

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: <ul style="list-style-type: none">• Aortic – 60240• Mitral - 60241 Valved Grafts: <ul style="list-style-type: none">• Aortic - 60423 Annuloplasty Rings: <ul style="list-style-type: none">• 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		
---	<ul style="list-style-type: none"> • 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**

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

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

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

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

A member of BSI Group of Companies.

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 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**

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Number	Device Name	Intended Purpose per IFU
Class IIa		
MD0106, MDS7006	Mechanical Heart Valve Leaflet Tester – Related Accessories	---
MD0106	<ul style="list-style-type: none"> • 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**

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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 Distrito 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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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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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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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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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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177 County Road B East
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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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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

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Subcontractor:

Service(s) supplied

Rio Branco Alimentos S.A. (Pif Paf)
BR 365 Km 455,
Patrocínio/MG
Brasil

Animal Tissues / Derivatives

Seara Alimentos Ltda
Rua Tranquilo Damo,
209 -Santo Antonio,
Frederico Westphalen/RS
Brasil

Animal Tissues / Derivatives

Sioux-Preme Packing Company
4241 U.S. 75 Ave
Sioux Center
Iowa
1250
USA

Animal Tissues / Derivatives

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

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

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USA

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

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EC Certificate - Full Quality Assurance System

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

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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

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

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07 March 2019	7780704	Traceable to NB 0086.
07 May 2019	9752176	Addition of Sterigenics US, LLC, Salt Lake City, Utah USA as a significant subcontractor for ETO Sterilization.
03 December 2019	9688437	Addition of Isomedix Operations Inc. (Steris), Minneapolis USA as a significant subcontractor for ETO sterilization, following inadvertent deletion.
Current	9775758	<p>Certificate Renewal. Removal of Pericardial Patches from the scope. Addition of product table. Removal of discontinued animal tissue suppliers: Greater Omaha Packaging Company, Frigorifico Argus Ltda, Frigorifico K-Celet Alimentos, Primaz Frigorifico Ltda and W&G Marketing Company.</p> <p>Addition of Abbott Medical Plymouth Site as a subcontractor for Manufacture.</p> <p>Addition of Midwest Sterilization Corporation as a subcontractor for ETO sterilization.</p> <p>Change subcontractor name 'SBR Suinos Brazil Ltda' to 'Agrodanieli Indústria e Comércio Ltda'.</p> <p>Additional minor alignments of subcontractor name and addresses with ISO certificates.</p>