

# ABBOTT MECHANICAL HEART VALVES

Regent, Masters HP and Masters

AORTIC VALVE

MITRAL VALVE



## IMPLANT CONFIDENTLY.

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Check the regulatory status of the device in areas where CE marking is not the regulation in force.  
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**CONFIDENTLY  
IMPLANT  
THE MOST  
TRUSTED  
MECHANICAL  
VALVES  
IN THE WORLD**

**3 MILLION PATIENTS  
TREATED WITH ABBOTT  
MECHANICAL HEART VALVES**

**MORE THAN 1,000  
PEER-REVIEWED  
PUBLICATIONS PROVIDE  
EVIDENCE FOR ABBOTT  
MECHANICAL HEART VALVES**

**LOW THROMBOGENICITY AND  
EXCELLENT PATIENT OUTCOMES**

## **PROVEN DESIGN TO RESTORE NATIVE VALVE HEMODYNAMICS**

**AN ABBOTT HALLMARK**

**Featured in all Abbott Mechanical Heart Valves the unique Pivot Guard Design offers benefits both during implant and post-implant.**



Shields pivot mechanism from pannus ingrowth



Minimizes interaction with sub-annular native valve apparatus in the mitral position and ensure coronary ostia clearance in the aortic position



Enables for an 85° leaflet opening angle, minimizing leaflet flutter and leading to smoother laminar flow through the orifice\*



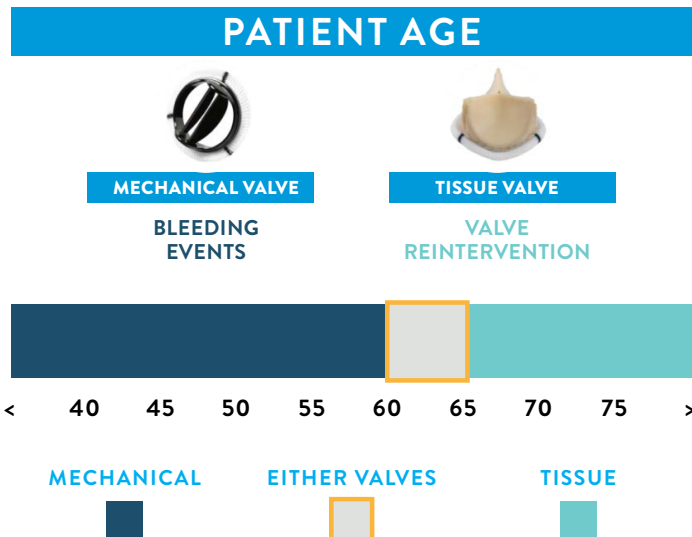
Can lessen thrombus formation by minimizing carbon surface area and thanks to the washout flow through the hinges\*

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**FIND OUT MORE  
ON ABBOTT  
MHV DESIGN**



# 2017 ESC/EACTS GUIDELINES<sup>1</sup>



## Target INR for mechanical prostheses

Prosthesis thrombogenicity	Patient-related factors <sup>a</sup>	
	None	≥1 risk factor
Low <sup>b</sup>	2.5	3.0
Medium <sup>c</sup>	3.0	3.5
High <sup>d</sup>	3.5	4.0

INR = international normalized ratio; LVEF = left ventricular ejection fraction.

<sup>a</sup> Mitral or tricuspid valve replacement; previous thromboembolism; atrial fibrillation; mitral stenosis of any degree; LVEF <35%.

<sup>b</sup> Carbomedics, Medtronic Hall, ATS, Medtronic Open-Pivot, St Jude Medical, OnX, Sorin Bicarbon.

<sup>c</sup> Other bileaflet valves with insufficient data.

<sup>d</sup> Lillehei-Kaster, Omniscience, Starr-Edwards (ball-cage), Björk-Shiley and other tilting-disc valves.

## OPERATE WITH THE FACTS

ABBOTT MECHANICAL HEART VALVES SHOW LOWER THROMBOEMBOLISM, THROMBOSIS AND BLEEDING EVEN AT A LOW INR RANGE

INR 1.5 ————— 2.0 ————— 2.5

### LOWERING-IT<sup>2</sup> (target INR 1.5–2.5)

Randomized Study	197 patients implanted* (44 with Abbott valves, 153 with LivaNova valves), 5 years
Thromboembolism	0.09%/pt-year
Thrombosis	0%/pt-year
Bleeding Events	0.56%/pt-year



### ESCAT III<sup>3</sup> (target INR 1.6–2.1)

Randomized Study	1137 patients** (all Abbott valves), 2 years
Thromboembolism	0%/pt-year, 0.58%/pt-year***
Bleeding Events	0.58%/pt-year, 1.07%/pt-year†



### PROACT<sup>4</sup> (target INR 1.5–2.0)

Randomized Study	375 patients (all On-X Valves), 3 years
Thromboembolism	2.67%/pt-year
Bleeding Events	2.67%/pt-year



\*44/197 patients in the Lowering-IT study were implanted with Abbott Valves. \*\*This was further stratified into a control group, a very low INR (monitored 1x weekly), and a very low INR (monitored 2x weekly) group. \*\*\*Thromboembolic events for VL1 and VL2 groups are listed together, respectively. †Bleeding events for VL1 and VL2 groups are listed together, respectively.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use provided inside the product carton (when available), at [eifu.abbottvascular.com](http://eifu.abbottvascular.com) or at [medical.abbott/manuals](http://medical.abbott/manuals) for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. Information contained herein for Europe, Middle East and Africa ONLY. Check the regulatory status of the device in areas where CE marking is not the regulation in force. Tests performed by and data on file at Abbott unless otherwise noted. Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

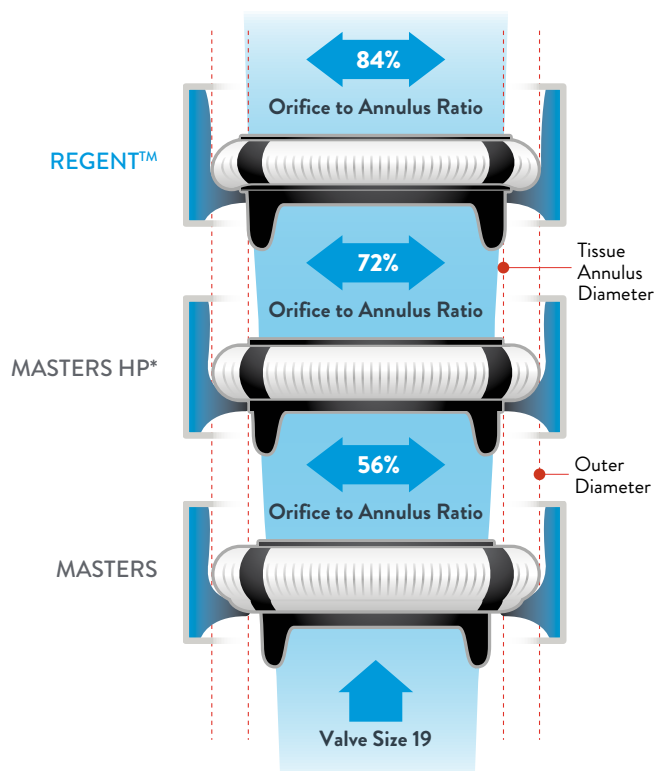
Abbott Vascular International BVBA  
Park Lane, Culliganlaan 2B, B-1831 Diegem, Belgium, Tel: +32 2 714 14 11 [www.Cardiovascular.Abbott](http://www.Cardiovascular.Abbott)  
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**FIND OUT MORE  
ON LOW INR  
CLINICAL EVIDENCE**



# A BROAD RANGE OF SOLUTIONS TO TAILOR THE IMPLANTATION TO EVERY PATIENT

## AORTIC VALVE



**Regent**  
EXCEPTIONAL HEMODYNAMICS  
IN THE AORTIC POSITION IN SMALL  
AORTIC ROOT PATIENTS

**Masters HP**  
HEMODYNAMICS MEETS  
IMPLANTABILITY IN BOTH THE  
AORTIC AND MITRAL POSITION,  
NOW AVAILABLE ALSO FOR BABIES  
AND NEWBORNS

**Masters**  
OPTIMAL IMPLANTABILITY IN BOTH  
THE AORTIC AND MITRAL POSITION

FIND OUT HOW TO MINIMIZE AV BLOCK  
WHEN IMPLANTING  
A MECHANICAL HEART VALVE



## TREATING THE TINIEST PATIENTS INCLUDING NEWBORNS AND BABIES IS NOW POSSIBLE...

with the world's smallest  
mechanical heart valves



15mm MASTERS HP  
MITRAL AND AORTIC VALVE

WATCH  
SADIE'S STORY





# VALVE ORDERING GUIDE

## STANDARD CUFF

Compact, double  
velour Dacron

## FLEXCUFF

Flanged and more  
conformable than the standard  
cuff, to accommodate variable  
anatomy

## EXPANDED CUFF

25% more cuff material  
than the standard cuff,  
for even more anatomic  
accommodation

## PTFE

Known for its low  
friction, very easy  
to suture

## EXPANDED PTFE

Easy to suture with  
16% more material,  
for extra anatomical  
conformability

## AORTIC VALVE

	REGENT™ VALVE		MASTERS HP Series		MASTERS Series		
SIZE (MM)	STANDARD CUFF	FLEXCUFF™ 4	STANDARD CUFF	EXPANDED CUFF 1,3	STANDARD CUFF	EXPANDED CUFF 1,3	PTFE
15			15AHPJ-505				
17	17AGN-751	17AGFN-756	17AHPJ-505	17AEHPJ-505			
19	19AGN-751	19AGFN-756	19AHPJ-505	19AEHPJ-505	19AJ-501	19AECJ-502	19ATJ-503
21	21AGN-751	21AGFN-756	21AHPJ-505	21AEHPJ-505	21AJ-501	21AECJ-502	21ATJ-503
23	23AGN-751	23AGFN-756	23AHPJ-505	23AEHPJ-505	23AJ-501	23AECJ-502	23ATJ-503
25	25AGN-751	25AGFN-756	25AHPJ-505	25AEHPJ-505	25AJ-501	25AECJ-502	25ATJ-503
27	27AGN-751	27AGFN-756	27AHPJ-505	27AEHPJ-505	27AJ-501	27AECJ-502	27ATJ-503
29	29AGN-751	29AGFN-756			29AJ-501	29AECJ-502	29ATJ-503
31					31AJ-501	31AECJ-502	31ATJ-503

## MITRAL VALVE

	MASTERS HP Series	MASTERS Series			
SIZE (MM)	STANDARD CUFF	STANDARD CUFF	EXPANDED CUFF 1,3	PTFE	EXPANDED PTFE 2
15	15MHPJ-505				
17	17MHPJ-505				
19	19MHPJ-505	19MJ-501	19MECJ-502	19MTJ-503	19METJ-504
21	21MHPJ-505	21MJ-501	21MECJ-502	21MTJ-503	21METJ-504
23	23MHPJ-505	23MJ-501	23MECJ-502	23MTJ-503	23METJ-504
25	25MHPJ-505	25MJ-501	25MECJ-502	25MTJ-503	25METJ-504
27	27MHPJ-505	27MJ-501	27MECJ-502	27MTJ-503	27METJ-504
29		29MJ-501	29MECJ-502	29MTJ-503	29METJ-504
31		31MJ-501	31MECJ-502	31MTJ-503	31METJ-504
33		33MJ-501	33MECJ-502	33MTJ-503	33METJ-504
35		35MJ-501			
37		37MJ-501			

1. The Expanded Aortic and Mitral Cuff has approximately 25% more cuff material than the standard cuff, for even more anatomic accommodation.
2. The Expanded PTFE Cuff easy to suture with 16% more material, for extra anatomical conformability
3. The Expanded HP Cuff has approximately 15% more cuff than the HP Series cuff.
4. The FlexCuff™ is flanged and more conformable than the standard cuff, to accommodate variable anatomy.

# ACCESSORIES

## ORDERING GUIDE

### MECHANICAL VALVE SIZER SETS AND ACCESSORIES

Model No.	DESCRIPTION
905	Universal Sizer Set contains 17-33 mm valve sizers and valve holder handle model 905-HH.
905-15	Mitral and Aortic Double-Ended Sizer for Masters HP 15 mm.
905-35	35mm Masters Series valve sizer.
905-37	37mm Masters Series valve sizer.
905-MHH	Mitral valve holder handle.
905-RHH	Rigid valve holder handle.
907	Regent Sizer Set contains 17-29mm valve sizers and valve holder handle model 905-HH.
A-RHR	Contains sizes 19mm-31mm aortic Masters Series holder/rotators.
M-RHR	Contains sizes 19mm-37mm mitral Masters Series holder/rotators.
AHP-RHR	Contains sizes 17mm-27mm Masters Series Hemodynamic Plus holder/rotators.
AG-RHR	Contains sizes 17mm-29mm Regent™ holder/rotators.
LT100	Mechanical valve leaflet tester.

#### REFERENCES

1. European Heart Journal, Volume 38, Issue 36, 21 September 2017, Pages 2739–2791, <https://doi.org/10.1093/eurheartj/ehx391>
2. Torella, Michele, et al. "LOWERING the INTensity of oral anticoagulant Therapy in patients with bileaflet mechanical aortic valve replacement: results from the "LOWERING-IT" Trial." American heart journal 160.1 (2010): 171-178.
3. Koertke, Heinrich, et al. "Efficacy and safety of very low-dose self-management of oral anticoagulation in patients with mechanical heart valve replacement." The Annals of thoracic surgery 90.5 (2010): 1487-1493.
4. Puskas JD et al. Reduced anticoagulation after mechanical aortic valve replacement: interim results from the prospective randomized on-X valve anticoagulation clinical trial randomized Food and Drug Administration investigational device exemption trial. J Thorac Cardiovasc Surg 2014;147:1202-11

**CAUTION:** This product is 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](http://eifu.abbottvascular.com) or at [medical.abbott.com](http://medical.abbott.com) for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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#### Abbott International BVBA

Park Lane, Culliganlaan 2B, 1831 Diegem, Belgium, Tel: 32.2.714.14.11

™ Indicates a trademark of the Abbott Group of Companies.

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# Masters HP™ Mechanical Heart Valve

## (Page 1 of 2)

### Aortic Valves

#### Product Highlights

- Sewing cuff redesigned to facilitate supra-annular placement, allowing for an increase in orifice size for a given tissue annulus diameter
- Increased effective orifice area (EOA), lower pressure gradients, and improved performance<sup>3,4,7-9</sup>
- 85 degree leaflet opening angle offers improved laminar flow and reduces turbulence<sup>2-4</sup>
- Controlled torque rotation mechanism allows for easy rotation and intraoperative adjustment
- St. Jude Medical heart valves are MR conditional<sup>5</sup>

#### Ordering Information

Contents: Aortic Valve (1 unit per box)

Model/Reorder Number	Tissue Annulus Diameter (mm)	Valve Orifice Inner Diameter (mm)	Geometric Orifice Area (cm <sup>2</sup> )	Effective Orifice Area <sup>6</sup> (cm <sup>2</sup> )	Cuff Style
17AHPJ-505	17	14.8	1.63	1.16	Standard
19AHPJ-505	19	16.7	2.06	1.51	Standard
21AHPJ-505	21	18.6	2.55	2.03	Standard
23AHPJ-505	23	20.4	3.09	2.59	Standard
25AHPJ-505	25	22.5	3.67	3.08	Standard
27AHPJ-505	27	24.2	4.41	3.73	Standard



Product referenced is approved for CE Mark.

## Masters HP™ Mechanical Heart Valve (Page 2 of 2)

### Aortic Valves

#### Product Highlights

- Sewing cuff redesigned to facilitate supra-annular placement, allowing for an increase in orifice size for a given tissue annulus diameter
- Increased effective orifice area (EOA), lower pressure gradients, and improved performance<sup>3,4,7-9</sup>
- 85 degree leaflet opening angle offers improved laminar flow and reduces turbulence<sup>2-4</sup>
- Controlled torque rotation mechanism allows for easy rotation and intraoperative adjustment
- The expanded HP cuff has approximately 15% more cuff than the standard HP cuff
- St. Jude Medical heart valves are MR conditional<sup>15</sup>

#### Ordering Information

Contents: Aortic Valve (1 unit per box)

Model/Reorder Number	Tissue Annulus Diameter (mm)	Valve Orifice Inner Diameter (mm)	Geometric Orifice Area (cm <sup>2</sup> )	Effective Orifice Area (cm <sup>2</sup> )	Cuff Style
17AEHPJ-505	17	14.8	1.63	1.16	Expanded
19AEHPJ-505	19	16.7	2.06	1.51	Expanded
21AEHPJ-505	21	18.6	2.55	2.03	Expanded
23AEHPJ-505	23	20.4	3.09	2.59	Expanded
25AEHPJ-505	25	22.5	3.67	3.08	Expanded
27AEHPJ-505	27	24.2	4.41	3.73	Expanded



Product referenced is approved for CE Mark.



## **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:**

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*Angie Riascos*  
Manager, Regulatory Affairs

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

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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<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

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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
<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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# 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 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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Page 4 of 4

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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.

# 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 Rodovia 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

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**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

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**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	<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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# EC Certificate - Full Quality Assurance System

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

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**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

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

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

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**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

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**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, 123  
 Aracoiaba de Serra  
 Sao Paulo  
 18190-000  
 Brasil

**ETO Sterilization**

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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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**55117**  
**USA**

Subcontractor:	Service(s) supplied
Rio Branco Alimentos S.A. (Pif Paf) BR 365 Km 455, Patrocínio/MG Brasil	<b>Animal Tissues / Derivatives</b>
Seara Alimentos Ltda Rua Tranquilo Damo, 209 -Santo Antonio, Frederico Westphalen/RS Brasil	<b>Animal Tissues / Derivatives</b>
Sioux-Preme Packing Company 4241 U.S. 75 Ave Sioux Center Iowa 1250 USA	<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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**Minnesota**  
**55117**  
**USA**

Subcontractor:	Service(s) supplied
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

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
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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# EC Certificate - Full Quality Assurance System

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

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

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**177 County Road B East**  
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**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

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**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**  
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**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

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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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# EC Certificate - Full Quality Assurance System

## Certificate History

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**177 County Road B East**  
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**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 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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Page 2 of 3

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**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	<p>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&amp;G Marketing Company.</p> <p>Addition of Abbott Medical Plymouth Site as a subcontractor for Manufacture.</p> <p>Addition of Midwest Sterilization Corporation as a subcontractor for ETO sterilization.</p> <p>Change subcontractor name 'SBR Suinos Brazil Ltda' to 'Agrodanieli Indústria e Comércio Ltda'.</p> <p>Additional minor alignments of subcontractor name and addresses with ISO certificates.</p>

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Page 3 of 3

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A member of BSI Group of Companies.



# EC Design-Examination Certificate

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

**No.****CE 578290****Issued To:**

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

In respect of:

**Nonactive implants, Mechanical Heart Valves:  
SJM Regent™ Valve (Rotatable)  
SJM™ Masters Series (Rotatable)**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

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

Date: **2019-03-01**

Expiry Date: **2024-02-17**

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Page 1 of 9

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.

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# EC Design-Examination Certificate

## Supplementary Information to CE 578290

Issued To:

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

### Product: Nonactive implants, Mechanical Heart Valves:

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
17AGN-751	SJM Regent™ Valve (Rotatable)	17 mm Standard Polyester Cuff	Intended to replace the native aortic heart valve or previously implanted prosthetic valves.	Class III
19AGN-751		19 mm Standard Polyester Cuff		
21AGN-751		21 mm Standard Polyester Cuff		
23AGN-751		23 mm Standard Polyester Cuff		
25AGN-751		25 mm Standard Polyester Cuff		
27AGN-751		27 mm Standard Polyester Cuff		
29AGN-751		29 mm Standard Polyester Cuff		
17AGFN-756	SJM Regent™ Valve (Rotatable)	17 mm Standard Polyester FlexCuff™		
19AGFN-756		19 mm Standard Polyester FlexCuff™		
21AGFN-756		21 mm Standard Polyester FlexCuff™		
23AGFN-756		23 mm Standard Polyester FlexCuff™		
25AGFN-756		25 mm Standard Polyester FlexCuff™		
27AGFN-756		27 mm Standard Polyester FlexCuff™		
29AGFN-756		29 mm Standard Polyester FlexCuff™		

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

Date: **2019-03-01**

Expiry Date: **2024-02-17**

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Page 2 of 9

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# EC Design-Examination Certificate

## Supplementary Information to CE 578290

Issued To:

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
19AJ-501	SJM™ Masters Series (Rotatable)	19 mm Aortic / Polyester Cuff	Intended to replace the native aortic heart valve or previously implanted prosthetic valves.	Class III
21AJ-501		21 mm Aortic / Polyester Cuff		
23AJ-501		23 mm Aortic / Polyester Cuff		
25AJ-501		25 mm Aortic / Polyester Cuff		
27AJ-501		27 mm Aortic / Polyester Cuff		
29AJ-501		29 mm Aortic / Polyester Cuff		
31AJ-501		31 mm Aortic / Polyester Cuff		
19AECJ-502	SJM™ Masters Series (Rotatable)	19 mm Aortic / Expanded Polyester Cuff	Intended to replace the native aortic heart valve or previously implanted prosthetic valves.	Class III
21AECJ-502		21 mm Aortic / Expanded Polyester Cuff		
23AECJ-502		23 mm Aortic / Expanded Polyester Cuff		
25AECJ-502		25 mm Aortic / Expanded Polyester Cuff		
27AECJ-502		27 mm Aortic / Expanded Polyester Cuff		
29AECJ-502		29 mm Aortic / Expanded Polyester Cuff		
31AECJ-502		31 mm Aortic / Expanded Polyester Cuff		

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

Date: **2019-03-01**

Expiry Date: **2024-02-17**

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# EC Design-Examination Certificate

## Supplementary Information to CE 578290

Issued To:

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
17AHPJ-505	SJM™ Masters Series (Rotatable)	17 mm Aortic / HP Polyester Cuff	Intended to replace the native aortic heart valve or previously implanted prosthetic valves.	Class III
19AHPJ-505		19 mm Aortic / HP Polyester Cuff		
21AHPJ-505		21 mm Aortic / HP Polyester Cuff		
23AHPJ-505		23 mm Aortic / HP Polyester Cuff		
25AHPJ-505		25 mm Aortic / HP Polyester Cuff		
27AHPJ-505		27 mm Aortic / HP Polyester Cuff		
17AEHPJ-505	SJM™ Masters Series (Rotatable)	17 mm Aortic / Expanded HP Polyester Cuff	Intended to replace the native aortic heart valve or previously implanted prosthetic valves.	Class III
19AEHPJ-505		19 mm Aortic / Expanded HP Polyester Cuff		
21AEHPJ-505		21 mm Aortic / Expanded HP Polyester Cuff		
23AEHPJ-505		23 mm Aortic / Expanded HP Polyester Cuff		
25AEHPJ-505		25 mm Aortic / Expanded HP Polyester Cuff		
27AEHPJ-505		27 mm Aortic / Expanded HP Polyester Cuff		

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

Date: **2019-03-01**

Expiry Date: **2024-02-17**

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# EC Design-Examination Certificate

## Supplementary Information to CE 578290

Issued To:

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
19ATJ-503	SJM™ Masters Series (Rotatable)	19 mm Aortic / PTFE Cuff	Intended to replace the native aortic heart valve or previously implanted prosthetic valves	Class III
21ATJ-503		21 mm Aortic / PTFE Cuff		
23ATJ-503		23 mm Aortic / PTFE Cuff		
25ATJ-503		25 mm Aortic / PTFE Cuff		
27ATJ-503		27 mm Aortic / PTFE Cuff		
29ATJ-503		29 mm Aortic / PTFE Cuff		
31ATJ-503		31 mm Aortic / PTFE Cuff		
19MJ-501	SJM™ Masters Series (Rotatable)	19 mm Mitral / Polyester Cuff	Intended to replace the native mitral heart valve or previously implanted prosthetic valves	Class III
21MJ-501		21 mm Mitral / Polyester Cuff		
23MJ-501		23 mm Mitral / Polyester Cuff		
25MJ-501		25 mm Mitral / Polyester Cuff		
27MJ-501		27 mm Mitral / Polyester Cuff		
29MJ-501		29 mm Mitral / Polyester Cuff		
31MJ-501		31 mm Mitral / Polyester Cuff		
33MJ-501		33 mm Mitral / Polyester Cuff		
35MJ-501		35 mm Mitral / Polyester Cuff		
37MJ-501		37 mm Mitral / Polyester Cuff		

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

Date: **2019-03-01**

Expiry Date: **2024-02-17**

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

# EC Design-Examination Certificate

## Supplementary Information to CE 578290

Issued To:

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
19MECJ-502	SJM™ Masters Series (Rotatable)	19 mm Mitral / Expanded Polyester Cuff	Intended to replace the native mitral heart valve or previously implanted prosthetic valves	Class III
21MECJ-502		21 mm Mitral / Expanded Polyester Cuff		
23MECJ-502		23 mm Mitral / Expanded Polyester Cuff		
25MECJ-502		25 mm Mitral / Expanded Polyester Cuff		
27MECJ-502		27 mm Mitral / Expanded Polyester Cuff		
29MECJ-502		29 mm Mitral / Expanded Polyester Cuff		
31MECJ-502		31 mm Mitral / Expanded Polyester Cuff		
33MECJ-502		33 mm Mitral / Expanded Polyester Cuff		
17MHPJ-505	SJM™ Masters Series (Rotatable)	17 mm Mitral / HP Polyester Cuff	Intended to replace the native mitral heart valve or previously implanted prosthetic valves	Class III
19MHPJ-505		19 mm Mitral / HP Polyester Cuff		
21MHPJ-505		21 mm Mitral / HP Polyester Cuff		
23MHPJ-505		23 mm Mitral / HP Polyester Cuff		
25MHPJ-505		25 mm Mitral / HP Polyester Cuff		
27MHPJ-505		27 mm Mitral / HP Polyester Cuff		

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

Date: **2019-03-01**

Expiry Date: **2024-02-17**

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# EC Design-Examination Certificate

## Supplementary Information to CE 578290

Issued To:

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
19MTJ-503	SJM™ Masters Series (Rotatable)	19 mm Mitral / PTFE Cuff	Intended to replace the native mitral heart valve or previously implanted prosthetic valves	Class III
21MTJ-503		21 mm Mitral / PTFE Cuff		
23MTJ-503		23 mm Mitral / PTFE Cuff		
25MTJ-503		25 mm Mitral / PTFE Cuff		
27MTJ-503		27 mm Mitral / PTFE Cuff		
29MTJ-503		29 mm Mitral / PTFE Cuff		
31MTJ-503		31 mm Mitral / PTFE Cuff		
33MTJ-503		33 mm Mitral / PTFE Cuff		
19METJ-504	SJM™ Masters Series (Rotatable)	19 mm Mitral / Expanded PTFE Cuff	Intended to replace the native mitral heart valve or previously implanted prosthetic valves	Class III
21METJ-504		21 mm Mitral / Expanded PTFE Cuff		
23METJ-504		23 mm Mitral / Expanded PTFE Cuff		
25METJ-504		25 mm Mitral / Expanded PTFE Cuff		
27METJ-504		27 mm Mitral / Expanded PTFE Cuff		
29METJ-504		29 mm Mitral / Expanded PTFE Cuff		
31METJ-504		31 mm Mitral / Expanded PTFE Cuff		
33METJ-504		33 mm Mitral / Expanded PTFE Cuff		

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

Date: **2019-03-01**

Expiry Date: **2024-02-17**

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# EC Design-Examination Certificate

## Supplementary Information to CE 578290

Issued To:

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

## Certificate History

Date	Reference Number	Action
30 January 2012	10130170	First Issue of mirror certificate to CE 544669
10 November 2013	10144187	Addition of InterVascular SAS (Maquet) La Ciotat, France facility as fabric supplier.
23 January 2014	10145129	Implementation of new sealing plate design and change in lid sealing parameters for SJM Mechanical Heart Valves and Annuloplasty Rings packaging.
14 February 2014	10145174	Certificate renewal. 70 product codes removed from the scope of the certificate.
25 February 2014	10144864	Updated Magnetic Resonance (MR) safety information in labelling.
28 March 2014	10146037	Change from Helium to Argon gas used in the pyrolytic carbon coating manufacturing process.
22 July 2014	10149696	Transfer of Heart Valve Components Manufacturing Steps to the St. Jude Medical, Caguas, Puerto Rico Facility.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.

First Issued: **2012-01-30**Date: **2019-03-01**Expiry Date: **2024-02-17**

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# EC Design-Examination Certificate

## Supplementary Information to CE 578290

Issued To:

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

## Certificate History

Date	Reference Number	Action
26 October 2017	8795241	Change to an orifice graphite substrate specification. Removal of all products references XXA-101 and XXM-101.
Current	9645156	Certificate Renewal. Changed the certificate format with new tables.

First Issued: **2012-01-30**Date: **2019-03-01**Expiry Date: **2024-02-17**

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# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Holds Certificate No:

**FM 558476**

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

Design, development and Manufacture of and finished Mechanical Heart Valves, Tissue Heart Valves, Annuloplasty Rings, Valve and Annuloplasty Ring Sizer Sets, Mechanical Valve Leaflet Testers, Holder Rotators, Transcatheter Heart Valve Delivery and Loading Systems and related accessories along with manufacturing of intermediate components used in other medical devices.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2009-12-24

Latest Revision Date: 2020-01-13

Effective Date: 2020-02-29

Expiry Date: 2023-02-28

Page: 1 of 2



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Certificate No: **FM 558476**

Location	Registered Activities
St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA	Design, development and Manufacture of and finished Mechanical Heart Valves, Tissue Heart Valves, Annuloplasty Rings, Valve and Annuloplasty Ring Sizer Sets, Mechanical Valve Leaflet Testers, Holder Rotators, Transcatheter Heart Valve Delivery and Loading Systems and related accessories along with manufacturing of intermediate components used in other medical devices.
St. Jude Medical Brasil Ltda. Rua Professor Jose Vieira de Mendonca 1301 Bairro Engenho Nogueira Pampulha, Belo Horizonte Minas Gerais 31.310-026 Brasil	The Manufacture and final inspection of tissue made heart valves and tissue vascular prostheses.



Original Registration Date: 2009-12-24

Effective Date: 2020-02-29

Latest Revision Date: 2020-01-13

Expiry Date: 2023-02-28

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](https://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

# 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.