

Epic™ Stented Tissue Valve with Linx™ AC Technology

Mitral Stented Valves

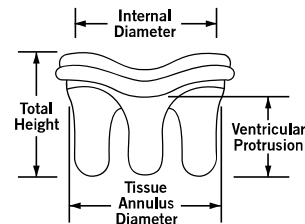
Product Highlights

- Identical in design to the Biocor™ stented tissue valve which delivers proven 20 year durability results^{3,4}
- Includes Linx AC Technology which is designed to improve long-term performance and valve durability*
- Three separate porcine leaflets are matched to optimize leaflet coaptation and reduce stress
- The outflow edge is covered with a pericardial shield, providing a tissue-to-tissue interface to reduce the risk of abrasion
- FlexFit™ mitral valve holder provides stent deflection (ratcheting), which reduces the potential for suture looping and maximizes visibility and access to the valve cuff
- Low combined valve and holder height facilitates minimally invasive surgical procedures
- Low profile design reduces the risk of LV outflow tract obstruction
- FlexFit stent reduces leaflet stress, adapts easily to annulus to enhance knot positioning, and returns stent posts to original shape after deflection
- Short 2 x 10 second rinse time

Ordering Information

Contents: Mitral Stented Tissue Valve (1 unit per box)

Model/Reorder Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (mm)	Ventricle Protusion (mm)	Total Height (mm)
E100-25M	25	25	23	9	16
E100-27M	27	27	25	9	17
E100-29M	29	29	27	10	19
E100-31M	31	31	29	10	20
E100-33M	33	33	31	11	20



*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.



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, and Commission Regulation (EU) 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: Porcine Bioprosthetic Heart Valve

Product Name(s): Biocor™ Aortic Valve
Biocor™ Mitral Valve
Epic™ Aortic Valve
Epic™ Mitral Valve
Epic™ Supra Valve

Model Number(s): See attached list

Classification: Class III per Annex IX, Rule 8 & 17

GMDN Code(s): 60242 (Aortic Valve)
60244 (Mitral Valve)

Annex II, Clause 3 Certificate Certificate No: CE 578287
Expiration Date: 26 May, 2024

Signature: 

Jeff Sturm
Associate Director, Regulatory Affairs

17 DEC 19

Date



SJM Declaration of Conformity

EC Design Examination Certificate Biocor /
Epic / Epic Supra Valve

Certificate No: CE 617865
Expiration Date: 26 May, 2024

Applicable Quality System Standards:

ISO 13485

Notified Body:

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
Netherlands

Notified Body Number:

2797

Manufacturing Facilities:

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
Belo Horizonte, Minas Gerais 31.310-260, Brasil

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

Signature:



Jeff Sturm
Associate Director, Regulatory Affairs

Date



17 DEC 19



SJM Declaration of Conformity

Product Name	Model Number		Original CE Mark Date
	Aortic	Mitral	
Biocor Valve	B100-21A B100-23A B100-25A B100-27A B100-29A	B100-25M B100-27M B100-29M B100-31M B100-33M	13 June, 2007
Epic Valve	E100-21A E100-23A E100-25A E100-27A E100-29A	E100-25M E100-27M E100-29M E100-31M E100-33M	13 June, 2007
Epic Supra Valve	ESP100-19 ESP100-21 ESP100-23 ESP100-25 ESP100-27 ESP100-29	N/A	13 June, 2007

Signature: 
 Jeff Sturm
 Associate Director, Regulatory Affairs

17 DEC 19
 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**

Date: **2019-12-11**

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

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Page 2 of 4

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

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

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

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

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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Page 3 of 4

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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	<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**

Date: **2019-12-11**

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

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Page 4 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.

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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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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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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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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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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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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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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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EC Certificate - Full Quality Assurance System

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

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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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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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EC Certificate - Full Quality Assurance System

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

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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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

List of Significant Subcontractors

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 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**
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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 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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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:

Vascutek Limited
Newmains Avenue
Inchinnan
PA4 9RR
United Kingdom

Service(s) supplied

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

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

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

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

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A member of BSI Group of Companies.

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 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.

EC Design-Examination Certificate

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

No. CE 617865
Issued To: **St. Jude Medical**
177 County Road B East
St Paul
Minnesota
55117
USA

In respect of:

Biocor™, Epic™ and Epic™ Supra Heart Valves

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC Annex II Section 4 and Regulation 722/2012. The design conforms to the requirements of this directive and regulation. 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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2014-12-01**

Date: **2019-11-25**

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

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Page 1 of 6

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, 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 Design-Examination Certificate

Supplementary Information to CE 617865

Issued To:

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

Biocor Valve

Catalogue Number	Device Name	Model Type	Intended Purpose	Classification
B100-21A	Biocor Valve	Aortic Model Number	Biocor™ and Epic™ valves are indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic and/or mitral heart valve. Biocor and Epic valves may also be used as replacements for previously implanted aortic and/or mitral prosthetic heart valves.	Class III
B100-23A	Biocor Valve	Aortic Model Number		Class III
B100-25A	Biocor Valve	Aortic Model Number		Class III
B100-27A	Biocor Valve	Aortic Model Number		Class III
B100-29A	Biocor Valve	Aortic Model Number		Class III
B100-25M	Biocor Valve	Mitral Model Number		Class III
B100-27M	Biocor Valve	Mitral Model Number		Class III
B100-29M	Biocor Valve	Mitral Model Number		Class III
B100-31M	Biocor Valve	Mitral Model Number		Class III
B100-33M	Biocor Valve	Mitral Model Number		Class III

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Epic Valve

Catalogue Number	Device Name	Model Type	Intended Purpose	Classification
E100-21A	Epic Valve	Aortic Model Number	Biocor™ and Epic™ valves are indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic and/or mitral heart valve. Biocor and Epic valves may also be used as replacements for previously implanted aortic and/or mitral prosthetic heart valves.	Class III
E100-23A	Epic Valve	Aortic Model Number		Class III
E100-25A	Epic Valve	Aortic Model Number		Class III
E100-27A	Epic Valve	Aortic Model Number		Class III
E100-29A	Epic Valve	Aortic Model Number		Class III
E100-25M	Epic Valve	Mitral Model Number		Class III
E100-27M	Epic Valve	Mitral Model Number		Class III
E100-29M	Epic Valve	Mitral Model Number		Class III
E100-31M	Epic Valve	Mitral Model Number		Class III
E100-33M	Epic Valve	Mitral Model Number		Class III

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Epic Supra Valve

Catalogue Number	Device Name	Model, Type	Intended Purpose	Classification
ESP100-19	Epic Supra Valve	Aortic Supra-annular Model Number	The Epic™ Supra valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic heart valve. The Epic Supra valve may also be used as a replacement for a previously implanted aortic prosthetic heart valve.	Class III
ESP100-21	Epic Supra Valve	Aortic Supra-annular Model Number		Class III
ESP100-23	Epic Supra Valve	Aortic Supra-annular Model Number		Class III
ESP100-25	Epic Supra Valve	Aortic Supra-annular Model Number		Class III
ESP100-27	Epic Supra Valve	Aortic Supra-annular Model Number		Class III
ESP100-29	Epic Supra Valve	Aortic Supra-annular Model Number		Class III

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Certificate History

Date	Reference Number	Action
01 December 2014	10149977	First issue - Transfer from another Notified Body.
03 August 2015	10156419	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.
25 August 2015	10156926	Dupont Tyvek Medical Transition Project Update.
30 March 2017	10165131	Addition of Agropecuária Bolson Ltda., Irmãos do Valle and W&G Marketing Company as animal tissue suppliers for the Biocor, Epic and Epic Supra Heart Valves.
26 October 2017	8694459	Addition of Sterigenics Costa Rica as ETO sterilizer for the jar set assemblies.
14 March 2018	8852511	Addition of ATEX Technologies Inc, as an alternate fabric supplier.
07 March 2019	7780704	Traceable to NB 0086.

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Date	Reference Number	Action
Current	9775426	Certificate Renewal. Administrative update to product table format.



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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Holds Certificate No:

FM 558476

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

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



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2009-12-24

Latest Revision Date: 2020-01-13

Effective Date: 2020-02-29

Expiry Date: 2023-02-28

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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

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](http://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.

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.

