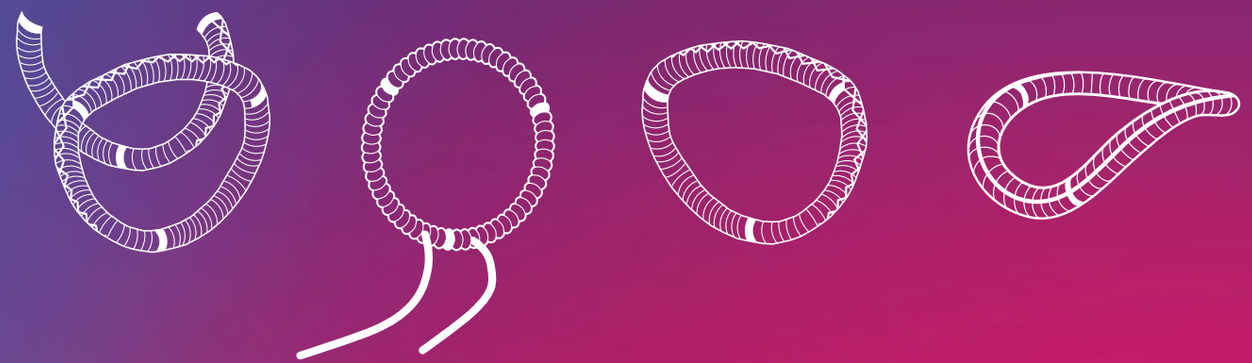
Abbott

MITRAL VALVE
REPAIR SOLUTIONS



A comprehensive portfolio of mitral valve repair products from a single source.

See Important Safety Information referenced within.

Abbott's customizable repair products are suitable for implant using open sternotomy and minimally invasive approaches such as robotic surgery.

Tailor Flexible Ring and Band

The Tailor Flexible Annuloplasty Ring and Band are designed to maintain the size of a repaired mitral or tricuspid annulus while sustaining physiologic movement.

- Customizable ring design can be tailored to address specific patient needs
- Pre-cut C band provides time savings simplicity

Attune™ Flexible Adjustable Ring

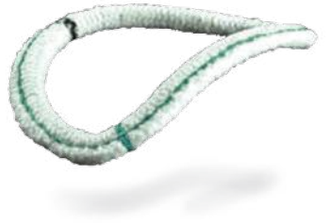
The symmetrical and asymmetrical adjustability of the Attune Ring allows the size and shape to be fine-tuned.

- The ability to make small adjustments to the ring after placement is designed to help eliminate residual mitral regurgitation
- Independent adjustability allows the annuloplasty to be localized to one side

Séguin Semi-Rigid Ring

The Séguin Semi-Rigid Ring provides surgeons a combination of rigidity and flexibility for mitral valve repair.

- Solid one-piece core resists needle penetration and reduces potential for suturing through the core
- More rigid anterior allows for annular remodeling
- One-step push button handle release simplifies the implantation process



Rigid Saddle Ring

A natural saddle-shaped ring designed for durable and complete remodeling.

- Titanium alloy core maintains anatomical shape and provides annular remodeling
- Saddle shape contributes to efficient distribution of leaflet stress and chordal tension[1-3]

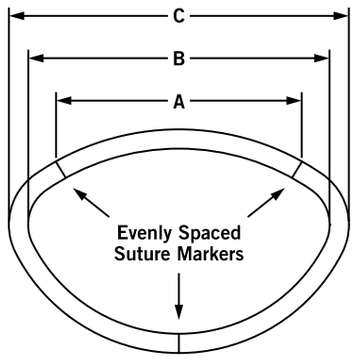
See Important Safety Information referenced within.

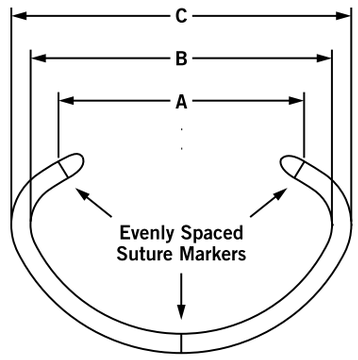
TAILOR FLEXIBLE RING AND BAND

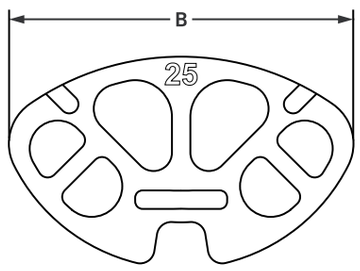
Ring Model Number	Band Model Number	Ring Size (mm)	Intertrigonal Dimension [A] (mm)	Inside Dimension [B] (mm)	Outside Dimension [C] (mm)
TARP-25	TAB-25	25	25	29	34
TARP-27	TAB-27	27	27	31	37
TARP-29	TAB-29	29	29	34	40
TARP-31	TAB-31	31	31	36	42
TARP-33	TAB-33	33	33	39	45
TARP-35	TAB-35	35	35	41	46

ACCESSORIES

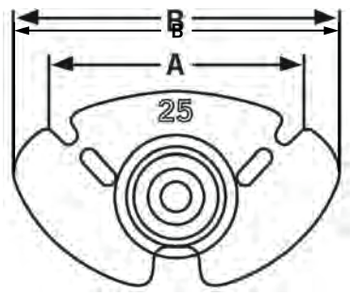
Model Number	Contents
TAR-505	Tailor Annuloplasty Ring Sizer Set One (1) malleable holder handle One (1) extension handle Six (6) sizers (25, 27, 29, 31, 33, 35) One (1) autoclavable tray for storage of components
TAR-510R	Tailor and Attune™ Ring Robotic Sizer Set Six low-profile robotic sizers in autoclavable tray
HH-05	Replacement Holder Handle
EX-05	Replacement Extension Handle







Robotic Sizer



Handled Sizer

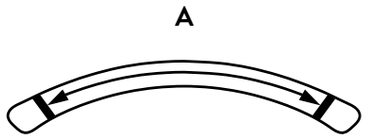
See Important Safety Information referenced within.

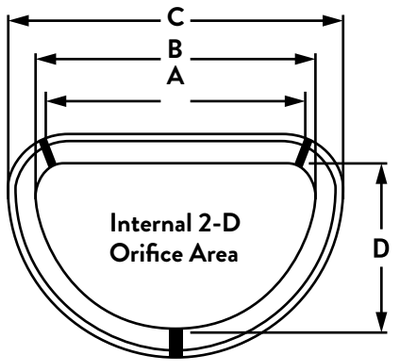
RIGID SADDLE RING

Ring Model Number	Ring Size [A] (mm)	Commissure Dimension [A] (mm)	Inside Dimension [B] (mm)	Outside Dimension [C] (mm)	A-P Dimension [D] (mm)	Internal 2-D Orifice Area (mm^2)
RSAR-24	24	24	22	30	21	227
RSAR-26	26	26	24	32	23	276
RSAR-28	28	28	26	34	24	331
RSAR-30	30	30	28	36	25	387
RSAR-32	32	32	30	38	27	450
RSAR-34	34	34	32	40	28	511

ACCESSORIES

Model/Reorder Number	Contents
RSAR-507A	RSAR Sizer Set Complete One (1) malleable holder handle One (1) extension handle Six (6) sizers (24, 26, 28, 30, 32, 34) One (1) autoclavable tray for storage of components One (1) autoclavable tray cover
HH-05	Replacement Holder Handle
EX-05	Replacement Extension Handle





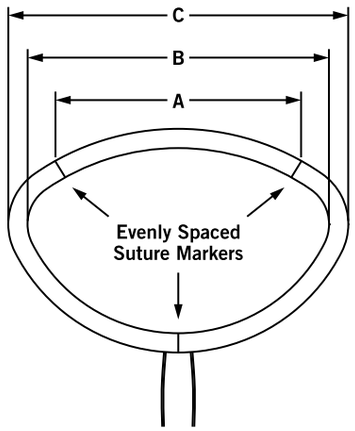
See Important Safety Information referenced within.

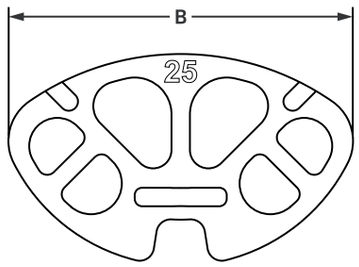
ATTUNE™ FLEXIBLE ADJUSTABLE RING

Model/Reorder Number	Ring Size	Fixed Dimension [A] (mm)	Ring Inner Dimension [B] (mm)	Ring Outer Dimension [C] (mm)
AFR-25	25	25	28	33
AFR-27	27	27	31	36
AFR-29	29	29	34	39
AFR-31	31	31	37	42
AFR-33	33	33	40	44
AFR-35	35	35	41	46
AFR-37	37	37	44	49
AFR-39	39	39	46	51
AFR-41	41	41	49	54
AFR-43	43	43	52	57

ACCESSORIES

Model/Reorder Number	Products	Contents
TAR-505	Tailor Annuloplasty Ring Sizer Set	6 handled sizers, 1 holder handle and 1 extension handle in autoclavable tray
TAR-510R	Tailor and Attune Ring Robotic Sizer Set	10 low-profile robotic sizers in autoclavable tray
HH-05	Replacement Holder Handle	Holder handle for TAR-505
EX-05	Replacement Extension Handle	Extension handle for TAR-505





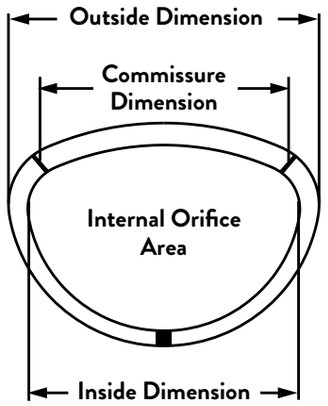
See Important Safety Information referenced within.

SÉGUIN SEMI-RIGID RING

Ring Model Number	Ring Size	Inside Dimension	Outside Dimension	Commissure Dimension	Internal Orifice Dimension
SARP-24	24 mm	22 mm	29 mm	24 mm	284 mm^2
SARP-26	26 mm	24 mm	31 mm	26 mm	334 mm^2
SARP-28	28 mm	27 mm	34 mm	28 mm	403 mm^2
SARP-30	30 mm	28 mm	35 mm	30 mm	463 mm^2
SARP-32	32 mm	30 mm	37 mm	32 mm	541 mm^2
SARP-34	34 mm	34 mm	41 mm	34 mm	602 mm^2
SARP-36	36 mm	35 mm	43 mm	36 mm	644 mm^2
SARP-38	38 mm	37 mm	45 mm	38 mm	735 mm^2
SARP-40	40 mm	39 mm	46 mm	40 mm	815 mm^2

ACCESSORIES

Model/Reorder Number	Contents
SAR-501	Séguin Annuloplasty Ring Sizer Set One (1) malleable holder handle One (1) extension handle Nine (9) mitral sizers (24, 26, 28, 30, 32, 34, 36, 38, 40) One (1) autoclavable tray for storage of components One (1) autoclavable tray cover
HH-05	Replacement Holder Handle
EX-05	Replacement Extension Handle



See Important Safety Information referenced within.

IMPORTANT SAFETY INFORMATION

SJM Tailor™ Ring

Rx ONLY

INDICATIONS

The [SJM Tailor™] ring/band is indicated for use in the repair of a mitral or tricuspid valve that is diseased or damaged due to acquired or congenital valvular disease. It is the responsibility of the surgeon to determine that the valve is repairable. The decision to undertake annuloplasty can be made only after visual analysis of the valve pathology. Only surgeons who have received appropriate training should perform valve repair using the ring/band.

CONTRAINDICATIONS

Use of the ring/band is contraindicated in cases where severe organic lesions with retracted chordae tendineae require valvular replacement, and where there are congenital malformations which lack valvular tissue. Additionally, use of the ring/band is contraindicated whenever the physician determines that the remaining functional valve tissue and valve support structures are not adequate to provide the required hemodynamic performance or structural strength.

Use of the ring/band is contraindicated for active bacterial endocarditis.

POTENTIAL ADVERSE EVENTS

As with prosthetic heart valves, serious complications may be associated with the use of this device, sometimes leading to death. Complications necessitating reoperation may occur at varying intervals and include: thrombus, hemolysis, left ventricular outflow tract obstruction, systolic anterior motion, damage to coronary arteries, stenosis, uncorrected or recurrent regurgitation, partial or complete dislodgment of the ring/band from its site of attachment, thromboembolism, A-V block, endocarditis, low cardiac output, and bleeding disorders relating to the use of anticoagulant therapy.

Attune™ Ring

INDICATIONS

The Attune™ Flexible Adjustable Annuloplasty Ring is indicated for use in the repair of a mitral or tricuspid valve that is diseased or damaged due to acquired or congenital valvular disease. It is the responsibility of the surgeon to determine that the valve is repairable and does not require replacement. The decision to undertake annuloplasty can be made only after visual analysis of the valve pathology. Only surgeons who have received appropriate training should perform valve repair using an Attune™ Ring.

CONTRAINDICATIONS

Use of the Attune™ Flexible Adjustable Annuloplasty Ring is contraindicated in cases where severe organic lesions with retracted chordae tendineae require valvular replacement, and where there are congenital malformations which lack valvular tissue. Additionally, use of the Attune™ Ring is contraindicated whenever the physician determines that the remaining functional valve tissue and valve support structures are not adequate to provide the required hemodynamic performance or structural strength.

Use of the Attune™ Ring is contraindicated for active bacterial endocarditis.

POTENTIAL ADVERSE EVENTS

As with prosthetic heart valves, serious complications may be associated with the use of this device, sometimes leading to death. Complications necessitating reoperation may occur at varying intervals and include: thrombus, hemolysis, left ventricular outflow tract obstruction, systolic anterior motion, damage to coronary arteries, stenosis, uncorrected or recurrent regurgitation, partial or complete dislodgment of the Attune™ Ring from its site of attachment, thromboembolism, A-V block, endocarditis, low cardiac output, and bleeding disorders relating to the use of anticoagulant therapy.

Séguin Ring

INDICATIONS

The SJM™ Séguin Annuloplasty Ring is indicated for use in the repair of mitral valves that are diseased or damaged due to acquired or congenital processes. It is the responsibility of the surgeon to determine that the valve is repairable and does not require replacement. The decision to undertake annuloplasty can be made only after visual analysis of the valve pathology. Only surgeons who have received appropriate training should perform valve repair using the SJM™ Séguin Annuloplasty Ring.

The SJM™ Séguin Annuloplasty Ring Sizer Set Model SAR-501 is indicated for use with the SJM™ Séguin Annuloplasty Ring.

CONTRAINDICATIONS

Use of the SJM™ Séguin Annuloplasty Ring is contraindicated in cases where severe organic lesions with retracted chordae tendineae require valvular replacement and where there are congenital malformations which lack valvular tissue. Additionally, use of the ring is contraindicated whenever the physician determines that the remaining functional valve tissue and valve support structures are not adequate to provide the required hemodynamic performance or structural strength.

Use of the SJM™ Séguin Annuloplasty Ring is contraindicated for active bacterial endocarditis.

Use of the SJM™ Séguin Annuloplasty Ring Sizer Set Model SAR-501 with products other than the SJM™ Séguin Annuloplasty Ring is contraindicated.

When sterilizing the SAR-501 sizer set, any sterilization method other than steam is contraindicated.

POTENTIAL ADVERSE EVENTS

As with prosthetic heart valves, serious complications may be associated with the use of this device, sometimes leading to death. Complications necessitating re-operation may occur at varying intervals and include: thrombus, hemolysis, ring fracture, left ventricular outflow tract obstruction, systolic anterior motion, damage to coronary arteries, stenosis, uncorrected or recurrent regurgitation, partial or complete dislodgment of the ring from its site of attachment, thromboembolism, A-V block, endocarditis, low cardiac output, and bleeding disorders relating to the use of anticoagulant therapy.

IMPORTANT SAFETY INFORMATION

SJM™ Rigid Saddle Ring

INDICATIONS FOR USE

The SJM™ Rigid Saddle Ring is indicated for use to correct annular dilation, increase leaflet coaptation, and prevent further dilation of the mitral valve annulus caused by disease states such as degenerative disease, rheumatic disease, ischemia, or vascular disease. The combination of prosthetic ring with valvuloplasty may be used in all acquired or congenital mitral insufficiencies with dilation and deformation of the fibrous mitral annulus.

For mitral insufficiencies with no subvalvular lesions and normal valvular movements, prosthetic ring implant alone may be sufficient. However, annuloplasty ring implant along with mitral valvuloplasty repair must be considered for insufficiencies with a prolapsed valve due to elongation or rupture of the chordae tendineae and for insufficiencies with limitation of valvular movements due to fusion of the commissures or chordae tendineae, or chordal hypertrophy.

CONTRAINDICATIONS

Use of the SJM™ Rigid Saddle Ring is contraindicated in cases where severe organic lesions with retracted chordae tendineae require valvular replacement and where there are congenital malformations which lack valvular tissue. Additionally, use of the ring is contraindicated whenever the physician determines that the remaining functional valve tissue and valve support structures are not adequate to provide the required hemodynamic performance or structural strength.

Use of the SJM Rigid Saddle Ring is contraindicated for active bacterial endocarditis.

POTENTIAL ADVERSE EVENTS

As with prosthetic heart valves, serious complications may be associated with the use of this device, sometimes leading to death. Complications necessitating reoperation may occur at varying intervals and include: thrombus hemolysis, ring fracture, left ventricular outflow tract obstruction, systolic anterior motion, damage to coronary arteries, stenosis, uncorrected or recurrent regurgitation, partial or complete dislodgment of the ring from its site of attachment, thromboembolism, A-V block, endocarditis, low cardiac output, and bleeding disorders relating to the use of anticoagulant therapy.

REFERENCES:

1. Jimenez JH, Soerensen DD, He Z, et al. Effects of a saddle shaped annulus on mitral valve function and chordal force distribution: an in vitro study. Ann Biomed Eng. 2003;31(10):1171-81.
2. Salgo IS, Gorman JH 3rd, Gorman RC, et al. Effect of annular shape on leaflet curvature in reducing mitral leaflet stress. Circulation. 2002;106(6):711-7
3. Jimenez JH, Liou SW, Padala M, et al. A saddle-shaped annulus reduces systolic strain on the central region of the mitral valve anterior leaflet. J Thorac Cardiovasc Surg. 2007;134(6):1562-8.

CAUTION: These products are intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

Abbott
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www.structuralheart.abbott

Abbott

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SJM® Rigid Saddle Ring

Rigid Annuloplasty Ring

Natural Saddle-shaped Design Allows Durable, Full Remodeling.

The unique shape of the Rigid Saddle Ring is designed to mimic a healthy mitral annulus. Multiple studies show that the saddle shape contributes to the efficient distribution of stresses and tension over the leaflets and chordae tendineae.[1–3] This redistribution of stress may increase repair durability.[2,3,5]

SHAPE MIMICS A HEALTHY ANNULUS

- Three-dimensional design restores the natural saddle shape.[1–4]
- Annular-height-to-commissural-width ratio of 15 percent mimics a healthy mitral annulus.[2]
- Complete titanium alloy core maintains anatomical shape and provides annular remodeling.

CLINICAL BENEFITS

- Saddle shape contributes to efficient distribution of leaflet stress and chordal tension.[1–3]
- Redistribution of leaflet stress and chordal tension through saddle-shape remodeling may increase repair durability.[2,3,5]
- Polyester double-velour EZ Suture™ Cuff may encourage tissue in-growth.[6,7]

PROPRIETARY FEATURES EASE IMPLANTATION

- EZ Suture Cuff is supported by a unique triangular core for a larger suture target.
- Clear, well-marked holder is designed to increase visibility during implant.
- Secure ergonomic handle quickly attaches and detaches to save time during implant.

St. Jude Medical™

More control. Less risk.

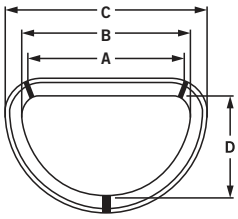
Ordering Information

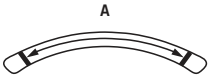
Rigid Saddle Ring

Model Number	Ring Size (mm)	Commissure Dimension (A) (mm)	Inside Dimension (B) (mm)	Outside Dimension (C) (mm)	A-P Dimension (D) (mm)	Internal 2-D Orifice Area (mm^2)
RSAR-24	24	24	22	30	13.6	227
RSAR-26	26	26	24	32	15.1	276
RSAR-28	28	28	26	34	16.2	331
RSAR-30	30	30	28	36	17.9	387
RSAR-32	32	32	30	38	19.2	450
RSAR-34	34	34	32	40	20.6	511

Accessories

Model Number	Contents
RSAR-507A	RSAR Sizer Set Complete
	One (1) malleable holder handle
	One (1) extension handle
	Six (6) sizers (24, 26, 28, 30, 32, 34)
	One (1) autoclavable tray for storage of components
	One (1) autoclavable tray cover
HH-05	Replacement Holder Handle
EX-05	Replacement Extension Handle





Specifications

Rigid Saddle Ring Specifications

Fabric: Polyester Double Velour
Core: Titanium

Sizer Specifications

Handle: Polyphenylsulfone
Shaft: Nitinol
Head: Polysulfone

1. Jimenez JH, Soerensen DD, He Z, et al. Effects of a saddle shaped annulus on mitral valve function and chordal force distribution: an in vitro study. *Ann Biomed Eng*. 2003;31(10):1171-81.
2. Salgo IS, Gorman JH 3rd, Gorman RC, et al. Effect of annular shape on leaflet curvature in reducing mitral leaflet stress. *Circulation*. 2002;106(6):711-7.
3. Jimenez JH, Liou SW, Padala M, et al. A saddle-shaped annulus reduces systolic strain on the central region of the mitral valve anterior leaflet. *J Thorac Cardiovasc Surg*. 2007;134(6):1562-8.
4. Flachskampf FA, Chandra S, Gaddipatti A, et al. Analysis of shape and motion of the mitral annulus in subjects with and without cardiomyopathy by echocardiographic 3-dimensional reconstruction. *J Am Soc Echocardiogr*. 2000;13(4):277-87.
5. Gorman JH 3rd, Jackson BM, Enomoto Y, et al. The effect of regional ischemia on mitral valve annular saddle shape. *Ann Thorac Surg*. 2004;77(2):544-8.
6. Haverich A, Maatz W, Stegmann T, et al. Experimental and clinical experiences with double-velour woven Dacron prostheses. *Thorac Cardiovasc Surg*. 1986;34(1):52-3.
7. Sato O, Tada Y, Takagi A. The biologic fate of Dacron double velour vascular prostheses. *Jpn J Surg*. 1989;19(3):301-11.

ATRIAL FIBRILLATION CARDIAC RHYTHM MANAGEMENT CARDIOVASCULAR NEUROMODULATION

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SJMprofessional.com

ST. JUDE MEDICAL™
MORE CONTROL. LESS RISK.

Caution: Federal Law restricts this device to sale by or on the order of a physician or properly licensed practitioner. Please see the physician's manual for a full description of indications, contraindications, side effects, precautions, warnings, and instructions for use.

Rx Only
Brief Summary: Please review the Instructions for Use prior to using this device for a complete listing of indications, contraindications, precautions, potential adverse events, and directions for use.

Item 100016611

CE 0086

SJM Declaration of Conformity
Mechanical Heart Valves and Valved Grafts

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC as amended by 2007/47/EC. Valved Graft products containing bovine material conform to Regulation 722/2012. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address:	St. Jude Medical 177 County Road B East St. Paul, Minnesota 55117 USA
European Representative:	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Mechanical Heart Valves Valved Grafts Annuloplasty Rings
Product Name(s):	SJM Masters Series (Rotatable) SJM Regent Valve (Rotatable) SJM™ Masters Series Aortic Valved Graft with Hemashield™ graft technology SJM Masters HP™ Valved Graft with Gelweave Valsalva™ Technology Rigid Saddle Ring St. Jude Medical Seguin Annuloplasty Ring Tailor Annuloplasty Ring Tailor Annuloplasty Band
Model Number(s):	*See attached.*
Classification:	Mechanical Heart Valves: Class III per MDD, Annex IX, rule 8 Valved Grafts: Class III per MDD, Annex IX, rule 17 Annuloplasty Rings: Class III per MDD, Annex IV, rule 8
GMDN Code(s):	Mechanical Heart Valves: • Aortic – 60240 • Mitral - 60241 Valved Grafts: • Aortic - 60423 Annuloplasty Rings: • Mitral - 45577 • Mitral/Tricuspid - 45578

SJM Declaration of Conformity
Mechanical Heart Valves and Valved Grafts

Original CE Mark Date:	*See attached.*
FQA Certificate No and expiration date:	Certificate No: CE 578287 Expiration Date: 26 May 2024
Annex II DE Certificate No and expiration date:	*See attached.*
Applicable Quality System Standards:	ISO 13485: 2016
Notified Body:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands
Notified Body Number:	2797
Manufacturing Facilities:	St. Jude Medical 177 County Road B East St. Paul, Minnesota 55117 USA St. Jude Medical Puerto Rico LLC Lot 20-B Street Caguas West Industrial Park Caguas, Puerto Rico 00725

Signature:

Digitally signed by Angie Riascos
Date: 2020.05.20 08:56:59 -05'00'

Angie Riascos
Manager, Regulatory Affairs

20 May, 2020
Issue Date

Mechanical Valve Products

SJM Masters Series (Rotatable)
EC Certificate No.: CE 578290
Expiration Date: 17 February 2024

Aortic Hemodynamic Plus (HP), size 15mm AHPJ-505
Original CE Mark Date: 21 Aug 2019

Mitral Hemodynamic Plus (HP), size 15mm MHPJ-505
Original CE Mark Date: 21 Aug 2019

Aortic Hemodynamic Plus (HP), sizes 17-27mm AHPJ-505
Original CE Mark Date: 13 Sep 1995

Aortic Standard Cuff-Polyester, sizes 19-31mm AJ-501
Mitral Standard Cuff-Polyester, sizes 19-33mm MJ-501
Aortic Expanded Cuff-Polyester, sizes 19-31mm AECJ-502
Mitral Expanded Cuff-Polyester, sizes 19-33mm MECJ-502
Mitral Hemodynamic Plus (HP), sizes 17-27mm MHPJ-505
Aortic Expanded Hemodynamic Plus (HP), sizes 17-27mm AEHPJ-505
Original CE Mark Date: 30 Jan 1996

Mitral Standard Cuff-Polyester, sizes 35-37mm MJ-501
Original CE Mark Date: 02 Nov 1998

Aortic Standard PTFE cuff, sizes 19-31mm ATJ-503
Mitral Standard PTFE cuff, sizes 19-33mm MTJ-503
Mitral Expanded PTFE cuff, sizes 19-33mm.....METJ-504
Original CE Mark Date: 31 Jul 1997

SJM Regent Valve (Rotatable)
EC Certificate No.: CE 578290
Expiration Date: 17 February 2024

Aortic standard cuff - polyester, sizes 17 - 29mm AGN-751
Aortic flex cuff - polyester, sizes 17-29mm AGFN-756
Original CE Mark Date: 27 Dec 1999

Valve Repair Products

Rigid Saddle Ring

EC Certificate No.: CE 578289
Expiration Date: 30 March 2024

Rigid Saddle Ring, sizes 24 – 34mm .....RSAR-(size)
Original CE Mark Date: 24 Feb 2005

St. Jude Medical Seguin Annuloplasty Ring

EC Certificate No.: CE 578288
Expiration Date: 14 May 2024

St. Jude Medical Seguin Annuloplasty Ring, sizes 24-40mm .....SARP-(size)
Original CE Mark Date: 28 Jan 2002

Tailor Annuloplasty Ring

EC Certificate No.: CE 578289
Expiration Date: 30 March 2024

Tailor Annuloplasty Ring, sizes 25-35mm.....TARP-(size)
Original CE Mark Date: 28 Jan 2002

Tailor Annuloplasty Band
EC Certificate No.: CE 578289
Expiration Date: 30 March 2024

Tailor Annuloplasty Band, sizes 25-35mm.....TAB-(size)
Original CE Mark Date: 24 Oct 2002

Valved Grafts[1]

SJM™ Masters Series Aortic Valved Graft with Hemashield™ graft technology

EC Certificate No.: CE 578292
Expiration Date: 26 May 2024

SJM™ Masters Series Aortic Valved Graft with Hemashield™ graft technology
Sizes 19 – 33mm.....CAVGJ-514 00
Original CE Mark Date: 04 May 2001

SJM Masters HP™ Valved Graft with Gelweave Valsalva™ Technology
EC Certificate No. : CE 578291
Expiration Date: 26 May 2024

SJM Masters HP™ Valved Graft with Gelweave Valsalva™ Technology
Sizes 19 – 29mm.....VAVGJ-515
Original CE Mark Date: 19 Aug 2005

[1] These products containing bovine material conform to Regulation 722/2012

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 578287**

Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

In respect of:

Design and manufacture of Mechanical and Tissue Heart Valves, Transcatheter Heart Valves, Valved Grafts, Annuloplasty Rings and Related Accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2012-01-30** Date: **2019-12-11** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 578287

Issued To:

St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Number	Device Name	Intended Purpose per IFU
Class III		
---	• Masters Series Mechanical Heart Valve – Mechanical Heart Valves • Masters Series Mechanical Heart Valve with Expanded Polyester Sewing Cuff – Mechanical Heart Valves • Masters Series Mechanical Heart Valve with PTFE Sewing Cuff – Mechanical Heart Valves • Masters Series Mechanical Heart Valve with Expanded PTFE Sewing Cuff – Mechanical Heart Valves • Masters Series Mechanical Heart Valve with Hemodynamic Plus (HP) Sewing Cuff – Mechanical Heart Valves • Masters Series Mechanical Heart Valve with Expanded Hemodynamic Plus (HP) Sewing Cuff – Mechanical Heart Valves • Regent Heart Valve – Mechanical Heart Valves • Regent Heart Valve with FlexCuff – Mechanical Heart Valves	See CE 578290

First Issued: **2012-01-30** Date: **2019-12-11** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 578287

Issued To:

St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Number	Device Name	Intended Purpose per IFU
Class III		
---	Masters HP Valved Graft with Gelweave Valsalva Technology (VAVGJ) – Valved Grafts	See CE 578291
---	Masters Valved Graft with Hemashield Graft Technology (CAVGJ) – Valved Grafts	See CE 578292
---	Tailor Annuloplasty Ring and Tailor Annuloplasty Band – Annuloplasty Rings Rigid Saddle Ring Annuloplasty Ring – Annuloplasty Rings	See CE 578289
---	Seguin Annuloplasty Ring – Annuloplasty Rings	See CE 578288
---	Portico Transcatheter Aortic Heart Valve System – Transcatheter Heart Valves	See CE 585003
---	Trifecta and Trifecta GT – Tissue Heart Valves	See CE 617862
---	Biocor, Epic and Epic Supra – Tissue Heart Valves	See CE 617865

First Issued: **2012-01-30** Date: **2019-12-11** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 578287

Issued To:

St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA

Number	Device Name	Intended Purpose per IFU
Class IIa		
MD0106, MDS7006	Mechanical Heart Valve Leaflet Tester – Related Accessories	---
MD0106	• Masters Series Mechanical Heart Valve Replacement Holder/Rotators – Related Accessories • Masters Series Hemodynamic Plus (HP) Mechanical Heart Valve Replacement Holder/Rotators – Related Accessories • Regent Mechanical Heart Valve Replacement Holder/Rotators – Related Accessories • Rigid Saddle Ring Annuloplasty Sizer Set – Related Accessories • Tailor Annuloplasty Ring Sizer Set– Related Accessories • Tailor Ring Robotic Sizer Set – Related Accessories • Seguin Annuloplasty Ring Sizer Set – Related Accessories • Mechanical Heart Valve Sizer – Related Accessories • Regent Mechanical Heart Valve Sizer Set– Related Accessories • Trifecta Valve Series Sizer Set – Related Accessories • Bioprosthetic Heart Valve Sizer Set – Related Accessories	---

First Issued: **2012-01-30** Date: **2019-12-11** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Abbott Medical 5050 Nathan Lane North Plymouth Minnesota 55442 USA	**Manufacture**
Abbyland PorkPak Inc. 539 North Meridian Street Curtiss Wisconsin 54422 USA	**Animal Tissues / Derivatives**
Agrodanieli Indústria e Comércio Ltda Rodivia 463, KM 14,5 Disrito Industrial Vila Langaro Rio Grande do Sul Brasil	**Animal Tissues / Derivatives**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Agropecuária Bolson Ltda. (Bolson) Rua Vereador Waldomiro Franco de Souza, S/N - Zona Suburbana Toledo Paraná Brasil	**Animal Tissues / Derivatives**
Bierig Brothers Inc. 3539 Reilly Ct. Vineland New Jersey 08360 USA	**Animal Tissues / Derivatives**
BRF - Brasil Foods S.A. Rua Senador Atilio Fontana, 86, Concordia/SC Brasil	**Animal Tissues / Derivatives**

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Frigoestrela S.A. Estrada Vicinal Romão Lopes Martins, S/N - KM 0+700M, Jardim Marabá, Tupã/SP Brasil	**Animal Tissues / Derivatives**
Frigorifico Miolar Ltda Estrada para Fazenda Mazurana S/N, Dois Vizinhos/PR Brasil	**Animal Tissues / Derivatives**
Frimesa Cooperativa Central Rua Bahia, 159, Medianeira/PR Brasil	**Animal Tissues / Derivatives**
Hereaus Medical Components, LLC 5030 Centerville Road St. Paul Minnesota 55127 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
InterVascular SAS Z.I. Athélia 1 13705 La Ciotat Cedex France	**Manufacture**
Irmãos do Valle (IDV) Rodovia BR 116, KM 116 Caixa Postal 04 - Bairro: Campo Alto - Santa Cecilia Santa Catarina Brasil	**Animal Tissues / Derivatives**
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 USA	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
JBS Aves Ltda Rua João Andriollo, 1167, Ana Rech Caxias do Sul/RS Brasil	**Animal Tissues / Derivatives**
JBS S.A. Parque Industrial S/N Distrito Industrial, LINS/SP Brasil	**Animal Tissues / Derivatives**
JBS S.A. Rodovia, GO 164, Km 167 S/N, Zona Rural, Mozarlândia/GO Brasil	**Animal Tissues / Derivatives**
JBS S.A. Rua Principal S/N, Vila Miisa, Ituiutaba/MG Brasil	**Animal Tissues / Derivatives**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
JBS S.A. Facility I Av. Duque de Caxias 7255 Vila Nova Campo Grande/MS Brasil	**Animal Tissues / Derivatives**
Mac Frios Rod. Antônio de Paiva Cantelmo, PR 566- KM 02, Zona Rural, Francisco Beltrão/PR Brasil	**Animal Tissues / Derivatives**
Marcho Farms Inc. 519 Allentown Road Franconia Pennsylvania 18924 USA	**Animal Tissues / Derivatives**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Midwest Sterilization Corporation 1204 Lenco Avenue Jackson Missouri 63755 USA	**ETO Sterilization**
Oakey Abattoir Lot 1, Oakey Connection Road, Oakey QLD 4401 Australia	**Animal Tissues / Derivatives**
P&N Packaging Inc. 11627 Route 187 Wyalusing Pennsylvania 18853 USA	**Animal Tissues / Derivatives**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Phillips-Medisize, LLC 705 Wisconsin Drive New Richmond Wisconsin 54017 USA	**Manufacture**
POCO Graphite, Inc. an Entegris Company 300 Old Greenwood Road Decatur Texas 76234 USA	**Crucial Supplier**
Quality Central de Esterilização Estrada Celso Charur, i23 Aracoiaba de Serra Sao Paulo 18190-000 Brasil	**ETO Sterilization**

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Rio Branco Alimentos S.A. (Pif Paf) BR 365 Km 455, Patrocínio/MG Brasil	**Animal Tissues / Derivatives**
Seara Alimentos Ltda Rua Tranquilo Damo, 209 -Santo Antonio, Frederico Westphalen/RS Brasil	**Animal Tissues / Derivatives**
Sioux-Preme Packing Company 4241 U.S. 75 Ave Sioux Center Iowa 1250 USA	**Animal Tissues / Derivatives**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
St. Jude Medical 14901 DeVeau Place Minnetonka Minnesota 55345-2126 USA	**Manufacture**
St. Jude Medical 177 County Road B East St. Paul Minnesota 55117 USA	**Final Inspection** **Labelling** **Manufacture** **Moist Heat Sterilization** **Packaging**
St. Jude Medical Brasil Ltda. Rua Professor Jose Vierra de Mendonca 1301 Bairro Engenho Nogueira Pampulha, Belo Horizonte Minas Gerais 31.310-026 Brasil	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem Belgium	**EU Representative** **Labelling** **Packaging**
St. Jude Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2 Zona Franca Coyol El Coyol, Alajuela Costa Rica	**Manufacture**
St. Jude Medical PR LLC Caguas West Industrial Park Lot 20 Caguas 00725 Puerto Rico	**Final Inspection** **Manufacture** **Moist Heat Sterilization**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
St. Jude Medical Puerto Rico LLC Lot A Interior - #2 Rd Km. 67.5 Santana Industrial Park Arecibo Puerto Rico 00612 USA	**ETO Sterilization**
Sterigenics Costa Rica S.R.L. Zona Franca Propark Calle Principal, Edificio 10, El Coyol Alajuela 20101 Costa Rica	**ETO Sterilization**
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 5725 West Harold Gatty Drive Salt Lake City Utah 84116 USA	**ETO Sterilization**
Steris Isomedix Puerto Rico LLC State Road 690 KM 1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico USA	**Gamma Irradiation**
Teys Australia Southern, Tamworth Phoenix street Tamworth, NSW 2340 Australia	**Animal Tissues / Derivatives**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 578287**
Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

Subcontractor:	**Service(s) supplied**
Vascutek Limited Newmains Avenue Inchinnan PA4 9RR United Kingdom	**Animal Tissues / Derivatives Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 578287**

Date: **2019-12-11**

Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

Date	Reference Number	Action
30 January 2012	7727627	First issue of mirror certificate to CE 544668.
8 June 2012	7816634	Addition of significant subcontractor for sterilization to St Jude Medical Puerto Rico LLC for VAVGJ devices.
16 November 2012	7910273	Transcatheter valves added to the scope. Addition of St Jude Medical (Minnetonka), St Jude Medical (Maple Grove), Marcho Farms and Abbyland PorkPak to the list of subcontractors.
13 December 2012	7930677	Update to subcontractor address St Jude Medical PR LLC.
16 January 2013	7943381	St Jude Medical (Costa Rica) added to the list of subcontractors.
18 April 2013	7984806	St Jude Medical (Maple Grove) removed from the list of subcontractors.
10 November 2013	8071312	Addition of significant subcontractor InterVascular SAS (Maquet) La Ciotat France facility as a fabric supplier for SJM Mechanical Heart Valves, Valved Grafts and Annuloplasty Rings.
19 November 2014	8245105	Certificate renewal.
01 December 2014	8194269	Tissue valves and pericardial patches added to the scope (transferred from another Notified Body). St Jude Medical Brasil, Phillips Plastics and bovine porcine abattoirs added to the list of subcontractors.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 578287**

Date: **2019-12-11**

Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

Date	Reference Number	Action
16 March 2015	8297445	Addition of Packaging & Labelling to activities of St. Jude Medical Coordination Center BVBA.
08 July 2015	8288225	Addition of the US abattoir Greater Omaha Packaging Company as a Bovine Tissue Source for Trifecta™ Heart Valve. Removal of subcontractors STERIS Spartanburg and Maquet Cardiovascular.
03 August 2015	8351515	Addition of Brazilian abbatoirs Frigorifico K-Celet Alimentos, Primaz Frigorifico Ltda, and SBR Suinos Brazil Ltda as porcine cusps suppliers for the manufacture of the Biocor, Epic and Epic Supra Heart Valves.
07 December 2015	8433259	Addition of Sterigenics US, LLC, Willowbrook, IL as a significant subcontractor for ETO sterilization.
01 August 2016	8520657	JBS S.A. Facility I added as a bovine pericardium supplier.
23 January 2017	8632751	Removal of subcontractor W&G Marketing.
30 March 2017	8576083	Addition of Agropecuária Bolson Ltda., Irmãos do Valle and W&G Marketing Company as animal tissue suppliers.
4 September 2017	8693815	Addition of subcontractor Quality Central de Esterilização, Brasil as an alternate sterilizer for Biocor Pericardial Patch.
26 October 2017	8694458	Addition of Poco Graphite as crucial supplier and Sterigenics Costa Rica as EO sterilizer. Removal of Steris Minneapolis.
02 May 2018	8917138	Addition of Bierig Brothers Inc. and P&N Packaging Inc. as bovine pericardium suppliers for the Portico valve.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 578287**
Date: **2019-12-11**
Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

Date	Reference Number	Action
07 March 2019	7780704	Traceable to NB 0086.
07 May 2019	9752176	Addition of Sterigenics US, LLC, Salt Lake City, Utah USA as a significant subcontractor for ETO Sterilization.
03 December 2019	9688437	Addition of Isomedix Operations Inc. (Steris), Minneapolis USA as a significant subcontractor for ETO sterilization, following inadvertent deletion.
Current	9775758	Certificate Renewal. Removal of Pericardial Patches from the scope. Addition of product table. Removal of discontinued animal tissue suppliers: Greater Omaha Packaging Company, Frigorifico Argus Ltda, Frigorifico K-Celet Alimentos, Primaz Frigorifico Ltda and W&G Marketing Company. Addition of Abbott Medical Plymouth Site as a subcontractor for Manufacture. Addition of Midwest Sterilization Corporation as a subcontractor for ETO sterilization. Change subcontractor name 'SBR Suinos Brazil Ltda' to 'Agrodanieli Indústria e Comércio Ltda'. Additional minor alignments of subcontractor name and addresses with ISO certificates.

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

St. Jude Medical PR, LLC
Caguas West Industrial Park
B Street, Lot 20
Caguas
00725
Puerto Rico

Holds Certificate No: **FM 578534**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Manufacturing and distribution of Annuloplasty Ring and Mechanical Heart Valves and manufacturing of Vascular Closure Device.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2011-10-17
Effective Date: 2019-02-18
Latest Revision Date: 2019-02-18
Expiry Date: 2022-02-17

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CERTIFICATE

This is to certify that

SANTE INTERNATIONAL S.A.

Str. Mantuleasa nr. 33, Sector 2
023961 Bucuresti
Romania

has implemented and maintains a **Quality Management System**.

Scope:
Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	497269 QM15
Valid from	2021-06-16
Valid until	2024-06-15
Date of certification	2021-06-16

DQS GmbH

Markus Bleher
Managing Director

Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Administrative Office: DQS Romania, Str. Bratului nr. 11, 020565 Bucharest - Romania

Annex to certificate
Registration No. 497269 QM15

SANTE INTERNATIONAL S.A.

Str. Mantuleasa nr. 33, Sector 2
023961 Bucuresti
Romania

Location	Scope
075906 **Sante International SA** **Sos. Mihai Bravu nr. 7, bl. P37-P37A, sector 2** **021303 Bucuresti** **Romania**	Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices. Consulting for state and private medical units.
497270 **Sante International SA** **Str. Pupitrului, nr. 81, sect. 3** **033036 Bucuresti** **Romania**	Storage of medical and laboratory equipment, disinfectants, laboratory reagents,cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.
31050285 **Sante International SA** **Calea Ghirodei, nr. 36** **300327 Timisoara** **Romania**	Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.
31050284 **Sante International SA** **Calea Dorobantilor, nr. 111** **400609 Cluj-Napoca** **Romania**	Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.
31050283 **Sante International SA** **Str. Lascar Catargi, nr. 37** **700107 Iasi** **Romania**	Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

This annex (edition:2021-06-16) is only valid in connection with the above-mentioned certificate.