Pericardial Patch
WITH ENCAP™ AC TECHNOLOGY

ENHANCED BIOCOMPATIBILITY FOR LASTING PERFORMANCE

The Pericardial Patch with EnCap AC Technology* combines strong, durable bovine pericardium with a proprietary anti-calcification treatment, making it suitable for a variety of cardiac repairs while offering improved handling and enhanced biocompatibility.

IMPROVED HANDLING AND SUTURABILITY SUPPORT CARDIOVASCULAR REPAIR

- Ready-to-use, rinseless preparation saves time during procedures.
- Bovine pericardium provides improved handling and suturability compared with synthetic patches.[1]
- The strength of glutaraldehyde-fixed tissue enhances durability and helps resist undesirable changes such as patch shrinkage and aneurysm formation, even in high-stress repairs.[2–6]
- Soft, pliable tissue conforms to anatomy and sutures into place with minimal leaking along suture line.

ANTI-CALCIFICATION TREATMENT ENHANCES BIOCOMPATIBILITY AND DURABILITY

- Proprietary EnCap AC Technology caps residual aldehydes to reduce antigenicity and cytotoxicity.[5,7,8]
- Resists calcification and promotes rapid binds, thorough healing with endothelial cell covering.[7–10]
- Improved endothelialization strengthens the reconstruction or repair, helping reduce calcification and other degeneration.[7–9]

APPROPRIATE FOR A WIDE RANGE OF CARDIAC AND VASCULAR REPAIRS[8]

- Annular reconstruction[3]
- Endocarditis leaflet repairs
- Septal defect repairs
- Aortic root enlargement
- Other vascular repairs.

* There is no clinical data currently available which evaluates the long-term impact of anticalcification tissue treatment in humans.

Abbott

ORDERING INFORMATION

Pericardial Patch

Model Number	Patch Size (cm)	Nominal Thickness (mm)
C0205	2 x 5	0.20 – 0.40
C0405	4 x 5	0.15 – 0.25
C0510	5 x 10	0.20 – 0.40
C0914	9 x 14	0.20 – 0.40

All sizes not currently available in all markets.

References:

1. Crawford FA Jr, Sade RM, Spinale F. Bovine pericardium for correction of congenital heart defects. Ann Thorac Surg. 1986;41(6):602-5.
2. Frater RWM, Vetter HO, Zussa C, et al. Chordal replacement in mitral valve repair. Circulation. 1990;82[suppl IV]:IV-125-IV-130.
3. David TE, Feindel CM, Armstrong, S, et al. Reconstruction of the mitral annulus: a ten-year experience. J Thorac Cardiovasc Surg. 1995;110(5):1323-32.
4. Bjornstad K, Duran RM, Nassau KG, et al. Clinical and echocardiographic follow-up after aortic valve reconstruction with bovine or autologous pericardium. Am Heart J. 1996;132(6):1173-8.
5. Gong G, Seifter E, WD Lyman, et al. Bioprosthetic cardiac valve degeneration: role of inflammatory and immune reactions. J Heart Valve Dis. 1993;2(6):684-93.
6. Gong G, Ling Z, Seifter E, et al. Aldehyde tanning: the villain in bioprosthetic calcification. Eur J Cardiothorac Surg. 1991;5:288-99.
7. Frater RWM, Seifter E, Liao K, et al. Anticalcification, proendothelial, and anti-inflammatory effect of post-aldehyde polyol treatment of bioprosthetic material. In: Gabbay S, Wheatley DJ (eds.). Advances in Anticalcific and Antidegenerative Treatment of Heart Valve Bioprostheses. Austin, TX: Silent Partners Inc; 1997:105-14.
8. Frater RWM, Liao K, Seifter E. Stentless chordally supported mitral bioprosthetic valve. In: Gabbay S, Frater RWM (eds.) New Horizons and the Future of Heart Valve Bioprostheses. Austin, TX: Silent Partners Inc; 1994:103-19.
9. Hoffman D, Gong G, Liao K, et al. Spontaneous host endothelial growth on bioprostheses. Circulation. 1992;86[suppl II]:II-75-II-79.
10. Moritz A, Grimm M, Eybl E, et al. Improved spontaneous endothelialization by postfixation treatment of bovine pericardium. Eur J Cardiothorac Surg. 1991;5:155-9.

Abbott Vascular International BVBA
Park Lane, Culliganlaan 2b, 1831 Diegem, Belgium

Abbott

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

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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

ST. JUDE MEDICAL

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):	*See attached.*
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

ST. JUDE MEDICAL

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

_____

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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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 578287

Issued To:

St. Jude Medical
177 County Road B East
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Number	Device Name	Intended Purpose per IFU
Class III		
---	• Masters Series Mechanical Heart Valve – Mechanical Heart Valves • Masters Series Mechanical Heart Valve with Expanded Polyester Sewing Cuff – Mechanical Heart Valves • Masters Series Mechanical Heart Valve with PTFE Sewing Cuff – Mechanical Heart Valves • Masters Series Mechanical Heart Valve with Expanded PTFE Sewing Cuff – Mechanical Heart Valves • Masters Series Mechanical Heart Valve with Hemodynamic Plus (HP) Sewing Cuff – Mechanical Heart Valves • Masters Series Mechanical Heart Valve with Expanded Hemodynamic Plus (HP) Sewing Cuff – Mechanical Heart Valves • Regent Heart Valve – Mechanical Heart Valves • Regent Heart Valve with FlexCuff – Mechanical Heart Valves	See CE 578290

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

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 578287

Issued To:

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

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

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

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 578287

Issued To:

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

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

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

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

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

List of Significant Subcontractors

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Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

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

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

List of Significant Subcontractors

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

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

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

List of Significant Subcontractors

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

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

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

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Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

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

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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

List of Significant Subcontractors

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Date:	**2019-12-11**
Issued To:	**St. Jude Medical** **177 County Road B East** **St Paul** **Minnesota** **55117** **USA**

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

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

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

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

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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
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USA

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

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 578287**

Date: **2019-12-11**

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

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

EC Certificate - Full Quality Assurance System Certificate History

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

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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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™		

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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		

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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		

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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		

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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		

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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		

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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.

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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.

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