SJM[™] Pericardial Patch with EnCap[™] AC Technology Pericardial Patch

Product Highlights

- Flexible and durable to provide enhanced biocompatibility and lasting performance⁹⁻¹¹
- Bovine pericardium provides improved handling and suturability compared with synthetic patches¹²
- Anti-calcification treatment enhances tissue healing, biocompatibility and long-term tissue stability^{9*}
- Soft, pliable tissue conforms to the anatomy and easily sutures into place
- Ready-to-use, rinseless preparation saves time during procedures

Ordering Information

Contents: Pericardial Patch (1 unit per box)

Model/Reorder Number	Patch Size (cm)	Nominal Thickness (mm)
C0205	2 x 5	0.20-0.60
C0510	5 x 10	0.20-0.60
C0914	9 x 14	0.20–0.60



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

Product referenced is approved for CE Mark.

EnCap is a trademark of Glycar, Inc.





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

86480 Rev A Template Page 1 of 2



SJM Declaration of Conformity

Original CE Mark Date:

FQA Certificate No and expiration date:

Annex II DE Certificate No and expiration date:

Applicable Quality System Standards:

Notified Body:

Notified Body Number:

Manufacturing Facilities:

See attached.

Certificate No: CE 578287

See attached.

ISO 13485: 2003 + AC:2007

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

0086

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:

manda Mortin

Amanda Martin Regulatory Affairs Specialist

30-November-2015

Issue Date





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

No. Issued To: CE 578287 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 C Stade

Gary E Slack, Senior Vice President Medical Devices

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

Date: 2019-12-11

Expiry Date: 2024-05-26

...making excellence a habit." 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.





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	See CE 578290
	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	(40) S (1)
	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	444 30
	 Masters Series Mechanical Heart Valve with Expanded Hemodynamic Plus (HP) Sewing Cuff – Mechanical Heart Valves 	
	Regent Heart Valve – Mechanical Heart Valves	515
	Regent Heart Valve with FlexCuff – Mechanical	
	Heart Valves	

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.





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.

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





Supplementary Information to CE 578287

Issued To:

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

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





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: Date: Issued To:

2019-12-11 St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA

CE 578287

Subcontractor:

Service(s) supplied

Manufacture

Abbott Medical 5050 Nathan Lane North Plymouth Minnesota 55442 USA

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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Page 1 of 14





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: Date: Issued To:

2019-12-11 St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA

CE 578287

Subcontractor:

Service(s) supplied

Agropecuária Bolson Ltda. (Bolson) Rua Vereador Waldomiro Franco de Souza, S/N - Zona Suburbana Toledo Paraná Brasil

Bierig Brothers Inc. 3539 Reilly Ct. Vineland New Jersey 08360 USA

BRF - Brasil Foods S.A. Rua Senador Atilio Fontana, 86, Concordia/SC Brasil Animal Tissues / Derivatives

Animal Tissues / Derivatives

Animal Tissues / Derivatives

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Page 2 of 14





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: Date:

Issued To:

2019-12-11 St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA

CE 578287

Subcontractor:

Frigoestrela S.A. Estrada Vicinal Romão Lopes Martins, S/N - KM 0+700M, Jardim Marabá, Tupã/SP Brasil

Frigorifico Miolar Ltda Estrada para Fazenda Mazurana S/N, Dois Vizinhos/PR Brasil

Frimesa Cooperativa Central Rua Bahia, 159, Medianeira/PR Brasil Animal Tissues / Derivatives

Service(s) supplied

Animal Tissues / Derivatives

Animal Tissues / Derivatives

Hereaus Medical Components, LLC 5030 Centerville Road St. Paul Minnesota 55127 USA Manufacture

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Page 3 of 14





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: Date:

Issued To:

2019-12-11 St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA

CE 578287

Subcontractor:

InterVascular SAS Z.I. Athélia 1 13705 La Ciotat Cedex France

Irmãos do Valle (IDV) Rodovia BR 116, KM 116 Caixa Postal 04 - Bairro: Campo Alto - Santa Cecilia Santa Catarina Brasil

Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 USA Service(s) supplied

Manufacture

Animal Tissues / Derivatives

ETO Sterilization

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Page 4 of 14





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: Date: Issued To:

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

CE 578287

Subcontractor:

JBS Aves Ltda Rua João Andriollo, 1167, Ana Rech Caxias do Sul/RS Brasil

JBS S.A.

Brasil

Ituiutaba/MG

JBS S.A. Parque Industrial S/N Distrito Industrial, LINS/SP Brasil

JBS S.A. Rodovia, GO 164, Km 167 S/N, Zona Rural, Mozarlândia/GO Brasil

Animal Tissues / Derivatives

Animal Tissues / Derivatives

Service(s) supplied

Animal Tissues / Derivatives

Rua Principal S/N, Vila Miisa,

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: Date: Issued To:

2019-12-11 St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA

CE 578287

Subcontractor:

JBS S.A. Facility I Av. Duque de Caxias 7255 Vila Nova Campo Grande/MS Brasil

Mac Frios Rod. Antônio de Paiva Cantelmo, PR 566- KM 02, Zona Rural, Francisco Beltrão/PR Brasil

Marcho Farms Inc. 519 Allentown Road Franconia Pennsylvania 18924 USA Service(s) supplied

Animal Tissues / Derivatives

Animal Tissues / Derivatives

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: Date:

Issued To:

2019-12-11 St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA

CE 578287

Subcontractor:

Service(s) supplied

Midwest Sterilization Corporation 1204 Lenco Avenue Jackson Missouri 63755 USA

Oakey Abattoir Lot 1, Oakey Connection Road, Oakey QLD 4401 Australia

P&N Packaging Inc. 11627 Route 187 Wyalusing Pennsylvania 18853 USA ETO Sterilization

Animal Tissues / Derivatives

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: Date:

Issued To:

2019-12-11 St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA

CE 578287

Subcontractor:

Service(s) supplied

Phillips-Medisize, LLC 705 Wisconsin Drive New Richmond Wisconsin 54017 USA Manufacture

Crucial Supplier

ETO Sterilization

POCO Graphite, Inc. an Entegris Company 300 Old Greenwood Road Decatur Texas 76234 USA

Quality Central de Esterilização Estrada Celso Charur, i23 Aracoiaba de Serra Sao Paulo 18190-000 Brasil

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Page 8 of 14





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: Date:

Issued To:

2019-12-11 St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA

CE 578287

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

Sioux-Preme Packing Company 4241 U.S. 75 Ave Sioux Center Iowa 1250 USA Animal Tissues / Derivatives

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: Date:

Issued To:

2019-12-11 St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA

CE 578287

Subcontractor:

Service(s) supplied

Manufacture

St. Jude Medical 14901 DeVeau Place Minnetonka Minnesota 55345-2126 USA

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

St. Jude Medical Brasil Ltda. Rua Professor Jose Vierra de Mendonca 1301 Bairro Engenho Nogueira Pampulha, Belo Horizonte Minas Gerais 31.310-026 Brasil S.

Final Inspection Labelling Manufacture Moist Heat Sterilization Packaging

Manufacture

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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: Date:

Issued To:

2019-12-11 St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA

CE 578287

Subcontractor:

St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem Belgium

St. Jude Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2 Zona Franca Coyol El Coyol, Alajuela Costa Rica

St. Jude Medical PR LLC Caguas West Industrial Park Lot 20 Caguas 00725 Puerto Rico Service(s) supplied

EU Representative Labelling Packaging

Manufacture

Final Inspection Manufacture Moist Heat 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: Date:

Issued To:

2019-12-11 St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA

CE 578287

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

Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA **ETO Sterilization**

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: Date:

Issued To:

2019-12-11 St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA

CE 578287

Subcontractor:

State Road 690

Vega Alta 00692 Puerto Rico Service(s) supplied

Sterigenics US, LLC 5725 West Harold Gatty Drive Salt Lake City Utah 84116 USA

Steris Isomedix Puerto Rico LLC

KM 1.7 Barrio Sabana Hoyos

ETO Sterilization

Gamma Irradiation

USA Teys Australia Southern, Tamworth Phoenix street Tamworth, NSW 2340 Australia

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: Date: Issued To:

2019-12-11 St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA

CE 578287

Subcontractor:

Vascutek Limited Newmains Avenue Inchinnan PA4 9RR United Kingdom Service(s) supplied

Animal Tissues / Derivatives Manufacture

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Page 14 of 14





EC Certificate - Full Quality Assurance System Certificate History

Certificate No: Date:

Issued To:

CE 578287 2019-12-11 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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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 Certificate History

Certificate No: Date: CE 578287 2019-12-11

Issued To:

2019-12-11 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.

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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.





EC Certificate - Full Quality Assurance System Certificate History

Certificate	No:
Date:	

Issued To:

CE 578287 2019-12-11 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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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.





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.

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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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This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. 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.

Certificate No: **FM 558476**

Location

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

St. Jude Medical Brasil Ltda. Rua Professor Jose Vieira de Mendonca 1301 Bairro Engenho Nogueira Pampulha, Belo Horizonte Minas Gerais 31.310-026 Brasil **Registered Activities**

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.

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

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. 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.





CERTIFICATE



This is to certify that



SANTE INTERNATIONAL S.A.

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

has implemented and maintains a Quality Management System.

Scope:

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

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

ISO 9001 : 2015

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



DQS GmbH

Markus Bleher Managing Director







Annex to certificate Registration No. 497269 QM15

SANTE INTERNATIONAL S.A.

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

Location

075906 Sante International SA Sos. Mihai Bravu nr. 7, bl. P37-P37A, sector 2 021303 Bucuresti Romania

497270 Sante International SA Str. Pupitrului, nr. 81, sect. 3 033036 Bucuresti Romania

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.

Scope

31050284 Sante International SA Calea Dorobantilor, nr. 111 400609 Cluj-Napoca Romania

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.

Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory

reagents, cardiovascular surgery devices.

Consulting for state and private medical units.

Storage of medical and laboratory equipment,

service for medical and laboratory equipment.

Consulting for state and private medical units.

reagents, cardiovascular surgery devices,

disinfectants, laboratory

Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.



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