

Masters Series Mechanical Heart Valve (Page 1 of 3)

Mitral Valves

Product Highlights

- Pyrolytic carbon leaflets and orifice ring offer exceptional durability and increased thromboresistance¹⁰
- 85 degree leaflet opening angle offers improved laminar flow and reduces turbulence²⁻⁴
- Controlled torque rotation mechanism allows for easy rotation and intraoperative adjustment
- St. Jude Medical heart valves are MR conditional⁵

Ordering Information

Contents: Mitral Valve (1 unit per box)

Model/Reorder Number	Tissue Annulus Diameter (mm)	Valve Orifice Inner Diameter (mm)	Geometric Orifice Area (cm ²)	Cuff Style
19MJ-501	19	14.8	1.63	Standard
21MJ-501	21	16.7	2.06	Standard
23MJ-501	23	18.6	2.55	Standard
25MJ-501	25	20.4	3.09	Standard
27MJ-501	27	22.5	3.67	Standard
29MJ-501	29	24.2	4.41	Standard
31MJ-501	31	26.1	5.18	Standard
33MJ-501	33	26.1	5.18	Standard
35MJ-501	35	26.1	5.18	Standard
37MJ-501	37	26.1	5.18	Standard



Product referenced is approved for CE Mark.

Masters Series Mechanical Heart Valve

(Page 2 of 3)

Mitral Valves

Product Highlights

- Pyrolytic carbon leaflets and orifice ring offer exceptional durability and increased thromboresistance¹⁰
- 85 degree leaflet opening angle offers improved laminar flow and reduces turbulence²⁻⁴
- Controlled torque rotation mechanism allows for easy rotation and intraoperative adjustment
- The expanded mitral cuff has approximately 25% more cuff than the standard mitral cuff
- St. Jude Medical heart valves are MR conditional⁵

Ordering Information

Contents: Mitral Valve (1 unit per box)

Model/Reorder Number	Tissue Annulus Diameter (mm)	Valve Orifice Inner Diameter (mm)	Geometric Orifice Area (cm ²)	Cuff Style
19MECJ-502	19	14.8	1.63	Expanded
21MECJ-502	21	16.7	2.06	Expanded
23MECJ-502	23	18.6	2.55	Expanded
25MECJ-502	25	20.4	3.09	Expanded
27MECJ-502	27	22.5	3.67	Expanded
29MECJ-502	29	24.2	4.41	Expanded
31MECJ-502	31	26.1	5.18	Expanded
33MECJ-502	33	26.1	5.18	Expanded



Product referenced is approved for CE Mark.

SJM Declaration of Conformity Mechanical Heart Valves and Valved Grafts

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):	SJM Masters Series (Rotatable) SJM Regent Valve (Rotatable) SJM™ Masters Series Aortic Valved Graft with Hemashield™ graft technology SJM Masters HP™ Valved Graft with Gelweave Valsalva™ Technology Rigid Saddle Ring St. Jude Medical Seguin Annuloplasty Ring Tailor Annuloplasty Ring Tailor Annuloplasty Band
Model Number(s):	<i>See attached.</i>
Classification:	Mechanical Heart Valves: Class III per MDD, Annex IX, rule 8 Valved Grafts: Class III per MDD, Annex IX, rule 17 Annuloplasty Rings: Class III per MDD, Annex IV, rule 8
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 Mechanical Heart Valves and Valved Grafts

Original CE Mark Date: *See attached.*

FQA Certificate No and expiration date: Certificate No: CE 578287
Expiration Date: 26 May 2024

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

Applicable Quality System Standards: ISO 13485: 2016

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

Notified Body Number: 2797

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

Signature:



Angie Riascos
Manager, Regulatory Affairs

Digitally signed by
Angie Riascos
Date: 2020.05.20
08:56:59 -05'00'

20 May, 2020
Issue Date

Mechanical Valve Products

SJM Masters Series (Rotatable)

EC Certificate No.: CE 578290

Expiration Date: 17 February 2024

Aortic Hemodynamic Plus (HP), size 15mmAHPJ-505
Original CE Mark Date: 21 Aug 2019

Mitral Hemodynamic Plus (HP), size 15mmMHPJ-505
Original CE Mark Date: 21 Aug 2019

Aortic Hemodynamic Plus (HP), sizes 17-27mmAHPJ-505
Original CE Mark Date: 13 Sep 1995

Aortic Standard Cuff-Polyester, sizes 19-31mmAJ-501
Mitral Standard Cuff-Polyester, sizes 19-33mmMJ-501
Aortic Expanded Cuff-Polyester, sizes 19-31mmAECJ-502
Mitral Expanded Cuff-Polyester, sizes 19-33mmMECJ-502
Mitral Hemodynamic Plus (HP), sizes 17-27mmMHPJ-505
Aortic Expanded Hemodynamic Plus (HP), sizes 17-27mmAEHPJ-505
Original CE Mark Date: 30 Jan 1996

Mitral Standard Cuff-Polyester, sizes 35-37mmMJ-501
Original CE Mark Date: 02 Nov 1998

Aortic Standard PTFE cuff, sizes 19-31mmATJ-503
Mitral Standard PTFE cuff, sizes 19-33mmMTJ-503
Mitral Expanded PTFE cuff, sizes 19-33mmMETJ-504
Original CE Mark Date: 31 Jul 1997

SJM Regent Valve (Rotatable)

EC Certificate No.: CE 578290

Expiration Date: 17 February 2024

Aortic standard cuff - polyester, sizes 17 - 29mmAGN-751
Aortic flex cuff - polyester, sizes 17-29mmAGFN-756
Original CE Mark Date: 27 Dec 1999

Valve Repair Products

Rigid Saddle Ring

EC Certificate No.: CE 578289

Expiration Date: 30 March 2024

Rigid Saddle Ring, sizes 24 – 34mmRSAR-(size)
Original CE Mark Date: 24 Feb 2005

St. Jude Medical Seguin Annuloplasty Ring

EC Certificate No.: CE 578288

Expiration Date: 14 May 2024

St. Jude Medical Seguin Annuloplasty Ring, sizes 24-40mmSARP-(size)

Original CE Mark Date: 28 Jan 2002

Tailor Annuloplasty Ring

EC Certificate No.: CE 578289

Expiration Date: 30 March 2024

Tailor Annuloplasty Ring, sizes 25-35mm.....TARP-(size)

Original CE Mark Date: 28 Jan 2002

Tailor Annuloplasty Band

EC Certificate No.: CE 578289

Expiration Date: 30 March 2024

Tailor Annuloplasty Band, sizes 25-35mm.....TAB-(size)

Original CE Mark Date: 24 Oct 2002

Valved Grafts¹

SJM™ Masters Series Aortic Valved Graft with Hemashield™ graft technology

EC Certificate No.: CE 578292

Expiration Date: 26 May 2024

SJM™ Masters Series Aortic Valved Graft with Hemashield™ graft technology

Sizes 19 – 33mm.....CAVGJ-514 00

Original CE Mark Date: 04 May 2001

SJM Masters HP™ Valved Graft with Gelweave Valsalva™ Technology

EC Certificate No. : CE 578291

Expiration Date: 26 May 2024

SJM Masters HP™ Valved Graft with Gelweave Valsalva™ Technology

Sizes 19 – 29mmVAVGJ-515

Original CE Mark Date: 19 Aug 2005

¹ These products containing bovine material conform to Regulation 722/2012

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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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 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

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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

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

List of Significant Subcontractors

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

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

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

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EC Certificate - Full Quality Assurance System

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

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

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Date: **2019-12-11**
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

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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 Cecília
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

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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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
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

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
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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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
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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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

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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
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

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

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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
St. Jude Medical Puerto Rico LLC Lot A Interior - #2 Rd Km. 67.5 Santana Industrial Park Arecibo Puerto Rico 00612 USA	ETO Sterilization
Sterigenics Costa Rica S.R.L. Zona Franca Propark Calle Principal, Edificio 10, El Coyol Alajuela 20101 Costa Rica	ETO Sterilization
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA	ETO Sterilization

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

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

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

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

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

Subcontractor:

Service(s) supplied

Vascutek Limited
 Newmains Avenue
 Inchinnan
 PA4 9RR
 United Kingdom

Animal Tissues / Derivatives
Manufacture

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EC Certificate - Full Quality Assurance System

Certificate History

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

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

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Page 1 of 3

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Certificate History

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

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

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Page 2 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

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

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

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Certificate History

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

Date	Reference Number	Action
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>

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Page 3 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

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

A member of BSI Group of Companies.

EC Design-Examination Certificate

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

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

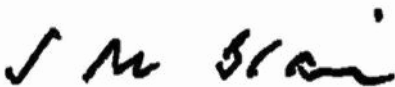
**St. Jude Medical
177 County Road B East
St Paul
Minnesota
55117
USA**

In respect of:

**Nonactive implants, Mechanical Heart Valves:
SJM Regent™ Valve (Rotatable)
SJM™ Masters Series (Rotatable)**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

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

Date: **2019-03-01**

Expiry Date: **2024-02-17**

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Page 1 of 9

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

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

EC Design-Examination Certificate

Supplementary Information to CE 578290

Issued To:

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

Product: Nonactive implants, Mechanical Heart Valves:

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
17AGN-751	SJM Regent™ Valve (Rotatable)	17 mm Standard Polyester Cuff	Intended to replace the native aortic heart valve or previously implanted prosthetic valves.	Class III
19AGN-751		19 mm Standard Polyester Cuff		
21AGN-751		21 mm Standard Polyester Cuff		
23AGN-751		23 mm Standard Polyester Cuff		
25AGN-751		25 mm Standard Polyester Cuff		
27AGN-751		27 mm Standard Polyester Cuff		
29AGN-751		29 mm Standard Polyester Cuff		
17AGFN-756	SJM Regent™ Valve (Rotatable)	17 mm Standard Polyester FlexCuff™		
19AGFN-756		19 mm Standard Polyester FlexCuff™		
21AGFN-756		21 mm Standard Polyester FlexCuff™		
23AGFN-756		23 mm Standard Polyester FlexCuff™		
25AGFN-756		25 mm Standard Polyester FlexCuff™		
27AGFN-756		27 mm Standard Polyester FlexCuff™		
29AGFN-756		29 mm Standard Polyester FlexCuff™		

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

Date: **2019-03-01**

Expiry Date: **2024-02-17**

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Page 2 of 9

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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
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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		

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

Date: **2019-03-01**

Expiry Date: **2024-02-17**

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Page 3 of 9

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EC Design-Examination Certificate

Supplementary Information to CE 578290

Issued To:

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
17AHPJ-505	SJM™ Masters Series (Rotatable)	17 mm Aortic / HP Polyester Cuff	Intended to replace the native aortic heart valve or previously implanted prosthetic valves.	Class III
19AHPJ-505		19 mm Aortic / HP Polyester Cuff		
21AHPJ-505		21 mm Aortic / HP Polyester Cuff		
23AHPJ-505		23 mm Aortic / HP Polyester Cuff		
25AHPJ-505		25 mm Aortic / HP Polyester Cuff		
27AHPJ-505		27 mm Aortic / HP Polyester Cuff		
17AEHPJ-505	SJM™ Masters Series (Rotatable)	17 mm Aortic / Expanded HP Polyester Cuff	Intended to replace the native aortic heart valve or previously implanted prosthetic valves.	Class III
19AEHPJ-505		19 mm Aortic / Expanded HP Polyester Cuff		
21AEHPJ-505		21 mm Aortic / Expanded HP Polyester Cuff		
23AEHPJ-505		23 mm Aortic / Expanded HP Polyester Cuff		
25AEHPJ-505		25 mm Aortic / Expanded HP Polyester Cuff		
27AEHPJ-505		27 mm Aortic / Expanded HP Polyester Cuff		

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

Date: **2019-03-01**

Expiry Date: **2024-02-17**

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Page 4 of 9

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EC Design-Examination Certificate

Supplementary Information to CE 578290

Issued To:

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
19ATJ-503	SJM™ Masters Series (Rotatable)	19 mm Aortic / PTFE Cuff	Intended to replace the native aortic heart valve or previously implanted prosthetic valves	Class III
21ATJ-503		21 mm Aortic / PTFE Cuff		
23ATJ-503		23 mm Aortic / PTFE Cuff		
25ATJ-503		25 mm Aortic / PTFE Cuff		
27ATJ-503		27 mm Aortic / PTFE Cuff		
29ATJ-503		29 mm Aortic / PTFE Cuff		
31ATJ-503		31 mm Aortic / PTFE Cuff		
19MJ-501	SJM™ Masters Series (Rotatable)	19 mm Mitral / Polyester Cuff	Intended to replace the native mitral heart valve or previously implanted prosthetic valves	Class III
21MJ-501		21 mm Mitral / Polyester Cuff		
23MJ-501		23 mm Mitral / Polyester Cuff		
25MJ-501		25 mm Mitral / Polyester Cuff		
27MJ-501		27 mm Mitral / Polyester Cuff		
29MJ-501		29 mm Mitral / Polyester Cuff		
31MJ-501		31 mm Mitral / Polyester Cuff		
33MJ-501		33 mm Mitral / Polyester Cuff		
35MJ-501		35 mm Mitral / Polyester Cuff		
37MJ-501		37 mm Mitral / Polyester Cuff		

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

Date: **2019-03-01**

Expiry Date: **2024-02-17**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

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EC Design-Examination Certificate

Supplementary Information to CE 578290

Issued To:

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
19MECJ-502	SJM™ Masters Series (Rotatable)	19 mm Mitral / Expanded Polyester Cuff	Intended to replace the native mitral heart valve or previously implanted prosthetic valves	Class III
21MECJ-502		21 mm Mitral / Expanded Polyester Cuff		
23MECJ-502		23 mm Mitral / Expanded Polyester Cuff		
25MECJ-502		25 mm Mitral / Expanded Polyester Cuff		
27MECJ-502		27 mm Mitral / Expanded Polyester Cuff		
29MECJ-502		29 mm Mitral / Expanded Polyester Cuff		
31MECJ-502		31 mm Mitral / Expanded Polyester Cuff		
33MECJ-502		33 mm Mitral / Expanded Polyester Cuff		
17MHPJ-505	SJM™ Masters Series (Rotatable)	17 mm Mitral / HP Polyester Cuff	Intended to replace the native mitral heart valve or previously implanted prosthetic valves	Class III
19MHPJ-505		19 mm Mitral / HP Polyester Cuff		
21MHPJ-505		21 mm Mitral / HP Polyester Cuff		
23MHPJ-505		23 mm Mitral / HP Polyester Cuff		
25MHPJ-505		25 mm Mitral / HP Polyester Cuff		
27MHPJ-505		27 mm Mitral / HP Polyester Cuff		

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

Date: **2019-03-01**

Expiry Date: **2024-02-17**

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EC Design-Examination Certificate

Supplementary Information to CE 578290

Issued To:

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
19MTJ-503	SJM™ Masters Series (Rotatable)	19 mm Mitral / PTFE Cuff	Intended to replace the native mitral heart valve or previously implanted prosthetic valves	Class III
21MTJ-503		21 mm Mitral / PTFE Cuff		
23MTJ-503		23 mm Mitral / PTFE Cuff		
25MTJ-503		25 mm Mitral / PTFE Cuff		
27MTJ-503		27 mm Mitral / PTFE Cuff		
29MTJ-503		29 mm Mitral / PTFE Cuff		
31MTJ-503		31 mm Mitral / PTFE Cuff		
33MTJ-503		33 mm Mitral / PTFE Cuff		
19METJ-504	SJM™ Masters Series (Rotatable)	19 mm Mitral / Expanded PTFE Cuff	Intended to replace the native mitral heart valve or previously implanted prosthetic valves	Class III
21METJ-504		21 mm Mitral / Expanded PTFE Cuff		
23METJ-504		23 mm Mitral / Expanded PTFE Cuff		
25METJ-504		25 mm Mitral / Expanded PTFE Cuff		
27METJ-504		27 mm Mitral / Expanded PTFE Cuff		
29METJ-504		29 mm Mitral / Expanded PTFE Cuff		
31METJ-504		31 mm Mitral / Expanded PTFE Cuff		
33METJ-504		33 mm Mitral / Expanded PTFE Cuff		

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

Date: **2019-03-01**

Expiry Date: **2024-02-17**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

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EC Design-Examination Certificate

Supplementary Information to CE 578290

Issued To:

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

Certificate History

Date	Reference Number	Action
30 January 2012	10130170	First Issue of mirror certificate to CE 544669
10 November 2013	10144187	Addition of InterVascular SAS (Maquet) La Ciotat, France facility as fabric supplier.
23 January 2014	10145129	Implementation of new sealing plate design and change in lid sealing parameters for SJM Mechanical Heart Valves and Annuloplasty Rings packaging.
14 February 2014	10145174	Certificate renewal. 70 product codes removed from the scope of the certificate.
25 February 2014	10144864	Updated Magnetic Resonance (MR) safety information in labelling.
28 March 2014	10146037	Change from Helium to Argon gas used in the pyrolytic carbon coating manufacturing process.
22 July 2014	10149696	Transfer of Heart Valve Components Manufacturing Steps to the St. Jude Medical, Caguas, Puerto Rico Facility.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.

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

Date: **2019-03-01**

Expiry Date: **2024-02-17**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

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

EC Design-Examination Certificate

Supplementary Information to CE 578290

Issued To:

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

Certificate History

Date	Reference Number	Action
26 October 2017	8795241	Change to an orifice graphite substrate specification. Removal of all products references XXA-101 and XXM-101.
Current	9645156	Certificate Renewal. Changed the certificate format with new tables.

First Issued: **2012-01-30**Date: **2019-03-01**Expiry Date: **2024-02-17**

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Page 9 of 9

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

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

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

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

St. Jude Medical PR, LLC
Caguas West Industrial Park
B Street, Lot 20
Caguas
00725
Puerto Rico

Holds Certificate No:

FM 578534

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

Manufacturing and distribution of Annuloplasty Ring and Mechanical Heart Valves and manufacturing of Vascular Closure Device.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2011-10-17

Latest Revision Date: 2019-02-18

Effective Date: 2019-02-18

Expiry Date: 2022-02-17

Page: 1 of 1



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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.