

# 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.<sup>1-3</sup> This redistribution of stress may increase repair durability.<sup>2,3,5</sup>

### SHAPE MIMICS A HEALTHY ANNULUS

- Three-dimensional design restores the natural saddle shape.<sup>1-4</sup>
- Annular-height-to-commissural-width ratio of 15 percent mimics a healthy mitral annulus.<sup>2</sup>
- 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.<sup>1-3</sup>
- Redistribution of leaflet stress and chordal tension through saddle-shape remodeling may increase repair durability.<sup>2,3,5</sup>
- Polyester double-velour EZ Suture™ Cuff may encourage tissue in-growth.<sup>6,7</sup>

### 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.

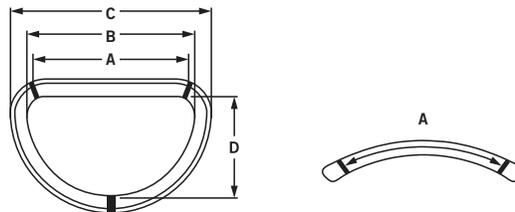
# Ordering Information

## 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 <sup>2</sup> )
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

- 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.
- Salgo IS, Gorman JH 3<sup>rd</sup>, Gorman RC, et al. Effect of annular shape on leaflet curvature in reducing mitral leaflet stress. *Circulation.* 2002;106(6):711-7.
- 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.
- Flachskampf FA, Chandra S, Gaddipati 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.
- Gorman JH 3<sup>rd</sup>, 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.
- 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.
- 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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3-1-30, Minami-Aoyama  
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+81 3 3423 6450  
+81 3 3402 5586 Fax

**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.

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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).

<b>Manufacturer Address:</b>	St. Jude Medical 177 County Road B East St. Paul, Minnesota 55117 USA
<b>European Representative:</b>	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
<b>Product Type:</b>	Mechanical Heart Valves Valved Grafts Annuloplasty Rings
<b>Product Name(s):</b>	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
<b>Model Number(s):</b>	<i>See attached.</i>
<b>Classification:</b>	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
<b>GMDN Code(s):</b>	Mechanical Heart Valves: <ul style="list-style-type: none"><li>• Aortic – 60240</li><li>• Mitral - 60241</li></ul> Valved Grafts: <ul style="list-style-type: none"><li>• Aortic - 60423</li></ul> Annuloplasty Rings: <ul style="list-style-type: none"><li>• Mitral - 45577</li><li>• Mitral/Tricuspid - 45578</li></ul>

## 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 Sequin Annuloplasty Ring

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

St. Jude Medical Sequin 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<sup>1</sup>**

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*

<sup>1</sup> 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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Page 1 of 4

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

# 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
<b>Class III</b>		
---	<ul style="list-style-type: none"> <li>• Masters Series Mechanical Heart Valve – Mechanical Heart Valves</li> <li>• Masters Series Mechanical Heart Valve with Expanded Polyester Sewing Cuff – Mechanical Heart Valves</li> <li>• Masters Series Mechanical Heart Valve with PTFE Sewing Cuff – Mechanical Heart Valves</li> <li>• Masters Series Mechanical Heart Valve with Expanded PTFE Sewing Cuff – Mechanical Heart Valves</li> <li>• Masters Series Mechanical Heart Valve with Hemodynamic Plus (HP) Sewing Cuff – Mechanical Heart Valves</li> <li>• Masters Series Mechanical Heart Valve with Expanded Hemodynamic Plus (HP) Sewing Cuff – Mechanical Heart Valves</li> <li>• Regent Heart Valve – Mechanical Heart Valves</li> <li>• Regent Heart Valve with FlexCuff – Mechanical Heart Valves</li> </ul>	See CE 578290

First Issued: **2012-01-30**

Date: **2019-12-11**

Expiry Date: **2024-05-26**

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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## 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
<b>Class III</b>		
---	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**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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Number	Device Name	Intended Purpose per IFU
<b>Class IIa</b>		
MD0106, MDS7006	Mechanical Heart Valve Leaflet Tester – Related Accessories	---
MD0106	<ul style="list-style-type: none"> <li>• Masters Series Mechanical Heart Valve Replacement Holder/Rotators – Related Accessories</li> <li>• Masters Series Hemodynamic Plus (HP) Mechanical Heart Valve Replacement Holder/Rotators – Related Accessories</li> <li>• Regent Mechanical Heart Valve Replacement Holder/Rotators – Related Accessories</li> <li>• Rigid Saddle Ring Annuloplasty Sizer Set – Related Accessories</li> <li>• Tailor Annuloplasty Ring Sizer Set– Related Accessories</li> <li>• Tailor Ring Robotic Sizer Set – Related Accessories</li> <li>• Seguin Annuloplasty Ring Sizer Set – Related Accessories</li> <li>• Mechanical Heart Valve Sizer – Related Accessories</li> <li>• Regent Mechanical Heart Valve Sizer Set– Related Accessories</li> <li>• Trifecta Valve Series Sizer Set – Related Accessories</li> <li>• Bioprosthetic Heart Valve Sizer Set – Related Accessories</li> </ul>	---

First Issued: **2012-01-30**

Date: **2019-12-11**

Expiry Date: **2024-05-26**

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BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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

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**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

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

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**55117**  
**USA**

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

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

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**177 County Road B East**  
**St Paul**  
**Minnesota**  
**55117**  
**USA**

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

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177 County Road B East  
St Paul  
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**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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USA**

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

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**Minnesota**  
**55117**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Phillips-Medisize, LLC 705 Wisconsin Drive New Richmond Wisconsin 54017 USA	<b>Manufacture</b>
POCO Graphite, Inc. an Entegris Company 300 Old Greenwood Road Decatur Texas 76234 USA	<b>Crucial Supplier</b>
Quality Central de Esterilização Estrada Celso Charur, 123 Aracoiaba de Serra Sao Paulo 18190-000 Brasil	<b>ETO Sterilization</b>

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**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**

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

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# EC Certificate - Full Quality Assurance System

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**St Paul**  
**Minnesota**  
**55117**  
**USA**

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

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**Minnesota**  
**55117**  
**USA**

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

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# EC Certificate - Full Quality Assurance System

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

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**St Paul**  
**Minnesota**  
**55117**  
**USA**

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

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# EC Certificate - Full Quality Assurance System

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

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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.

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Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 578287**  
 Date: **2019-12-11**  
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 177 County Road B East  
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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 abattoirs 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.

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 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.

# 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

Latest Revision Date: 2019-02-18

Effective Date: 2019-02-18

Expiry Date: 2022-02-17

Page: 1 of 1



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# CERTIFICATE



This is to certify that



**SANTE**  
INTERNATIONAL S.A.

## 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.

