

ABBOTT MECHANICAL HEART VALVES

Regent, Masters HP and Masters

AORTIC VALVE

MITRAL VALVE

IMPLANT
CONFIDENTLY.

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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*



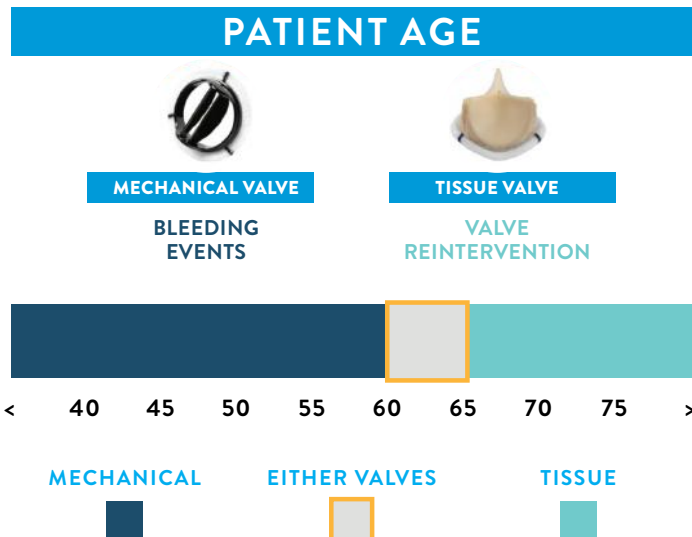
Can lessen thrombus formation by minimizing carbon surface area and thanks to the washout flow through the hinges*

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**FIND OUT MORE
ON ABBOTT
MHV DESIGN**



2017 ESC/EACTS GUIDELINES¹



Target INR for mechanical prostheses

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

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

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

^b Carbomedics, Medtronic Hall, ATS, Medtronic Open-Pivot, St Jude Medical, OnX, Sorin Bicarbon.

^c Other bileaflet valves with insufficient data.

^d 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-IT² (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 III³ (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†



PROACT⁴ (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.

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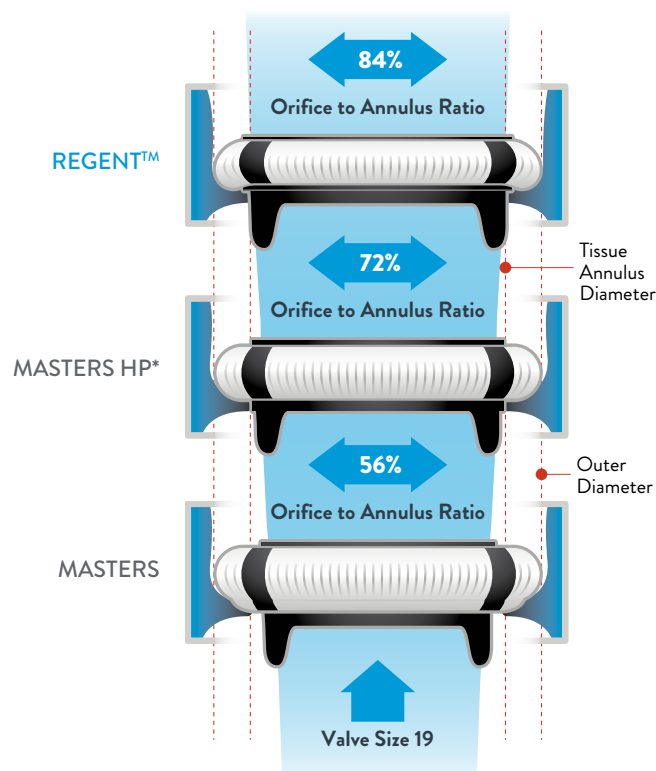
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**FIND OUT MORE
ON LOW INR
CLINICAL EVIDENCE**



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.

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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

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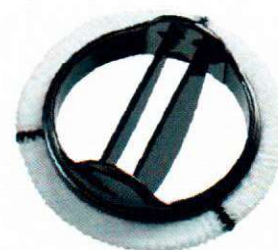
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Regent™ Mechanical Heart Valve

Standard Cuff

Aortic Valves



Product Highlights

- Designed to deliver exceptional hemodynamics and performance while maintaining low complication rates, structural integrity and durability
- Single-digit gradients, even in sizes as small as 19 mm¹
- Up to 84% orifice to annulus ratio
- 85 degree leaflet opening angle offers improved laminar flow and reduces turbulence²⁻⁴
- Supra-annular placement and low implant height
- The FlexCuff™ is flanged and more pliable than the standard cuff
- St. Jude Medical heart valves are MR Conditional⁵

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 ²)	Effective Orifice Area ⁶ (cm ²)	Cuff Style
17AGN-751	17	15.9	1.87	1.42	Standard
19AGN-751	19	17.8	2.39	1.84	Standard
21AGN-751	21	19.6	2.90	2.47	Standard
23AGN-751	23	21.4	3.45	2.91	Standard
25AGN-751	25	23.0	4.02	3.34	Standard
27AGN-751	27	24.9	4.69	4.28	Standard
29AGN-751	29	26.8	5.44	Not reported	Standard

*All sizes currently not available in all markets.

1. St. Jude Medical, Inc. Pre-Market Approval Application Supplement. Regent Heart Valve. Washington, D.C.; U.S. Food and Drug Administration. 2002. P810002/S57.
2. King, M., David T, Fisher J. An initial parametric study on fluid flow through bileaflet mechanical heart valves using computational fluid dynamics. *J Eng Med.* 1994;208:63-72.
3. Feng Z, Nakamura T, Fujimoto T, et al. In vitro investigation of opening behavior and hydrodynamics of bileaflet valves in the mitral position. *Artificial Organs.* 2002;26(1):32-9.
4. Shipkowitz T, Ambrus J, Kurk J, et al. Evaluation technique for bileaflet mechanical valves. *J Heart Valve Dis.* 2002;11(2):275-82.
5. St. Jude Medical MRI Safety Document.
6. Walker DK, Brendzel AM, Scotten LN. The new St. Jude Medical Regent mechanical heart valve: Laboratory measurements of hydrodynamic performance. *J Heart Valve Dis.* 1999;8(6):687-96.

Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Product referenced is approved for CE Mark.

Regent, FlexCuff, ST. JUDE MEDICAL, the nine-squares symbol and MORE CONTROL, LESS RISK. are registered and unregistered trademarks and service marks of St. Jude Medical, Inc. and its related companies.

SJM Regent[®]

Heart Valve

REDEFINING HEMODYNAMIC PERFORMANCE.[™]



THE NEWEST MEMBER OF THE ST. JUDE MEDICAL
MECHANICAL HEART VALVES FAMILY

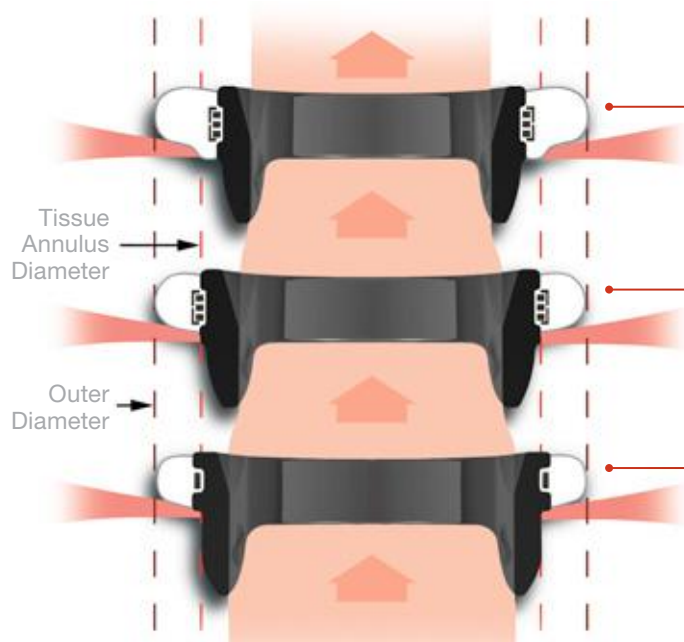
REACHING NEW LEVELS.

The SJM Regent® heart valve represents a significant step forward in prosthetic valve design. It provides outstanding hemodynamics while maintaining the traditional quality and proven features that have established St. Jude Medical® mechanical valves as the gold standard.



Evolutionary improvement

Development of the St. Jude Medical® mechanical heart valve has led to a progressively greater geometric orifice area within a given tissue annulus dimension.



SJM® Masters Series mechanical heart valve

- Intraannular cuff.
- Intraannular carbon rim.

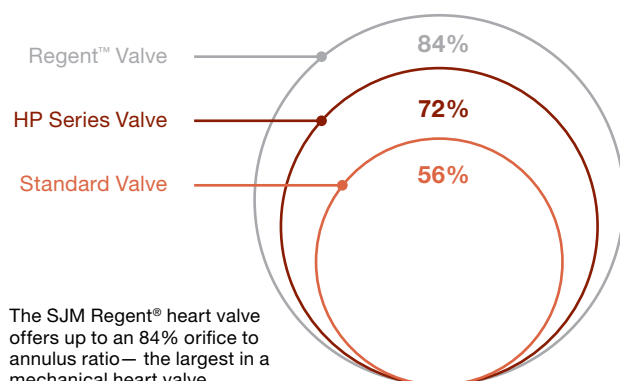
SJM® Masters Series Hemodynamic Plus valve

- Supraannular cuff.
- Carbon rim remains intraannular.

SJM Regent® heart valve

- Supraannular cuff.
- Carbon rim shifts to supraannular position.
- New rotation mechanism is completely housed within the carbon rim.

Orifice to annulus ration — 19mm valve²



"The energy loss results show an approximate one-size increment improvement of the SJM Regent™ heart valve over the St. Jude Medical® HP Series valve, which is equivalent to a two-size increment improvement over the standard valve."

(Walker et al, 1999)¹

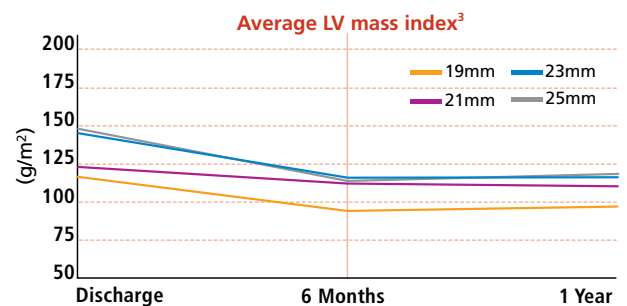
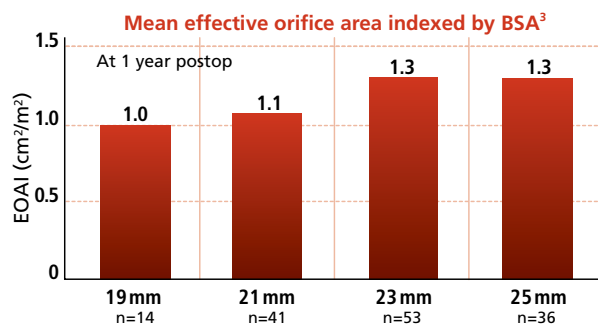
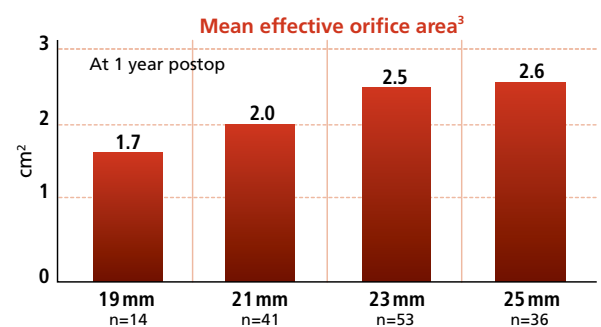
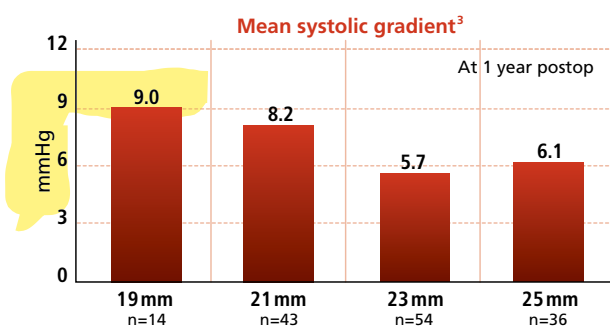
SJM REGENT® HEART VALVE

Redefining Hemodynamic Performance.™

Unprecedented hemodynamics

The SJM Regent® heart valve delivers exceptional hemodynamics and performance while maintaining the design features that have set the standard for low complication rates, structural integrity, and durability in a mechanical valve. The SJM Regent® heart valve provides:

- Single digit in vivo pressure gradients—even in valve sizes as small as 19mm.³
- Significantly larger EOAs.³
- Excellent patient-prosthesis match⁴—even in small sizes.
- Significant reduction of LV Mass.³ Numerous studies have shown a direct correlation between LV hypertrophy and morbidity and mortality.⁵⁻¹⁶ Even moderate LV hypertrophy can result in: congestive heart failure,¹⁷ arrhythmias,⁵ myocardial infarction,¹⁷ and sudden death.^{5,17}



"Significant and rapid left ventricular mass regression with all valve sizes confirms excellent hemodynamics associated with the valve. . . ."

(Bach et al, 2001)¹⁸

Traditional reliability

The SJM Regent® heart valve retains the same design features that have made St. Jude Medical® mechanical heart valves the standard for reliability and proven performance for more than 25 years.

- All blood-contact surfaces remain unchanged.
- In seven broad categories of structural integrity and durability tests, the SJM Regent® heart valve met all the demanding standards set by previous St. Jude Medical® mechanical heart valves.²
- The SJM Regent® heart valve is made of the same pyrolytic carbon used in more than one million St. Jude Medical® mechanical heart valve implants.

FAMILIAR TECHNIQUE

The technique for implanting the SJM Regent® heart valve remains the same as for other St. Jude Medical® mechanical heart valves. For added convenience, it's available in two cuff configurations to suit your implant preferences.

FlexCuff™ sewing ring

- Provides enhanced conformability and maximum suture target area while offering lateral flange to accommodate the tissue annulus.



Standard cuff sewing ring

- Rounded cuff designed for excellent conformability and suturability.

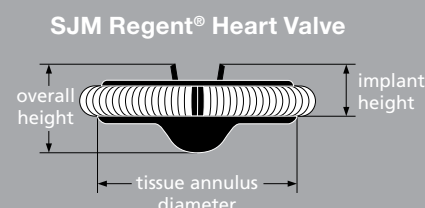


Product Specifications*

Valve Size (mm)	Tissue Annulus Diameter (mm)	Overall Height Open (mm)	Implant Height (mm)	Geometric Orifice Area (cm ²)
17	17.0	10.6	5.3	1.87
19	19.0	11.5	5.9	2.39
21	21.0	12.5	6.7	2.90
23	23.0	13.7	7.3	3.45
25	25.0	13.9	7.6	4.02
27	27.0	14.9	8.5	4.69
29	29.0	16.1	9.1	5.44

*From manufacturer's data

Sizes 17 mm and 29 mm are not currently approved in the United States



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The Global Leader in Heart Valve Devices.™

AVERTISMENT: Nu introduceți catetere sau alte instrumente prin valvele mecanice St. Jude Medical. Aceasta poate duce la zgărirea sau deteriorarea componentelor valvelor, ruperea sau dislocarea cuspelor.

Pentru toți pacienții care sunt supuși unor proceduri stomatologice se va analiza oportunitatea tratamentului antibiotic profilactic.

Terapia anticoagulantă

În lipsa unor date suficiente care să demonstreze contrariul, St. Jude Medical recomandă ca pacienții care suferă implanturi cu valve cardiace mecanice SJM Regent™ să primească în mod curent agenți anticoagulanți, cu excepția cazurilor în care, din alte motive, tratamentul este contraindicat.

ÎNREGISTRAREA PACIENȚILOR

Fiecare dispozitiv este însoțit de un formular de înregistrare a dispozitivului medical și de un plic pentru trimitere poștală. Completați cardul de identificare atașat la formularul de înregistrare al dispozitivului medical și înmânați-l pacientului. După implantare, completați toate informațiile necesare și trimiteți formularul inițial înapoi la St. Jude Medical. În unele țări este obligatorie monitorizarea pacienților de către producători. Nu luați în considerare eventualele solicitări de informații despre pacient, dacă acestea contravin normelor locale legale sau de reglementare privind confidențialitatea datelor pacientului.

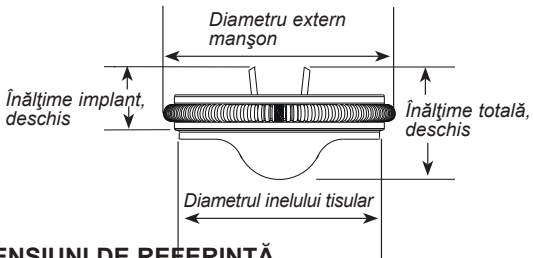
GARANȚIE LIMITATĂ

St. Jude Medical, Inc (SJM) garantează că la producerea prezentului dispozitiv s-au depus toate eforturile rezonabile. PREZENTA GARANȚIE ȚINE LOC DE ȘI EXCLUDE ORICE ALTE GARANȚII CARE NU SUNT STABILITE ÎN MOD EXPRES ÎN PREZENTUL DOCUMENT, INDIFERENT DACĂ ACESTEA SUNT IMPLICATE ÎN MOD SPECIAL SAU GENERAL DE RESPECTAREA LEGISLAȚIEI, ȘI INCLUZÂND FĂRĂ A SE LIMITA LA ORICE ALTE GARANȚII IMPLICITE DE COMERCIALIZARE SAU ADECVARE LA UN ANUMIT SCOP, dat fiind că manevrarea, depozitarea, curățarea și sterilizarea prezentului dispozitiv, precum și o serie de alți factori care privesc pacientul, diagnosticul, tratamentul aplicat, procedurile chirurgicale folosite, precum și orice alte aspecte similare sunt imposibil de controlat în mod direct de către SJM și pot afecta atât dispozitivul, cât și rezultatele obținute în urma folosirii acestuia. SJM NU ESTE RESPONSABIL PENTRU PAGUBE, PIERDERI SAU CHELTUIELI ÎNTÂMPLĂTOARE SAU PE CALE DE CONSECINȚĂ survenite în mod direct sau indirect ca urmare a folosirii acestui dispozitiv, cu excepția înlocuirii dispozitivului sau a componentelor acestuia. SJM nu își asumă și nu autorizează terțe părți să își asume în numele său orice alte răspunderi sau responsabilități suplimentare în legătură cu acest dispozitiv.

Unele state din Statele Unite ale Americii nu permit limitări în privința duratei garanției implicite, prin urmare este posibil ca limitările menționate anterior să nu fie valabile în cazul dvs. Prezentă garanție limitată vă conferă anumite drepturi legale, fiind însă posibil să aveți și alte drepturi care pot varia în funcție de jurisdicția aplicabilă.

Descrierile dimensiunilor de referință furnizate în cadrul documentațiilor oferite de SJM au ca scop unic descrierea cu caracter general a dispozitivului la data fabricației și nu se constituie în garanții speciale.

* În funcție de disponibilitate.



DIMENSIUNI DE REFERINȚĂ

Număr de catalog	Diametru inel tisular (mm)	Arie geometrică orificiu (cm²)	Înălțime implant, deschis (mm)	Înălțime totală, deschis (mm)	Diametru extern manșon (mm)
Manșon standard					
17 AGN-751**	17	1,9	5,4	10,8	22,7
19 AGN-751	19	2,4	6,1	11,6	24,7
21 AGN-751	21	2,9	7,3	13,0	26,7
23 AGN-751	23	3,5	8,0	14,3	28,7
25 AGN-751	25	4,0	8,2	14,6	30,7
27 AGN-751	27	4,7	9,1	15,4	32,7
29 AGN-751**	29	5,4	9,5	16,5	34,7
Manșon FlexCuff					
17 AGFN-756**	17	1,9	5,4	10,8	25,0
19 AGFN-756	19	2,4	6,1	11,6	27,0
21 AGFN-756	21	2,9	7,3	13,0	29,0
23 AGFN-756	23	3,5	8,0	14,3	31,0
25 AGFN-756	25	4,0	8,2	14,6	33,0
27 AGFN-756	27	4,7	9,1	15,4	35,0
29 AGFN-756**	29	5,4	9,5	16,5	37,0

**Dimensiunile de 17 mm și 29 mm nu sunt aprobate în prezent în Statele Unite.



Figura 1: Valva cardiacă SJM Regent



Figura 2: Valvă cardiacă SJM Regent cu manșon FlexCuff

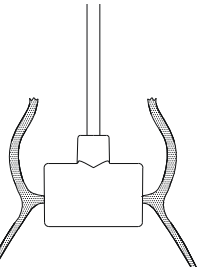


Figura 3: Capătul cilindric al dispozitivului de măsurare 905 sau 907 trebuie să treacă ușor prin inel.

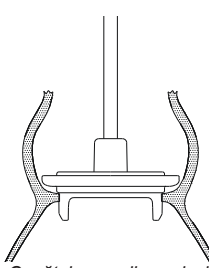


Figura 4: Capătul cu replica valvulară SJM Regent al dispozitivului de măsurare 907 simulează poziția supra-anulară a valvei.

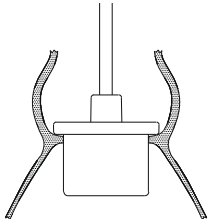


Figura 5: Capătul cu flanșă al dispozitivului de măsurare 905 simulează poziția supra-anulară a manșonului de sutură.

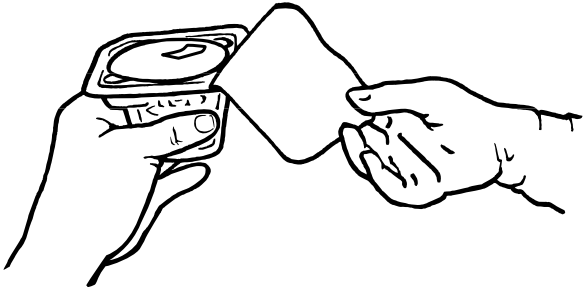


Figura 6: Îndepărtați protecția containerului extern.

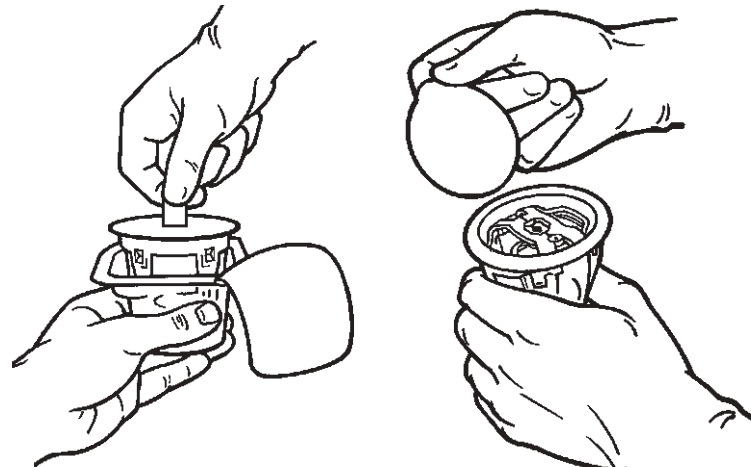


Figura 7: Scoateți containerul intern.

Figura 8: Îndepărtați protecția containerului intern.



Figura 9: Introduceți mânerul susținătorului valvei în valvă.



Figura 10: Scoateți valva și colierul din containerul intern.

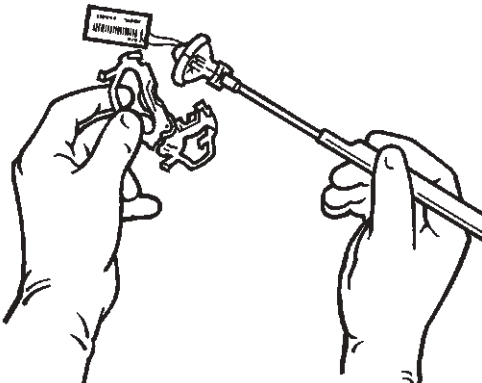


Figura 11: Scoateți colierul și eticheta valvei înainte de implantare.

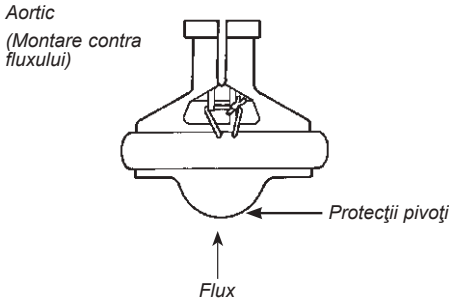


Figura 12: Fluxul sanguin vine întotdeauna spre protecțiile pivoților.



Figura 13: Trei markeri de sutură pe manșonul de sutură al valvei aortice.

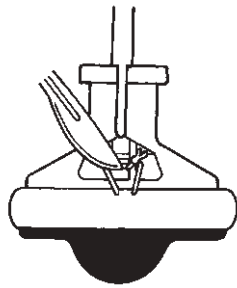


Figura 14: Folosiți un bisturiu pentru a tăia suturile și elibera valva din suportul său de susținere/rotație.

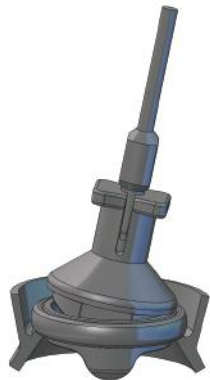


Figura 15a: Suport de susținere/rotație a valvei fixat impropriu.

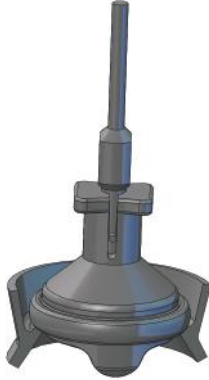


Figura 15b: Suport de susținere/rotație a valvei fixat corect.



St. Jude Medical
177 County Road B East
St. Paul, Minnesota 55117 USA
+1 855 478 5833
+1 651 756 5833
sjm.com



FlexCuff, ST. JUDE MEDICAL, forma valvei cardiace, simbolul cu nouă pătrate și MORE CONTROL. LESS RISK. („Mai mult control. Mai puțin risc”) sunt mărci și servicii înregistrate ale St. Jude Medical, Inc. și ale companiilor înrudite.

© 2012 St. Jude Medical. Toate drepturile rezervate

09/2012

Rx only

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
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.

SJM Declaration of Conformity

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):	St Jude Medical Mechanical Heart Valve (Non-Rotatable) SJM Masters Series (Rotatable) SJM Regent Valve (Rotatable) Tailor Annuloplasty Ring Tailor Annuloplasty Band Rigid Saddle Ring Attune™ Flexible Adjustable Annuloplasty Ring St Jude Medical Seguin Annuloplasty Ring SJM Masters Valved Graft with Hemashield® Technology SJM Masters HP™ Valved Graft with Gelweave Valsalva™ Technology
Model Number(s):	<i>See attached.</i>
Classification:	Mechanical heart valves and annuloplasty rings: Class III per MDD, Annex IX, rule 8 Valved Grafts: Class III per MDD, Annex IX, rule 17
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

Original CE Mark Date: *See attached.*

FQA Certificate No and expiration date: Certificate No: CE 578287

Annex II DE Certificate No and expiration date: *See attached.*

Applicable Quality System Standards: ISO 13485: 2003 + AC:2007

Notified Body: BSI Product Service
Kitemark House, Maylands Avenue
Hemel Hempstead, Hertfordshire
HP2 4SQ, UK

Notified Body Number: 0086

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 USA

Signature:



Amanda Martin
Regulatory Affairs Specialist

30-November-2015

Issue Date

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
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**

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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 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

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**

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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 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.

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Supplementary Information to CE 578287

Issued To:

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177 County Road B East
St Paul
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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**

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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
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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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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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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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 Cecília Santa Catarina Brasil	Animal Tissues / Derivatives
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 USA	ETO Sterilization

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177 County Road B East
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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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177 County Road B East
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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

List of Significant Subcontractors

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

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 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, 123
 Aracoiaba de Serra
 Sao Paulo
 18190-000
 Brasil

ETO Sterilization

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177 County Road B East
St Paul
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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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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.

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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**
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 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

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.

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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**
 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.

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Page 3 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.

EC Design-Examination Certificate

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

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

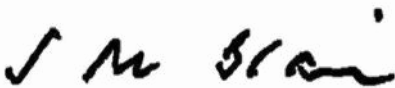
**St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA**

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.

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

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

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
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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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Page 3 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.

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
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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Page 4 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.

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
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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Page 5 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

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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Page 6 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.

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
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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Page 7 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.

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

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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Page 8 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.

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

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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Page 9 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.

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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of 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.

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
Latest Revision Date: 2020-01-13

Effective Date: 2020-02-29
Expiry Date: 2023-02-28

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