bsi.

By Royal Charter

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, Pericardial Patches, 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 0086):

Pietro Foschi - Strategic Delivery Director

First Issued: **30 January 2012** Date: **01 December 2014** Expiry Date: **15 December 2019**

...making excellence a habit.

bsi.

By Royal Charter

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: **01 December 2014**

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

Subcontractor:	Service(s) supplied
Abbyland PorkPak Inc. 539 North Meridian Street Curtiss Wisconsin 54422 USA	**Animal substances**
BRF - Brasil Foods S.A. Rua Senador Atilio Fontana, 86, Concordia/SC Brasil	**Animal substances**
Frigoestrela S.A. Estrada Vicinal Romão Lopes Martins, S/N - KM 0+700M, Jardim Marabá, Tupã/SP Brasil	**Animal substances**
Frigorifico Argus Ltda BR 376 KM 621, São José do Pinhais/PR Brasil	**Animal substances**

...making excellence a habit.

bsi.

By Royal Charter

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: **01 December 2014**

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

Subcontractor:	Service(s) supplied
Frigorifico Miolar Ltda Estrada para Fazenda Mazurana S/N, Dois Vizinhos/PR Brasil	**Animal substances**
Frimesa Cooperativa Central Rua Bahia, 159, Medianeira/PR Brasil	**Animal substances**
Heraeus Medical Components 5030 Centerville Road St. Paul Minnesota 55127-2203 USA	**Manufacture**
InterVascular SAS Z.I Athelia 1 13705 La Ciotat Cedex France	**Manufacture**

...making excellence a habit.

bsi.

By Royal Charter

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: 01 December 2014

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 substances**
JBS S.A. Parque Industrial S/N Distrito Industrial, LINS/SP Brasil	**Animal substances**
JBS S.A. Rodovia, GO 164, Km 167 S/N, Zona Rural, Mozarlândia/GO Brasil	**Animal substances**
JBS S.A. Rua Principal S/N, Vila Miisa, Ituiutaba/MG Brasil	**Animal substances**

...making excellence a habit.

bsi.

By Royal Charter

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: **01 December 2014**

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

Subcontractor:	Service(s) supplied
Mac Frios Rod. Antônio de Paiva Cantelmo, PR 566- KM 02, Zona Rural, Francisco Beltrão/PR Brasil	**Animal substances**
Maquet Cardiovascular 45 Barbour Pond Drive Wayne NJ 07470 USA	**Animal substances** **Manufacture**
Marcho Farms Inc. 519 Allentown Road Franconia Pennsylvania 18924 USA	**Animal substances**
Oakey Abattoir Lot 1, Oakey Connection Road, Oakey QLD 4401 Australia	**Animal substances**

...making excellence a habit.

bsi.

By Royal Charter

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: 01 December 2014

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

Subcontractor:	Service(s) supplied
Phillips Plastics Corporation Phillips Medical New Richmond 705 Wisconsin Drive New Richmond Wisconsin 54017 USA	**Manufacture**
Rio Branco Alimentos S.A. (Pif Paf) BR 365 Km 455, Patrocínio/MG Brasil	**Animal substances**
Seara Alimentos Ltda Rua Tranquilo Damo, 209 -Santo Antonio, Frederico Westphalen/RS Brasil	**Animal substances**

...making excellence a habit.

bsi.

By Royal Charter

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: **01 December 2014**

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

Subcontractor:	Service(s) supplied
Sioux-Preme Packing Company 4241 U.S. 75 Ave Sioux Center Iowa 51250 USA	**Animal substances**
St. Jude Medical Brasil Ltda. Rua Professor Jose Vieira de Mendonca, 1301 Bairro Engenho Nogueira Belo Horizonte Minas Gerais 33.310-260 Brasil	**Manufacture**
St. Jude Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2, Zona Franca Coyol El Coyol Alajuela Costa Rica	**Manufacture**

making excellence a habit.

bsi.

By Royal Charter

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: 01 December 2014

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

Subcontractor:	Service(s) supplied
St. Jude Medical PR LLC Caguas West Industrial Park Lot 20 and 21 Caguas 00726 Puerto Rico	**Final Inspection** **Manufacture** **Moist Heat Sterilization**
St. Jude Medical Puerto Rico LLC Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park Arecibo PR 00612 USA	**ETO Sterilization**
St. Jude Medical 14901 DeVeau Place Minnetonka Minnesota 55345-2126 USA	**Manufacture**

making excellence a habit.

bsi.

By Royal Charter

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: **01 December 2014**

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

Subcontractor:	Service(s) supplied
St. Jude Medical 177 County Road B East St. Paul Minnesota 55117 USA	**Distribution** **Final Inspection** **Labelling** **Manufacture** **Moist Heat Sterilization** **Packaging**
St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem Belgium	**EU Representative**
Steris Corporation Isomedix Services State Road 690 KM1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico	**Gamma Irradiation**

..making excellence a habit.

bsi.

By Royal Charter

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: 01 December 2014

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

Subcontractor:	Service(s) supplied
STERIS Isomedix Services, Inc. 2072 Southport Road Spartanburg SC 29306 USA	**ETO Sterilization**
STERIS Isomedix Services 380 90th Avenue NW Minneapolis Minnesota 55433 USA	**ETO Sterilization**
Teys Australia Southern, Tamworth Phoenix street Tamworth, NSW 2340 Australia	**Animal substances**

..making excellence a habit.

bsi.

By Royal Charter

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: **01 December 2014**

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

Subcontractor:	Service(s) supplied
Vascutek Limited Newmains Avenue Inchinnan Renfrewshire Scotland PA4 9RR United Kingdom	**Animal substances** **Manufacture**
W & G Marketing Co. 2824 Northridge Drive Sidney, IA USA	**Animal substances**

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System
Certificate History

Certificate No: **CE 578287**

Date: **01 December 2014**

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.

...making excellence a habit™

bsi.

By Royal Charter

EC Design-Examination Certificate

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

No. **CE 617862**

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

In respect of:

Trifecta™ 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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2014-12-01** Date: **2017-10-26** Expiry Date: **2019-11-30**

...making excellence a habit.™

bsi.

By Royal Charter

EC Design-Examination Certificate

Suppiementary Information to CE 617862

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

Trifecta™ Valve

Tissue Annulus Diameter (mm)	Model Number
19	TF-19A
21	TF-21A
23	TF-23A
25	TF-25A
27	TF-27A
29	TF-29A

First Issued: **2014-12-01** Date: **2017-10-26** Expiry Date: **2019-11-30**

...making excellence a habit.™

bsi.

By Royal Charter

EC Design-Examination Certificate

Suppiementary Information to CE 617862

Issued To:

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

Trifecta™ Valve with Glide™ Technology

Tissue Annulus Diameter (mm)	Model Number
19	TFGT-19A
21	TFGT-21A
23	TFGT-23A
25	TFGT-25A
27	TFGT-27A
29	TFGT-29A

First Issued: **2014-12-01** Date: **2017-10-26** Expiry Date: **2019-11-30**

...making excellence a habit.

bsi.

By Royal Charter

EC Design-Examination Certificate

Suppiementary Information to CE 617862

Issued To:

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

Certificate History

Date	Reference Number	Action
01 December 2014	10149976	First issue. Transfer from another notified body.
08 July 2015	10153860	Addition of the US abattoir Greater Omaha Packaging Company as a Bovine Tissue Source for Trifecta™ Heart Valve.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
01 February 2016	10158815	Introduction of Trifecta GT.
03 December 2016	10164719	Shelf-life extension from 2 to 4 years.
30 March 2017	10165131	Addition of Agropecuária Bolson Ltda., Irmãos do Valle and W&G Marketing Company as animal tissue suppliers for the Trifecta Heart Valves.
28 July 2017	10169589	Addition of St. Jude Medical Brazil Manufacturing Site for Trifecta™ GT.
Current	8694459	Addition of Sterigenics Costa Rica as ETO sterilizer for the jar set assemblies.

First Issued: **2014-12-01** Date: **2017-10-26** Expiry Date: **2019-11-30**

...making excellence a habit.

ST. JUDE MEDICAL
MORE CONTROL LESS RISK

St. Jude Medical Inc. Global Headquarters
One St. Jude Medical Drive
St. Paul, MN 55117 USA
651 756 2000 Tel
651 756 3301 Fax

November 1, 2013

To Whom it May Concern:

I certify that this is a true and correct copy of a document.

Beatrice Evans

Beatrice Evans
Sr. Regulatory Affairs Specialist

State of: Minnesota
County of: Dakota

This document was acknowledged before me on November 1, 2013.

Deborah Edlund

Deborah Edlund, Notary Public
My Commission Expires: January 31, 2017

DEBORAH K EDLUND
Notary Public
State of Minnesota
My Commission Expires
January 31, 2017

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Annex II
Declaration of Conformity

St. Jude Medical (SJM), Cardiovascular Division 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 Directive 2003/32/EC.

Manufacturer Address:	St. Jude Medical, Inc. One Lillehei Plaza St. Paul, MN 55117 U.S.A.
European Representative:	St. Jude Medical Coordination Center BVBA The Corporate Village Da VincilLaan, 11 Box F1 1935 Zaventem, Belgium
Manufacturing Facility:	St. Jude Medical, Brasil Ltda. Rua Da Paisagem, 310B Vila de Serra Nova Lima, MG CEP 34.000-000, Brazil
Product Types:	Pericardial Bioprosthetic Heart Valve Porcine Bioprosthetic Heart Valve Bovine Pericardial Patch
Classification:	Class III per Annex IX, Rule 8 & 17
GMDN Code:	47471
Annex II, Clause 3:	Certificate: QS-0430 Certification No: 0430GB410130815 Expiration Date: June 14, 2018
Applicable Quality System Standards:	ISO 13485:2003 + AC:2007
EC Design Examination Certificate	Process No: PP-10031B Certificate No: 10031GB411120106B Expiration Date: November 23, 2016

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Notified Body: MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Notified Body Number: 0482

Products and Model Numbers:

Aortic, SJM Biocor™ Stented Pericardial Heart Valve, sizes 21 – 29mm..... B30-A
Mitral, SJM Biocor™ Stented Pericardial Heart Valve, sizes 25 – 35mm..... B30-M
Original CE Mark Date: November 23, 1995

Aortic, Biocor™ Valve, sizes 21 – 29mm..... B100-A
Mitral, Biocor™ Valve, sizes 25 – 33mm..... B100-M
Original CE Mark Date: June 13, 2007

Aortic, Epic™ Valve, sizes 21 – 29mm..... E100-A
Mitral, Epic™ Valve, sizes 25 – 33mm..... E100-M
Original CE Mark Date: June 13, 2007

Epic™ Supra Valve, sizes 19 – 29mm..... ESP100
Original CE Mark Date: June 13, 2007

SJM Biocor™ Bovine Pericardial Patch..... B40
Sizes: 5x4, 7x5, 10x6, 12.5x10, and 15x10 cm
Original CE Mark Date: November 23, 1995

Signature: _____ Issue Date: 3 Sep 13
Lisa Becker
Sr. Director, Regulatory Affairs

Annex II
Declaration of Conformity

St. Jude Medical (SJM), Cardiovascular and Ablation Technologies Division (CATD) hereby declare 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 Directive 2003/32/EC. All supporting documentation is retained under the premises of the CATD. 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: Bioprosthetic Heart Valve

Product Name(s): Trifecta™ Heart Valve

Model Number(s):

Product	Model Numbers		Original CE Mark Date
	Aortic	Mitral	
Trifecta Heart Valve	TF-19A TF-21A TF-23A TF-25A TF-27A TF-29A	N/A	04 March, 2010

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

GMDN Code(s): 60242

Annex II, Clause 3 Certificate Number and Expiration Date: Certificate No: CE 578287
Expiration Date: 15 December, 2019

EC Design Examination Certificate Certificate No: CE 617862
Expiration Date: 30 November, 2019

Applicable Quality System Standards: ISO 13485:2012 + AC:2012

Signature: **Place and Issue Date: St. Paul, Minnesota US**

Rashmi Bhushan
Senior Manager, Regulatory Affairs

December 8, 2016

ST. JUDE MEDICAL

Notified Body: BSI
Kitemark Court
Davy Avenue
Knowlhill, Milton Keynes
MK5 8PP UK

Notified Body Number: 0086

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
Barrio Engenho Nogueira
Belo Horizonte, MG
31.310-260, Brazil

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

Signature: **Place and Issue Date: St. Paul, Minnesota US**

Rashmi Bhushan
Senior Manager, Regulatory Affairs

December 8, 2016

90140679 ver. B Declaration of Conformity Template

This confidential document is the property of St. Jude Medical and shall not be reproduced, distributed or used without the express written consent of St. Jude Medical.

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

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 13485:2003 for the following scope:

Design, Development, and Manufacture of 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 ventricular assist device components.

For and on behalf of BSI:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 12/24/2009 Effective Date: 03/01/2017 Expiry Date: 02/28/2019

CMDCAS Recognized Registrar

...making excellence a habit.

Certificate No: **FM 558476**

Location	Registered Activities
St. Jude Medical 177 County Road B East St Paul Minnesota 55117 USA	Design, Manufacturing and Distribution of 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 ventricular assist device components.
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, tissue vascular prostheses and pericardial patch.

Original Registration Date: 12/24/2009 Effective Date: 03/01/2017 Expiry Date: 02/28/2019

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

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 13485:2003 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:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2011-10-17
Latest Revision Date: 2017-10-05

Effective Date: 2017-10-17
Expiry Date: 2019-02-28

...making excellence a habit.

Masters HP™ Mechanical Heart Valve Standard Cuff

Aortic Valves

Product Highlights

* Sewing cuff redesigned to facilitate supra-annular placement, allowing for an increase in orifice size for a given tissue annulus diameter
* Increased effective orifice area (EOA), lower pressure gradients and improved performance[1-3]
* 85 degree leaflet opening angle offers improved laminar flow and reduces turbulence[4-6]
* Controlled torque rotation mechanism allows for easy rotation and intraoperative adjustment
* St. Jude Medical heart valves are MR conditional[7]

Ordering Information

Contents: Aortic Valve (1 unit per box)

Model/Reorder Number	Tissue Annulus Diameter (mm)	Valve Orifice Inner Diameter (mm)	Geometric Orifice Area (cm²)	Effective Orifice Area[8] (cm²)	Cuff Style
17AHPJ-505	17	14.8	1.63	1.16	Standard
19AHPJ-505	19	16.7	2.06	1.51	Standard
21AHPJ-505	21	18.6	2.56	2.03	Standard
23AHPJ-505	23	20.4	3.09	2.59	Standard
25AHPJ-505	25	22.5	3.67	3.08	Standard
27AHPJ-505	27	24.2	4.41	3.73	Standard

1. Feng Z, Nakamura T, Fujimoto T, et al. [illegible] *Artificial Organs*. 2002 [illegible]
2. Smolkowitz T, Ameduri [illegible] et al. Evaluation technique for bileaflet mechanical valves. *J Heart Valve Dis*. 2002;11(2):275-82.
3. Vitale N, Caldarera I, Muneretto C, et al. Italian Multicenter Study Group for the St. Jude Medical Hemodynamic Plus Aortic Valve Prosthesis. Clinical evaluation of St. Jude Medical Hemodynamic Plus versus standard aortic valve prostheses: The Italian multicenter, prospective, randomized study. *J Thorac Cardiovasc Surg*. 2001;122(4):691-8.
4. [illegible] *Ann Thorac Surg*. [illegible]
5. [illegible] *J Thorac Cardiovasc Surg*. [illegible]
6. King, M, [illegible] *J Eng Med*. 1994;208:63-72.
7. St. Jude Medical MRI Safety Document.
8. Walker DK, Brendzel AM, Scotten LN. The new St. Jude Medical Regent [illegible] *J Heart Valve Dis*. [illegible]

[illegible]

Regent™ Mechanical Heart Valve Standard Cuff

Aortic Valves

Product Highlights

* Designed to deliver exceptional hemodynamics and performance while maintaining low complication rates, structural integrity and durability
* Single-digit gradients, even in sizes as small as 19 mm[1]
* Up to 84% orifice to annulus ratio
* 85 degree leaflet opening angle offers improved laminar flow and reduces turbulence[2-4]
* Supra-annular placement and low implant height
* The FlexCuff™ is flanged and more pliable than the standard cuff
* St. Jude Medical heart valves are MR Conditional[5]

Ordering Information

Contents: Aortic Valve (1 unit per box)

Model/Reorder* Number	Tissue Annulus Diameter (mm)	Valve Orifice Inner Diameter (mm)	Geometric Orifice Area (cm²)	Effective Orifice Area[6] (cm²)	Cuff Style
17AGN-751	17	15.9	1.87	1.42	Standard
19AGN-751	19	17.8	2.39	1.84	Standard
21AGN-751	21	19.6	2.90	2.47	Standard
23AGN-751	23	21.4	3.45	2.91	Standard
25AGN-751	25	23.0	4.02	3.34	Standard
27AGN-751	27	24.9	4.69	4.28	Standard
29AGN-751	29	26.8	5.44	Not reported	Standard

*All sizes currently not available in all markets.

1. St. Jude Medical, Inc. Pre-Market Approval Application Supplement: Regent Heart Valve. Washington, D.C.: U.S. Food and Drug Administration, [illegible]
2. King, M, [illegible] *J Eng Med*. 1994;208:63-72.
3. Feng Z, Nakamura T, Fujimoto T, et al. In vitro investigation [illegible] *Artificial Organs*. [illegible]
4. Smolkowitz T, Ameduri [illegible] et al. Evaluation technique for bileaflet mechanical valves. [illegible]
5. St. Jude Medical MRI Safety Document.
6. Walker DK, Brendzel AM, Scotten LN. The new St. Jude Medical Regent mechanical heart valve: [illegible] *J Heart Valve Dis*. [illegible]

Please review the Instructions for Use prior to using these devices [illegible]

Product referenced is approved for CE Mark.

Masters Series Mechanical Heart Valve Standard Cuff

Mitral Valves

Product Highlights

- Pyrolytic carbon leaflets and orifice ring offer exceptional durability and increased thromboresistance
- 85 degree leaflet opening angle offers improved laminar flow and reduces turbulence[2-4]
- Controlled torque rotation mechanism allows for easy rotation and intraoperative adjustment
- St. Jude Medical heart valves are MR conditional[5]

Ordering Information

Contents: Mitral Valve (1 unit per box)

Model/Reorder Number	Tissue Annulus Diameter (mm)	Valve Orifice Inner Diameter (mm)	Geometric Orifice Area (cm²)	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

1. Emery RW, Krogh CC, Arom KV, [illegible]. Ann Thorac Surg. [illegible]
2. King M, [illegible] J Eng Med. 1994;208:63-72.
3. Feng Z, Nakamura T, [illegible] Artificial Organs. 2002;26(1):32-9.
4. Ellis JT, [illegible] J Heart Valve Dis. 2002;11(2):[illegible]
5. St. Jude Medical MRI [illegible]

Please review the Instructions for Use [illegible] events and directions for use.

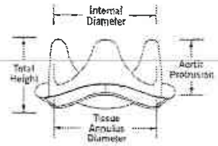
Product referenced [illegible]

Epic™ Supra Stented Tissue Valve with Linx™ AC Technology

Aortic Supra-Annular Stented Valves

Product Highlights

- Provides a larger stent-to-annulus ratio than Epic aortic valve
- Identical in design to the Biocor™ Supra stented tissue valve, which delivers proven 20-year durability results[1,2]
- 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™ stent reduces leaflet stress, adapts easily to annulus to enhance knot positioning, and returns stent posts to original shape after deflection
- Low-profile design provides optimal coronary ostia clearance
- Short 2 x 10-second rinse time



Ordering Information

Contents: Aortic Supra-Annular Stented Tissue Valve (1 unit per box)

Model/Reorder Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (mm)	Aortic Protrusion (mm)	Total Height (mm)
ESP100-19	19	19	19	11	14
ESP100-21	21	21	21	11	15
ESP100-23	23	23	23	13	16
ESP100-25	25	25	25	13	17
ESP100-27	27	27	27	14	19
ESP100-29	29	29	29	15	20

1. Myken PS, Bech-Hansen O. A 20-year experience [illegible]
2. Eichinger WB, [illegible] 2008;86(4):1204-[illegible]

*There is no clinical data currently [illegible]

Please review the Instructions for Use [illegible] events and directions for use.

Product referenced [illegible]

Trifecta™ Stented Tissue Valve with Linx™ AC Technology

Aortic Supra-Annular Stented Valves

Product Highlights

- Exceptional hemodynamic performance[1]
- Exterior mounted pericardial leaflets with unique suture attachment allows for maximum leaflet excursion and larger EOAs[2]
- Designed to provide excellent durability with the pericardial-covered stent for tissue-to-tissue contact to reduce the risk of abrasion
- Includes Linx™ AC Technology, which is designed to improve long-term performance and valve durability*
- Designed to maintain structural integrity with a high-strength, fatigue-resistant, titanium alloy stent[3]
- Short 2 x 10-second rinse time

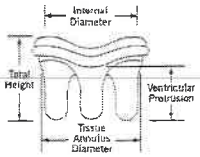
Ordering Information

Contents: Aortic Supra-Annular Stented Tissue Valve (1 unit per box)

Model/Reorder Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Cuff Outer Diameter (mm)	Aortic Protrusion (mm)	Total Height (mm)
TF-19A	19	19	24	12	15
TF-21A	21	21	26	13	16
TF-23A	23	23	28	13	17
TF-25A	25	25	31	14	18
TF-27A	27	27	33	15	19
TF-29A	29	29	35	16	20

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[4,5]
- 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 Protrusion (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

SJM™ Séguin Semi-Rigid Annuloplasty Ring

Rigid/Semi-Rigid Rings

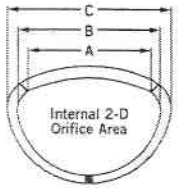
Product Highlights

- Designed to aid cardiac output and left ventricular function[1]
- Semi-rigid, three-dimensional posterior section is designed to preserve the physiologic movement of the valve annulus[1]
- Increased rigidity of the anterior section of the ring promotes annular remodeling[2]
- The solid, one-piece inner core resists needle penetration, reducing the potential for suturing through the core

Ordering Information

Contents: Semi-Rigid Ring (1 unit per box)

Model/Reorder Number	Ring Size	Commissure Dimension (mm) [A]	Inside Dimension (mm) [B]	Outside Dimension (mm) [C]	Internal 2-D Orifice Area (mm^2)
SARP-24	24	24	22	29	284
SARP-26	26	26	24	31	334
SARP-28	28	28	27	34	404
SARP-30	30	30	28	36	463
SARP-32	32	32	30	37	541
SARP-34	34	34	34	41	602
SARP-36	36	36	36	43	630
SARP-38	38	38	37	45	735
SARP-40	40	40	39	46	815



1. [illegible] 2. [illegible] 3. [illegible]

SJM™ Rigid Saddle Ring

Rigid/Semi-Rigid Rings

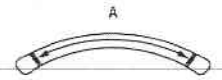
Product Highlights

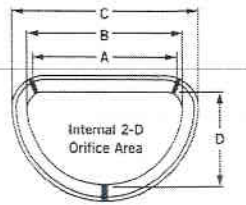
- Designed to restore the shape of a healthy mitral annulus[1]
- Titanium core maintains the anatomical shape and provides annular re-modeling
- Saddle shape contributes to efficient distribution of leaflet stress and chordal tension, which may increase repair durability[1-4]
- EZ Suture™ cuff is supported by a unique triangular core for a larger suture target

Ordering Information

Contents: Rigid Saddle Ring (1 unit per box)

Model/Reorder Number	Ring Size	Commissure Dimension (mm) [A]	Inside Dimension (mm) [B]	Outside Dimension (mm) [C]	A-P Dimension (mm) [D]	Internal 2-D Orifice Area (mm^2)
RSAR-24	24	24	22	30	13.6	227
RSAR-26	26	26	24	32	15.1	276
RSAR-28	28	28	26	34	16.2	331
RSAR-30	30	30	28	36	17.9	387
RSAR-32	32	32	30	38	19.2	450
RSAR-34	34	34	32	40	20.6	511





1. [illegible] 2. [illegible] 3. [illegible] 4. [illegible]

SJM™ Pericardial Patch with EnCap™ AC Technology

Pericardial Patch

Product Highlights

- Flexible and durable to provide enhanced biocompatibility and lasting performance[1,*]
- Bovine pericardium provides improved handling and suturability compared with synthetic patches[2]
- Anti-calcification treatment is designed to enhance tissue healing, biocompatibility and long-term tissue stability[*]
- Thinner patch available to accommodate pediatric applications[5]
- Soft, pliable tissue conforms to the anatomy and easily sutures into place
- Ready-to use, rinseless preparation saves time during procedures

Ordering Information

Contents: Pericardial Patch (1 unit per box)

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

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

1. Frater RWM, Seifter E, Liao K, et al. [illegible] In: Gabbay S, Wheatley DJ (eds.). *Advances in Anticalcific and Antidegenerative Treatment of Heart Valve Bioprostheses.* Austin, TX: Silent Partners Inc. 1997;105-11.
2. Frater RWM, Liao K, Seifter E. [illegible] *New Horizons and the Future of Heart Valve Bioprostheses.* Austin, TX: Silent Partners Inc. [illegible]
3. Hoffman D, Gong G, Liao K, et al. [illegible] *Circulation.* 1992;86(5 Suppl):II75-9.
4. Crawford FA Jr, Sade RM, [illegible] *Ann Thorac Surg.* 1986;41(6):602-5.
5. [illegible] *Ann Thorac Surg.* 2004;77(6):2144-50.

[illegible]

Masters Valved Graft with Hemashield® Technology

Aortic Valved Grafts

Product Highlights

- Hemashield technology graft with collagen impregnation provides uniform tissue ingrowth and biocompatibility[1]
- Low porosity graft requires no pre-clotting[1]
- No pleats at valve cuff allow for easy positioning and attachment of coronary anastomosis[1]
- Graft length is 12 cm
- St. Jude Medical heart valves are MR conditional[2]

Ordering Information

Contents: Aortic Valved Graft (1 unit per box)

Model/Reorder Number	Tissue Annulus Diameter (mm)	Graft Inner Diameter (mm)	Valve Orifice Inner Diameter (mm)	Geometric Orifice Area (cm²)
19CAVGJ-514-00	19	20	14.8	1.63
21CAVGJ-514-00	21	22	16.7	2.06
23CAVGJ-514-00	23	24	18.6	2.55
25CAVGJ-514-00	25	28	20.4	3.09
27CAVGJ-514-00	27	30	22.5	3.57
29CAVGJ-514-00	29	32	24.2	4.41
31CAVGJ-514-00	31	34	26.1	5.18
33CAVGJ-514-00	33	34	26.1	5.18

1. From Manufacturer's Literature, MAQUET Cardiovascular
2. St. Jude Medical MRI Safety Document

[illegible]

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
199909-2016-AQ-ROU-NA

Initial certification date:
28 June 2016

Valid:
28 June 2016 – 28 February 2019

This is to certify that the management system of

BIOSINTEX S.R.L.

4 Vladiceasca Str., RO 077168, Snagov, Ilfov County, Romania

has been found to conform to the Quality Management System standard:
ISO 13485:2003 / NS-EN ISO 13485:2012

This certificate is valid for the following scope:
Manufacturing and trade of sterile surgical sutures, with/without needles, surgical sterile prosthesis for soft tissues and surgical meshes for women urinary incontinence.

Place and date:
Hovik, 28 June 2016

NORWEGIAN ACCREDITATION
MSYS 002

For the issuing office:
DNV GL Business Assurance Norway AS.
Veritasveien 1, 1322 Hovik, Norway

Eugenie Winger Husebye

Eugenie Winger Husebye
Management Representative

BioSintex

	Material	Structure	Coating	Sizes (USP)	Tensile strength	Absorption	Properties	Features
Absorbable Suture								
BICRIL Synthetic, multifilament, absorbable suture	Polyglycolic acid	Multifilament braided	Polycaprolactone and calcium stearate coating	6/0→3&4	Preserves more than 65% of the initial tensile strength after 14 days at 37°C	Absorbable Completely between 60 and 90 days post-implant	Synthetic suture which preserves its properties regardless of tissue condition, having a minimal tissular reaction. Absorption is done by hydrolysis and not by enzymatic digestion as biological sutures (catgut). Thus, the absorption time is constant regardless of the tissue or of the suture's size. Soft, with safe & easy knot tie down due to the braided structure, but atraumatic and with a smooth passage through the tissues due to its external coating which makes it a virtual monofilament.	Colour: violet or undyed (natural) Sterilised EO Available as ligature and atraumatic suture with needle Different lengths
BICRIL 910 Synthetic, multifilament, absorbable suture	90% glycolide and 10% L-lactide	Multifilament braided	Poly (glycolide-co-L-lactide) 90:70 and calcium stearate coating	5/0→2	Preserves more than 65% of the initial tensile strength after 14 days at 37°C	Absorbable Completely between 60 and 80 days post-implant	Synthetic suture which preserves its properties regardless of tissue condition, having a minimal tissular reaction. Absorption is done by hydrolysis and not by enzymatic digestion as biological sutures (catgut). Thus, the absorption time is constant regardless of the tissue or of the suture's size. Soft, with safe & easy knot tie down due to the braided structure, but atraumatic and with a smooth passage through the tissues due to its external coating which makes it a virtual monofilament.	Colour: violet or undyed (natural) Sterilised EO Available as ligature and atraumatic suture with needle Different lengths
BICRIL RAPID Synthetic, multifilament, absorbable suture	Polyglycolic acid	Multifilament braided	Polycaprolactone and calcium stearate coating	5/0→2	Preserves more than 45% of the initial tensile strength after 7 days at 37°C	Rapid Absorbable Completely between 42 and 63 days post-implant	Synthetic suture which preserves its properties regardless of tissue condition, having a minimal tissular reaction. Absorption is done by hydrolysis and not by enzymatic digestion as biological sutures (catgut). Thus, the absorption time is constant regardless of the tissue or of the suture's size. Soft, with safe & easy knot tie down due to the braided structure, but atraumatic and with a smooth passage through the tissues due to its external coating which makes it a virtual monofilament.	Colour: undyed (natural) or violet Sterilised EO Available as ligature and atraumatic suture with needle Different lengths
MONOX Synthetic, monofilament, medium absorbable suture	Copolimer consisting of 75% polyglycolide and 25% caprolactone	Monofilament	—	5/0→2	Preserves 50% of the initial tensile strength after 7 days at 37°C.	Medium Absorbable Completely between 90 and 120 days post-implant	Synthetic suture which preserves its properties regardless of tissue condition, having a minimal tissular reaction. Absorption is done by hydrolysis and not by enzymatic digestion as biological sutures (catgut). Thus, the absorption time is constant regardless of the tissue or of the suture's size. Soft, with safe & easy knot tie down, but atraumatic and with a smooth passage through the tissues due to its monofilament structure. Minimal inflammatory tissue reaction.	Colour: violet or undyed (natural) Sterilised EO Available as ligature and atraumatic suture with needle Different lengths
PDOX Synthetic, monofilament, absorbable suture	Polydioxanone	Monofilament	—	6/0→2	Preserves more than 60% of the initial tensile strength after 28 days at 37°C	Slowly Absorbable Completely between 180 and 220 days post-implant	Synthetic suture which preserves its properties regardless of tissue condition, having a minimal tissular reaction. Absorption is done by hydrolysis and not by enzymatic digestion as biological sutures (catgut). Thus, the absorption time is constant regardless of the tissue or of the suture's size. Smooth and atraumatic passage through the tissues, due to its monofilament structure.	Colour: violet or undyed (natural) Sterilised EO Available as ligature and atraumatic suture with needle Different lengths
PDOX ANCHOR Synthetic, monofilament, absorbable, anchoring suture	Polydioxanone	Monofilament	—	4/0→2	Preserves more than 50% of the initial tensile strength after 14 days at 37°C	Slowly Absorbable Completely between 120 and 180 days post-implant	Synthetic suture which preserves its properties regardless of tissue condition, having a minimal tissular reaction. The anchoring system eliminates the need to tie knots. The spiral distribution of the anchors provides the optimal approximation of the tissue and a fast tissue healing. Absorption is done by hydrolysis and not by enzymatic digestion as biological sutures (catgut). Thus, the absorption time is constant regardless of the tissue or of the suture's size. Smooth and atraumatic passage through the tissues, due to its monofilament structure.	Colour: violet Sterilised EO Available as atraumatic suture with needle, unidirectional (with endloop) and bidirectional Different lengths
Non-Absorbable Suture								
BIOPRO Synthetic, monofilament, non-absorbable suture	Polypropylene	Monofilament	—	7/0→2	—	Non-Absorbable	Synthetic suture which preserves its properties regardless of tissue condition, having a minimal tissular reaction. Polypropylene suture is the most inert suture material. Non-absorbable, which allows sustained support of the wound. Smooth and atraumatic passage through the tissues, due to its monofilament structure.	Colour: blue or undyed (white) Sterilised EO Available as ligature and atraumatic suture with needle Different lengths
BIOSTER Synthetic, multifilament, non-absorbable suture	Polyester	Multifilament braided	Waxed or silicone coating	5/0→5	—	Non-Absorbable	Synthetic suture which preserves its properties regardless of tissue condition, having a minimal tissular reaction. Non-absorbable, which allows sustained support of the wound. Soft, with safe & easy knot tie down due to the braided structure, but atraumatic and with a smooth passage through the tissues due to its external coating, which makes it a virtual monofilament. It may need an additional knot for security.	Colour: green, black (or white) Sterilised EO Available as ligature and atraumatic suture with needle Different lengths
BIOSILK Biological, multifilament, non-absorbable suture	Natural silk	Multifilament braided	Waxed or silicone coating	5/0→2	—	Non-Absorbable	Biological suture made of natural silk. While silk sutures are not absorbed, progressive degradation of the silk fibers in vivo may result in gradual loss of the suture's tensile strength over time. Soft, with safe & easy knot tie down due to the braided structure, silk suture is the malleability standard for sutures. At the same time, coated silk is atraumatic and with a smooth transition through the tissues due to its external coating which makes it a virtual monofilament.	Colour: black Sterilised EO Available as ligature and atraumatic suture with needle Different lengths
Synthetic, multifilament, non-absorbable suture	Polyamide (nylon 6.6)	Multifilament braided	Uncoating, waxed or silicone coating	4/0→2	—	Non-Absorbable	Synthetic suture which preserves its properties regardless of tissue condition, having minimal tissular reaction. While Nylon Multi sutures are not absorbed, progressive hydrolysis in vivo may result in gradual loss over time of tensile strength. Structure which offers excellent flexibility of suture. Soft, with safe & easy knot tie down due to the braided structure, but atraumatic and with a smooth passage through the tissues due to its external coating which makes it a virtual monofilament.	Colour: white (or black or blue) Sterilised EO Available as ligature and atraumatic suture with needle Different lengths
Synthetic, monofilament, non-absorbable suture	Polyamide (nylon 6.6)	Monofilament	—	6/0→2	—	Non-Absorbable	Synthetic suture which preserves its properties regardless of tissue condition, having minimal tissular reaction. While Nylon Mono sutures are not absorbed, progressive hydrolysis in vivo may result in gradual loss over time of tensile strength. Smooth and atraumatic passage through the tissues due to its monofilament structure as well as due to uniform diameter of suture. Minimal memory of suture and excellent flexibility due to structure of suture.	Colour: white or blue or black Sterilised EO Available as ligature and atraumatic suture with needle Different lengths

OFICIUL TEHNIC de DISPOZITIVE MEDICALE CERTIFICARE
Organism notificat conform Directivei 93/42/CEE a
Consiliului pentru dispozitive medicale,
cu numar de identificare 1868

acreditat pentru
CERTIFICARE

SR EN 17021:2011
CERTIFICAT DE ACREDITARE
nr. ON 008/2013

EC CERTIFICATE

EXAMINAREA PROIECTULUI PRODUSULUI
(DESIGN EXAMINATION)

(Anexa II , sectiunea 4, a Directivei 93/42/CEE privind Dispozitivele Medicale, revizuită)
(Annex II , section 4, of the MDD 93/42/EEC on Medical Devices, as revised)

Nr. (No.) 4 DM 2.4

Prezentul certificat se acordă producatorului:
(The certificate is granted to the manufacturer)

S.C. BIOSINTEX S.R.L.

Sediu social (Headquarters): *Str. Paris, nr. 49, sector 1, Bucureşti, România*
Punct de lucru (Production site): *Str. N. Gogol, nr. 1A, sector 1, Bucureşti, România*
Sat Vladiceasca, Sos. Vladiceasca, nr. 4, Snagov, Jud. Ilfov, România

Pentru următoarele dispozitive medicale:
(For the following medical devices:)

Materiale de sutură chirurgicală, sterile, cu/fără ac
Proteze chirurgicale sterile pentru tesuturi moi
(Sterile surgical sutures, with / without needle and surgical sterile prosthesis for soft tissues)

OTDM CERTIFICARE declară că examinarea proiectului produsului a fost realizată conform Anexei II secţiunea 4 a Directivei 93/42/EEC privind dispozitivele medicale, cu modificarile ulterioare, transpusă in HG nr. 54/2009 privind condiţiile de introducere pe piată a dispozitivelor medicale şi certifică conformitatea proiectului produsului cu prevederile relevante ale directivei menţionate.

OTDM CERTIFICARE hereby declares that a design examination has been carried out on the medical device following the requirements of the annex II section 4 of the Directive 93/42/EEC on medical devices, with subsequent modifications, transposed into HG No. 54/2009, regarding the rules to place on the market the medical devices and certifies that the design of this device conforms with the relevant provisions of the above mentioned Directive.

Președinte Comitet pentru Asigurarea Imparțialității
(President of the Committee for Safeguarding Impartiality)
Ing. Lazăr IORDACHE

Director
(Director)
Ing. Ioana ŢENE

05.05.2014
Data emiterii
(Issue date)

04.05.2019
Data expirării
(Valid until)

Menţinerea valabilităţii certificatului se face in conformitate cu prevederile Anexei II, sectiunea 5, a DDM 93/42/CEE si a Contractului de Certificare nr. 4DM / 19.09.2013.
The validity of this certificate will be in accordance with the provisions of MDD 93/42/EEC, Annex II, Section 5 and the Certification Contract no. 4DM / 19.09.2013.

OFICIUL TEHNIC de DISPOZITIVE MEDICALE CERTIFICARE
Organism notificat conform Directivei 93/42/CEE a
Consiliului pentru dispozitive medicale,
cu numar de identificare 1868

acreditat pentru
CERTIFICARE

SR EN 17021:2011
CERTIFICAT DE ACREDITARE
nr. ON 008/2013

ANEXA LA CERTIFICAT CE
(ANNEX TO EC CERTIFICATE)

Informaţii suplimentare la Certificatul CE nr. 4 DM 2.4 / 05.05.2014
(Additional information on EC certificate No. 4 DM 2.4 / 05.05.2014)

Certificatul este valabil pentru următoarele locuri de producţie:
(The certificate is valid for the following production site)
SC BIOSINTEX SRL - *Sat Vladiceasca, Sos. Vladiceasca, nr. 4, Snagov, Jud. Ilfov, România*

Certificatul este valabil pentru următoarele produse / tipuri:
(The certificate is valid for the following products / types):

Produs (Product)	Tip (Type)
Materiale de sutura chirurgicala, sterile, cu/fara ac (Surgical sterile sutures with/without needle)	**Bicril** – fir resorbabil din acid poliglicolic (absorbable suture made of polyglycolic acid)
	Bicril rapid - fir resorbabil rapid din acid poliglicolic (rapid absorbable suture made of polyglycolic acid)
	Bicril 910 - fir resorbabil din copolimerul poli(glicolid-co-L-lactid) (absorbable suture made of copolymer poly(glycolide-co-L-lactide)
	PDO x– fir resorbabil din polidioxanona (absorbable suture made of polydioxanone)
	Mono x - fir resorbabil din copolimer pe baza de acid poliglicolic si caprolactona (absorbable suture made of copolymer based on polyglycolic acid and caprolactone)
	Biopro – fir neresorbabil din polipropilena (non-absorbable suture made of polypropylene)
Proteze chirurgicale sterile pentru tesuturi moi (Surgical sterile prosthesis for soft tissues)	**HerniPro Plus** - proteza partial resorbabila din Poli(glicolid-co-caprolactona)/ polipropilena (partially absorbable prosthesis made of poly(glycolide-co-caprolactone) / polypropylene)

Informaţiile necesare identificării proiectului aprobat, a dispozitivelor (tipuri) ce fac obiectul certificatului, a verificărilor efectuate, se regăsesc în (Data needed for identification of the approved design, devices (types) covered by the certificate, performed examinations are found in):

Raport de examinare a dosarului de proiect: Nr. 4-P-RI/12.03.2014 si Nr. 4-P-RI/17.03.2014 (Examination report of the Design Dossier No. 4-P-RI/12.03.2014 and no. 4-P-RI/17.03.2014)
Raport de validare a sterilizării cod BX-R-V.RC / 10.02.2014 emis de S.C. BIOSINTEX S.R.L.
(Sterilization validation report code BX-R-V.RC / 10.02.2014, issued by the S.C. BIOSINTEX SRL)
Rapoarte de evaluare a documentatiei tehnice nr. 4-Ev-DT-RI / 04.11.2013
(Technical documentation assessement reports no. 4-Ev-DT-RI / 04.11.2013)

care fac parte integrantă din certificat (which forms part of this certificate)

Președinte Comitet pentru Asigurarea Imparțialității
(President of the Committee for Safeguarding Impartiality)
Ing. Lazăr IORDACHE

Director
(Director)
Ing. Ioana ŢENE

Sos. Nicolae Titulescu 58, sector 1, Bucureşti
Tel. 031-432 91 20 / Fax: 031-432 91 21
www.otdm-certificare.ro
Page 2/2

OFICIUL TEHNIC de DISPOZITIVE MEDICALE CERTIFICARE
Organism notificat conform Directivei 93/42/CEE a
Consiliului pentru dispozitive medicale,
cu numar de identificare 1868

acreditat pentru CERTIFICARE
SR EN 17021:2011
CERTIFICAT DE ACREDITARE nr. ON 008/2013

EC CERTIFICATE

SISTEM COMPLET DE ASIGURARE A CALITATII

(FULL QUALITY ASSURANCE SYSTEM)

(Anexa II, exclusiv secţiunea 4, a Directivei 93/42/CEE privind Dispozitivele Medicale, revizuită)
(Annex II, excluding section 4, of the MDD 93/42/EEC on Medical Devices, as revised)

Nr. (No) 4 DM 2.3

Prezentul certificat se acordă producatorului:
(The certificate is granted to the manufacturer:)

S.C. BIOSINTEX S.R.L.

Sediu social (Headquarters): *Str. Paris, nr. 49, sector 1, Bucureşti, România*
Punct de lucru (Production site): *Str. N. Gogol, nr. 1A, sector 1, Bucureşti, România*
Sat Vladiceasca, Sos. Vladiceasca, nr. 4, Snagov, Jud. Ilfov, România

Pentru următoarele dispozitive medicale:
(For the following medical devices)

Materiale de sutură chirurgicală, sterile, cu/fără ac
Proteze chirurgicale sterile pentru tesuturi moi
Bandelete sterile pentru incontinenţă urinară
(Sterile surgical sutures, with / without needle, surgical sterile prosthesis for soft tissues and surgical meshes for urogynecology)

OTDM CERTIFICARE declară că examinarea sistemului de asigurare totală a calităţii a fost realizată conform Anexei II a Directivei 93/42/CEE privind dispozitivele medicale, cu modificarile ulterioare, transpusă în HG nr. 54/2009 privind condiţiile de introducere pe piaţă a dispozitivelor medicale, excluzand secţiunea 4 şi certifică conformitatea sistemului complet de asigurare a calităţii cu prevederile relevante ale directivei menţionate.

Punerea pe piaţă a dispozitivelor medicale de clasa III prevăzute in prezentul certificat este conditionată de existenţa certificatului de examinare a proiectului produsului nr. 4 DM 2.4 / 05.05.2014.

OTDM CERTIFICARE hereby declares that an examination of the full quality assurance system has been carried out following the requirements of the annex II of the Directive 93/42/EEC on medical devices, with subsequent modifications, transposed into HG No. 54/2009, regarding the rules to place on the market the medical devices, excluding section 4, and certifies that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

For placing on the market of class III devices above mentioned, this certificate is valid only together with the EC Design-Examination Certificate No. 4 DM 2.4 / 05.05.2014.

Președinte Comitet pentru Asigurarea Imparţialităţii
(President of the Committee for Safeguarding Impartiality)
Ing. Lazăr IORDACHE

05.05.2014
Data emiterii
(Issue date)

Director
(Director)
Ing. Ioana ŢENE

04.05.2019
Data expirării
(Valid until)

Se poate aplica marcajul CE₁₈₆₈ numai pentru dispozitivele medicale specificate in anexa certificatului.
Mentinerea valabilităţii certificatului se face in conformitate cu prevederile Anexei II, sectiunea 5, a DDM 93/42/EEE si a Contractului de Certificare nr. 1 DM / 19.09.2013.
The CE₁₈₆₈ mark can be affixed only for the devices specified in the annex of the certificate.
The validity of the certificate is kept in accordance with the provisions of MDD 93/42/EEC - Annex II, section 5 and the Certification Contract no. 40 / 19.09.2013.

Sos. Nicolae Titulescu 58, sector 1, Bucureşti
Tel. 031 432 91 20 / Fax: 031 432 91 21
www.otdm-certificare.ro

OFICIUL TEHNIC de DISPOZITIVE MEDICALE CERTIFICARE
Organism notificat conform Directivei 93/42/CEE a
Consiliului pentru dispozitive medicale,
cu numar de identificare 1868

acreditat pentru CERTIFICARE
SR EN 17021:2011
CERTIFICAT DE ACREDITARE nr. ON 008/2013

ANEXA LA CERTIFICAT CE
(ANNEX TO EC CERTIFICATE)

Informaţii suplimentare la Certificatul CE nr. 4 DM 2.3 / 05.05.2014
(Additional information on EC certificate No. 4 DM 2.3 / 05.05.2014)

Certificatul este valabil pentru următoarele locuri de producţie:
(The certificate is valid for the following production site)
SC BIOSINTEX SRL - *Sat Vladiceasca, Sos. Vladiceasca, nr. 4, Snagov, Jud. Ilfov, România*

Certificatul este valabil pentru următoarele produse / tipuri:
(The certificate is valid for the following products / types):

Produs (Product)	Tip (Type)
Materiale de sutura chirurgicala, sterile, cu/fara ac (Surgical sterile sutures with/without needle)	**Bicril** – fir resorbabil din acid poliglicolic (absorbable suture made of polyglycolic acid)
	Bicril rapid - fir resorbabil rapid din acid poliglicolic (rapid absorbable suture made of polyglycolic acid)
	Bicril 910 - fir resorbabil din copolimerul poli(glicolid-co-L-lactid) (absorbable suture made of copolymer poly(glycolide-co-L-lactide)
	PDO x– fir resorbabil din polidioxanona (absorbable suture made of polydioxanone)
	Mono x - fir resorbabil din copolimer pe baza de acid poliglicolic si caprolactona (absorbable suture made of copolymer based on polyglycolic acid and caprolactone)
	Biopro – fir neresorbabil din polipropilena (non-absorbable suture made of polypropylene)
	Bioster – fir neresorbabil din poliester (non-absorbable suture made of polyester)
	Biosilk – fir neresorbabil din matase naturala (non-absorbable suture made of silk)
	Nylon Multi - fir neresorbabil multifilament din poliamida (nylon 6,6) (multifilament non-absorbable suture made of polyamide (nylon 6,6)
	Nylon Mono - fir neresorbabil monofilament din poliamida(nylon 6,6) (monofilament non-absorbable suture made of polyamide (nylon 6,6)
Proteze chirurgicale sterile pentru tesuturi moi (Surgical sterile prosthesis for soft tissues)	**HerniPro** - proteza neresorbabila din polipropilena (non-absorbable prosthesis made of polypropylene)
	HerniPro Plus - proteza partial resorbabila din Poli(glicolid-co-caprolactona)/ polipropilena (partially absorbable prosthesis made of poly(glycolide-co-caprolactone) / polypropylene)
Bandelete sterile pentru incontinenta urinara (Surgical sterile meshes for urinary incontinence)	**HerniPro** - bandeleta neresorbabila din polipropilena (non-absorbable surgical meshes for urinary incontinence made of polypropylene)

Documentele care stau la baza acordării certificării sunt :
(The certification is based on:)

- **Raport de audit nr. 4-R-A2-RI / 04.11.2013**
  (Audit report No. 4-R-A2-RI / 04.11.2013)
- **Rapoarte de evaluare a documentatiei tehnice nr. 4-Ev-DT-RI/ 04.11.2013**
  (Technical documentation assessement reports no. 4-Ev-DT-RI/ 04.11.2013)
- **Proces-verbal al Comitetului Tehnic de Evaluare nr. 324 / 17.04.2014**
  (Protocol of the Evaluation Technical Committee No. 324/17.04.2014)

Președinte Comitet pentru Asigurarea Imparţialităţii
(President of the Committee for Safeguarding Impartiality)
Ing. Lazăr IORDACHE

Director
(Director)
Ing. Ioana ŢENE

Sos. Nicolae Titulescu 58, sector 1, Bucureşti
Tel. 031 432 91 20 / Fax: 031 432 91 21
www.otdm-certificare.ro

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 02 16316 019

Manufacturer:	**BOWA-electronic GmbH & Co. KG** Heinrich-Hertz-Strasse 4-10 72810 Gomaringen GERMANY
Facility(ies):	BOWA-electronic GmbH & Co. KG Heinrich-Hertz-Strasse 4-10, 72810 Gomaringen, GERMANY
Product Category(ies):	**Elecrosurgical Unit and accessories** **Argon Coagulation Unit and accessories** **Electrode handles** **Active electrodes and instruments** **monopolar and bipolar forceps** **endoscopic and laparoscopic instruments** **instruments for vessel sealing** **neutral electrodes** **bipolar scissors**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713102471

Valid from: 2017-03-09
Valid until: 2022-03-08

Date, 2017-03-08

Stefan Preiß

0405276667446

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

Zertifiziervertrag

Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:

– Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:

– Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.

– Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract

Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.

On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuev-sued.de/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:

– Validity of the quoted test standard(s)

In addition for certificates with the right to use a certification mark and for QM certificates:

– Conditions for an adequate manufacturing are maintained

– Regular surveillance of the facility is performed

Akkreditierungen / Benennungen (Status 14.10.2013) /
Accreditations / notifications (as of 2013-10-14)

Deutschland / Germany

Produktsicherheitsgesetz (ProdSG) /
Product Safety Act (ProdSG)

Europa / Europe

- Niederspannungsrichtlinie 2006/95/EG
- Spielzeugrichtlinie 2009/48/EG
- Richtlinie für aktive medizinische Implantate 90/385/EWG
- Richtlinie für Medizinprodukte 93/42/EWG
- Richtlinie für In-vitro-Diagnostika 98/79/EG
- Richtlinie für Gasverbrauchseinrichtungen 2009/142/EG
- Richtlinie für persönliche Schutzausrüstungen 89/686/EWG
- EMV-Richtlinie 2004/108/EG
- Richtlinie für Sportboote 94/25/EG + 2003/44/EG
- Richtlinie für Maschinen 2006/42/EG
- Richtlinie für Ex-Schutz Geräte 94/9/EG

- Low Voltage Directive 2006/95/EC
- Toys Directive 2009/48/EC
- Directive for Active Implantable Medical Devices 90/385/EEC
- Directive for Medical Devices 93/42/EEC
- Directive on In Vitro Diagnostic Medical Devices 98/79/EC
- Directive for Gas Appliances 2009/142/EC
- Directive for Personal Protective Equipment 89/686/EEC
- EMC Directive 2004/108/EC
- Directive for Recreational Craft 94/25/EC + 2003/44/EC
- Directive for Machinery 2006/42/EC
- Directive for Ex Safe Equipment 94/9/EC

- ENEC Agreement for luminaires, household and IT equipment

USA

- Nationally Recognized Testing Laboratory (NRTL) to 29 CFR 1910.7 by OSHA
- Accredited for FDA 510(k) Third Party Review
- Conformity Assessment Body to the MRA for Medical Devices; FDA QSReg Inspections, FDA 510(k) Third Party Review

Asien-Pazifik Region / Asia Pacific

- Recognized Certification Body to Electrical Products (Safety) Regulation; Hong Kong
- Konformitätsbewertungsstelle / Conformity Assessment Body to the MRA for Medical Devices; Australien / Australia
- Konformitätsbewertungsstelle / Conformity Assessment Body to the MRA for Medical Devices; Neuseeland / New Zealand

Weltweit / Worldwide

- NCB im CB-Scheme des IECEE /
  NCB in the CB Scheme of IECEE
- ExCB im IECEx-Scheme des IECEE /
  ExCB in the IECEx Scheme of IECEE
- Zertifizierstellen durch DAkkS akkreditiert
  DE-ZE-11321-01, DE-ZM-11321-09 und DE-ZM-11321-10
  Certification Bodies accredited by DAkkS
  DE-ZE-11321-01, DE-ZM-11321-09 and DE-ZM-11321-10

EC DECLARATION OF CONFORMITY

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz Strasse 4-10
72810 Gomaringen / Germany

We hereby declare in sole responsibility that the medical devices listed on the following pages
are conform with the essential requirements of the following standard:

Medical Device Directive (Council Directive 93/42/EEC of 14 June 1993)

with applied standards:

EN ISO 14971 / EN 60601-1 / EN 60601-2-2 / EN ISO 10993-1 / EN ISO 13485 / DIN EN 1041

CE Marking

Class I	according to annex VII	CE
Class Is	according to annex II	CE 0123
Class IIa	according to annex II	CE 0123
Class IIb	according to annex II	CE 0123

Notified Body
TÜV Product Service
Ridlerstr. 65, D-80339 München
Nr. 0123

The declaration of conformity is valid until: 08.03.2022

Gomaringen, 08.03.2017

Quality Management /
Regulatory Affairs

, (Wolf-Rüdiger Fritz)

BOWA
EINFACH SICHER

REF	Product description	Class	Rule	UMDNS	GMDN
040-400	Generator trunk, for BOWA ARC (without generator)	IIb	9	15-895	44683
040-401	ARC 400 Starter Set	IIb	9	15-895	44683
040-402	Argon trunk for ARC PLUS (without argon unit)	IIb	9	15-895	44683
050-240	COMFORT BOX (4 mm)	IIb	9	15-895	44683
050-241	COMFORT BOX (2.4 mm)	IIb	9	15-895	44683
050-242	COMFORT BOX	IIb	9	15-895	44683
100-016	Electrode handle, without switches, shaft 4 mm, for Erbe-T, 4.5 m	IIa	6	11-494	44677
101-000	Bipolar cable, E.U. forceps, for Erbe, 4 m	I	1	11-493	35042
101-003	Cable, rubber return plate, for Erbe, 4.5 m	I	1	11-493	35042
101-040	Bipolar cable, BOWA forceps, for Erbe, 4 m	I	1	11-493	35042
101-045	Bipolar cable, U.S. forceps, for Erbe, 4 m	I	1	11-493	35042
101-051	Monopolar cable, 4 mm socket, for Erbe, 4.5 m	I	1	11-493	35042
101-060	Monopolar cable, arthroscopy and LAP electrode, for Erbe, 4.5 m	I	1	11-493	35042
101-140	Bipolar cable, BOWA forceps, COMFORT, 4.5 m	I	1	11-493	35042
101-145	Monopolar cable, ErgoLAP, for Erbe, 4.5 m	I	1	11-493	35042
101-150	Cable, single-use return plate, for ALSA, Eschmann, 4.5 m	I	1	11-493	35042
101-245	Cable, ErgoLAP BIPOLAR, for Erbe, 4.5 m	I	1	11-493	35042
104-045	ErgoPEN slim, 2 switches, shaft 4 mm, for Erbe, cable 4.5 m	IIb	9	11-494	44680
105-045	ErgoPEN slim, 2 switches, shaft 2.4 mm, for Erbe, cable 4.5 m	IIb	9	11-494	44680
106-045	Monopolar cable, 2 mm socket, for Erbe, 4.5 m	I	1	11-493	35042
106-145	Monopolar cable, resectoscope Wolf/Storz, COMFORT, 4.5 m	I	1	11-493	35042
106-245	Monopolar cable, Storz resectoscope, COMFORT, 4.5 m	I	1	11-493	35042
106-345	Monopolar cable, resectoscope Olympus, COMFORT, 4.5 m	I	1	11-493	35042
110-045	ErgoPEN large, 2 switches, shaft 4 mm, for Erbe, cable 4.5 m	IIb	9	11-494	44680
111-000	Adapter bipolar, 3-pin instrument, for Erbe	I	1	16-490	35041
111-001	Adapter monopolar, 2 - 4 mm instrument, for Erbe, footswitched	I	1	16-490	35041
112-045	ErgoPEN large, 2 switches, shaft 4 mm, for Erbe-T, cable 4.5 m	IIb	9	11-494	44680
120-045	JackKNIFE, 2 switches, shaft 2.4 mm, for Erbe, cable 4.5 m	IIb	9	11-494	44680
120-145	JackKNIFE, 2 switches, shaft 4 mm, for Erbe, cable 4.5 m	IIb	9	11-494	44680
131-045	Monopolar cable, endoscopy 2.8 mm socket, for Erbe, 4.5 m	I	1	11-493	35042
131-145	Monopolar cable, endoscopy 2.8 mm socket, COMFORT, 4.5 m	I	1	11-493	35042
132-045	Monopolar cable, endoscopy 4 mm socket, for Erbe, 4.5 m	I	1	11-493	35042
193-008	Rubber return plate, adults, 250 x 150 mm, for Erbe	I	1	11-500	42551
193-016	Rubber return plate, children, 150 x 80 mm, for Erbe	I	1	11-500	42551
194-000	Fixation button for rubber band	I	1	11-429	35709
194-050	Rubber band with fixation button, 50 cm	I	1	11-429	35709
194-075	Rubber band with fixation button, 75 cm	I	1	11-429	35709
194-100	Rubber band with fixation button, 100 cm	I	1	11-429	35709
210-030	Electrode handle, without switches, shaft 4 mm, for Martin, cable 4.5 m	IIa	6	11-494	44677
214-045	ErgoPEN slim, 2 switches, shaft 4 mm, for Martin, cable 4.5 m	IIb	9	11-494	44680
215-045	ErgoPEN slim, 2 switches, shaft 4 mm, for 3-pin, cable 4.5 m	IIb	9	11-494	44680
215-145	ErgoPEN slim, 2 switches, shaft 4 mm, COMFORT, cable 4.5 m	IIb	9	11-494	44680
218-045	ErgoPEN slim, 2 switches, shaft 2.4 mm, for 3-pin, cable 4.5 m	IIb	9	11-494	44680
218-145	*ErgoPEN slim, 2 switches, shaft 2.4 mm, COMFORT, cable 4.5 m*	IIb	9	11-494	44680
219-030	Electrode handle, without switches, shaft 2.4 mm, Martin, cable 4.5 m	IIa	6	11-494	44677

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen / Germany
Telefon +49 (0) 7072-6002-0
Telefax +49 (0) 7072-6002-33
info@bowa.de | bowa.de
Registergericht: Stuttgart HRA 381478
Geschäftsführer: Jens Kröber
Martin Heinrich

REF	Product description	Class	Rule	UMDNS	GMDN
220-045	JackKNIFE, 2 switches, shaft 2.4 mm, for 3-pin, cable 4.5 m	IIb	9	11-494	44680
220-145	JackKNIFE, 2 switches, shaft 4 mm, for 3-pin, cable 4.5 m	IIb	9	11-494	44680
220-245	JackKNIFE, 2 switches, shaft 4 mm, for Martin, cable 4.5 m	IIb	9	11-494	44680
220-345	JackKNIFE ARC 100, shaft 2.4 mm with cable for bipolar forceps 4 m	IIb	9	11-494	44680
222-000	Adapter monopolar, 3-pin, for Martin	I	1	16-490	35041
227-045	ErgoPEN large, 2 switches, shaft 4 mm, for Martin, cable 4.5 m	IIb	9	11-494	44680
232-003	Rubber return plate, children, 150 x 80 mm, international	I	1	11-500	42551
242-003	Rubber return plate, adults, 250 x 150 mm, international	I	1	11-500	42551
270-145	Cable, ErgoLAP MONOPOLAR, for Martin, 4.5 m	I	1	11-493	35042
280-031	Monopolar cable, U.K., for 4 mm, 4.5 m	I	1	11-493	35042
280-035	Monopolar cable, arthroscopy and LAP electrode, for 4 mm, 4.5 m	I	1	11-493	35042
280-050	Monopolar cable, 4 mm socket, for 4 mm, 4.5 m	I	1	11-493	35042
285-050	Monopolar cable, for Martin handles, 4.5 m	I	1	11-493	35042
287-040	Bipolar cable, BOWA forceps, for Martin, 4.5 m	I	1	11-493	35042
287-045	Bipolar cable, U.S. forceps, for Martin, 4.5 m	I	1	11-493	35042
287-050	Bipolar cable, E.U. forceps, for Martin, 4.5 m	I	1	11-493	35042
287-245	Cable, ErgoLAP BIPOLAR, for Martin, 4.5 m	I	1	11-493	35042
294-050	Cable, single-use return plate, for Erbe, 4.5 m	I	1	11-493	35042
295-050	Cable, rubber return plate, for Martin, 4.5 m	I	1	11-493	35042
322-045	ErgoPEN large, 2 switches, shaft 4 mm, for 3-pin, cable 4.5 m	IIb	9	11-494	44680
327-045	ErgoPEN large, 2 switches, shaft 2.4 mm, for 3-pin, cable 4.5 m	IIb	9	11-494	44680
330-030	Electrode handle, without switches, shaft 4 mm, for 8 mm, cable 4.5 m	IIa	6	11-494	44677
331-045	Monopolar cable, endoscopy 2.8 mm, for 8 mm Bovie, 4.5 m	I	1	11-493	35042
332-045	Monopolar cable, endoscopy 4 mm socket, for 8 mm Bovie, 4.5 m	I	1	11-493	35042
333-001	Adapter monopolar, 2 - 4 mm instrument, for 8 mm Bovie	I	1	16-490	35041
335-030	Electrode handle, without switches, shaft 2.4 mm, 6mm Bovie, cable 4.5 m	IIa	6	11-494	44677
340-000	Adapter bipolar, 2-pin 28 mm, for Erbe	I	1	16-490	35041
350-245	Cable, ErgoLAP BIPOLAR, for 2-pin 22 mm, 4.5 m	I	1	11-493	35042
351-040	Bipolar cable, BOWA forceps, for 2-pin 28 mm, 4.5 m	I	1	11-493	35042
351-045	Bipolar cable, U.S. forceps, for 2-pin 28 mm, 4.5 m	I	1	11-493	35042
351-051	Bipolar cable, E.U. forceps, for 2-pin 28 mm, 4.5 m	I	1	11-493	35042
351-245	Cable, ErgoLAP BIPOLAR, for 2-pin 28 mm, 4.5 m	I	1	11-493	35042
351-345	Cable, ErgoLAP BIPOLAR, COMFORT, 4.5 m	I	1	11-493	35042
352-145	Bipolar cable, Storz resectoscope, COMFORT, 4.5 m	I	1	11-493	35042
353-040	Bipolar cable, BOWA forceps, for 2-pin 22 mm, 4.5 m	I	1	11-493	35042
353-045	Bipolar cable, U.S. forceps, for 2-pin 22 mm, 4.5 m	I	1	11-493	35042
353-050	Bipolar cable, E.U. forceps, for 2-pin 22 mm, 4.5 m	I	1	11-493	35042
354-145	Bipolar cable, Wolf resectoscope, COMFORT, 4.5 m	I	1	11-493	35042
355-030	Bipolar cable, E.U. forceps, for Valleylab, 3 m	I	1	11-493	35042
355-031	Bipolar cable, BOWA forceps, for Valleylab, 3 m	I	1	11-493	35042
355-145	Bipolar cable, Olympus resectoscope, COMFORT, 4.5 m	I	1	11-493	35042
358-145	Cable, NightKNIFE / LIGATOR, COMFORT, 4.5 m	I	1	11-493	35042
360-050	Monopolar cable, 4 mm socket, for 8 mm Bovie, 4.5 m	I	1	11-493	35042
360-145	Cable, ErgoLAP MONOPOLAR, for 8 mm Bovie, 4.5 m	I	1	11-493	35042
360-245	Cable, ErgoLAP MONOPOLAR, COMFORT, 4.5 m	I	1	11-493	35042

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen , Germany
Telefon +49 (0) 7072-6002-0
Telefax +49 (0) 7072-6002-33
info@bowa.de | bowa.de
Registergericht: Stuttgart HRA 381478
Geschäftsführer: Jens Kröber
Martin Heinrich

BOWA
EINFACH SICHER

REF	Product description	Class	Rule	UMDNS	GMDN
365-030	Monopolar cable, U.K., for 8 mm Bovie, 4.5 m	I	1	11-493	35042
370-050	Monopolar cable, arthroscopy and LAP electrode, for 8 mm, 4.5 m	I	1	11-493	35042
375-045	Monopolar cable, 2 mm socket, for 8 mm Bovie, 4.5 m	I	1	11-493	35042
378-045	Cable, BiZZER / TissueSeal, 4.5 m	I	1	11-493	35042
378-145	Cable, BiZZER, for Erbe, 4.5 m	I	1	11-493	35042
378-245	Cable, BiZZER, for Martin, 4.5 m	I	1	11-493	35042
380-050	Cable, single-use return plate, international, 4.5 m	I	1	11-493	35042
385-050	Cable, rubber return plate, international, 4.5 m	I	1	11-493	35042
386-050	Cable, single-use return plate, international (NON-REM), 4.5 m	I	1	11-493	35042
401-051	Cable, bipolar scissors, for 2-pin 28 mm, 4.5 m	I	1	11-493	35042
401-052	Cable, bipolar scissors, for Erbe, 4.5 m	I	1	11-493	35042
401-053	Cable, bipolar scissors, for Martin, 4.5 m	I	1	11-493	35042
405-045	Monopolar cable, 2 mm socket, for 4 mm, 4.5 m	I	1	11-493	35042
431-045	Monopolar cable, endoscopy, 2.8 mm socket, for 4 mm, 4.5 m	I	1	11-493	35042
432-045	Monopolar cable, endoscopy, 4 mm socket, for 4 mm, 4.5 m	I	1	11-493	35042
480-145	Cable, ErgoLAP MONOPOLAR, for 4 mm, 4.5 m	I	1	11-493	35042
500-000	Electrode container, 12 standard electrodes, shaft 4 mm	IIb	9	15-895	44683
500-007	Knife electrode, straight, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-008	Knife electrode, angled, rhombic, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-009	Knife electrode, straight, rhombic, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-011	Needle electrode, straight, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-014	Wire loop electrode, Ø 5 mm, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-015	Wire loop electrode, Ø 10 mm, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-016	Wire loop electrode, Ø 14 mm, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-017	Ribbon loop electrode, Ø 10 mm, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-018	Ribbon loop electrode, Ø 17 mm, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-019	Ball electrode, straight, Ø 1.5 mm, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-020	Ball electrode, straight, Ø 2 mm, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-021	Ball electrode, straight, Ø 4 mm, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-022	Ball electrode, straight, Ø 6 mm, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-023	Plate electrode, 8 x 10 mm, shaft 4 mm	IIb	9	11-499	44683
500-024	Plate electrode, straight, 10 x 15 mm, shaft 4 mm	IIb	9	11-499	44683
500-112	Micro needle electrode, tungsten wire, straight, shaft 4 mm	IIb	9	11-499	44683
500-113	Micro needle electrode, tungsten wire, angled, shaft 4 mm	IIb	9	11-499	44683
500-124	Needle electrode, 45° angled, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-125	Lancet electrode, angled, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-126	Lancet electrode, straight, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-127	Knife electrode, thin, straight, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-129	Ball electrode, angled, Ø 1.5 mm, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-130	Ball electrode, angled, Ø 2 mm, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-131	Ball electrode, angled, Ø 4 mm, shaft 4 mm (5 pcs.)	IIb	9	11-499	44683
500-150	Electrode extension, 172 mm, shaft 4 mm	IIb	9	11-499	44683
510-108	Needle electrode, arthroscopy, 90 ° angled, 1.5 x 0.8 mm	IIb	9	16-206	44683
510-109	Needle electrode, arthroscopy, 90 ° angled, 4 x 0.8 mm	IIb	9	16-206	44683
510-110	Knife electrode, arthroscopy, 45 ° angled, 3 x 1.5 mm	IIb	9	16-206	44683

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen | Germany
Telefon +49 (0) 7072-6002-0
Telefax +49 (0) 7072-6002-33
info@bowa.de | bowa.de
Registergericht: Stuttgart HRA 381478
Geschäftsführer: Jens Kröber
Martin Heinrich

REF	Product description	Class	Rule	UMDNS	GMDN
510-112	Keying electrode, arthroscopy, 90 ° angled, 3 x 1.5 mm	IIb	9	16-206	44683
520-027	Needle electrode, straight, 136 mm, insulated shaft 4 mm	IIb	9	11-499	44683
520-028	Knife electrode, straight, 154 mm, insulated shaft 4 mm	IIb	9	11-499	44683
520-029	Ball electrode, straight, Ø 4 mm, 122 mm, insulated shaft 4 mm	IIb	9	11-499	44683
520-030	Ball electrode, straight, Ø 6 mm, 124 mm, insulated shaft 4 mm	IIb	9	11-499	44683
520-031	Wire loop electrode, straight, Ø 5 mm, 123 mm, insulated shaft 4 mm	IIb	9	11-499	44683
520-032	Wire loop electrode, straight, Ø 10 mm, 128 mm, insulated shaft 4 mm	IIb	9	11-499	44683
520-035	Ball electrode, angled, Ø 6 mm, 124 mm, insulated shaft 4 mm	IIb	9	11-499	44683
520-110	MetraLOOP set	IIb	9	11-499	44683
520-113	MetraLOOP, inner shaft	IIb	9	11-499	44683
520-114	MetraLOOP, outer shaft	IIb	9	11-499	44683
520-115	MetraLOOP set, COMFORT	IIb	9	11-499	44683
520-116	MetraLOOP, COMFORT, inner shaft	IIb	9	11-499	44683
520-117	MetraLOOP, spare loops, Ø 100 mm, single use, sterile (10 pcs.)	IIb	9	11-499	44684
520-118	MetraLOOP, spare loops, Ø 175 mm, single use, sterile (10 pcs.)	IIb	9	11-499	44684
520-122	Needle electrode, angled, 132 mm, insulated shaft 4 mm	IIb	9	11-499	44683
520-123	Knife electrode, angled, rhombic, 142 mm, insulated shaft 4 mm	IIb	9	11-499	44683
520-124	Knife electrode, straight, rhombic, 142 mm, insulated shaft 4 mm	IIb	9	11-499	44683
520-132	Loop electrode, 20 x 20 mm, 138 mm, insulated shaft 4 mm	IIb	9	11-499	44683
520-133	Loop electrode, 20 x 15 mm, 133 mm, insulated shaft 4 mm	IIb	9	11-499	44683
520-134	Loop electrode, 10 x 10 mm, 128 mm, insulated shaft 4 mm	IIb	9	11-499	44683
520-135	Loop electrode, 15 x 15 mm, 133 mm, insulated shaft 4 mm	IIb	9	11-499	44683
520-136	Loop electrode, 25 x 25 mm, 143 mm, insulated shaft 4 mm	IIb	9	11-499	44683
530-000	Electrode container,12 standard electrodes, shaft 2.4 mm	IIb	9	15-895	44683
530-008	Knife electrode, angled, rhombic, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683
530-009	Knife electrode, straight, rhombic, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683
530-012	Micro needle electrode, tungsten wire, straight, shaft 2.4 mm	IIb	9	11-499	44683
530-013	Micro needle electrode, tungsten wire, angled, shaft 2.4 mm	IIb	9	11-499	44683
530-014	Wire loop electrode, Ø 5 mm, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683
530-015	Wire loop electrode, Ø 10 mm, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683
530-016	Wire loop electrode, Ø 14 mm, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683
530-017	Ribbon loop electrode, Ø 10 mm, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683
530-020	Ball electrode, straight, Ø 2 mm, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683
530-021	Ball electrode, straight, Ø 4 mm, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683
530-022	Ball electrode, straight, Ø 6 mm, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683
530-027	Needle electrode, straight, 140 mm, insulated shaft 2.4 mm	IIb	9	11-499	44683
530-028	Knife electrode, straight, 152 mm, insulated shaft 2.4 mm	IIb	9	11-499	44683
530-029	Ball electrode, Ø 4 mm, 126 mm, insulated shaft 2.4 mm	IIb	9	11-499	44683
530-030	Ball electrode, Ø 6 mm, 128 mm, insulated shaft 2.4 mm	IIb	9	11-499	44683
530-032	Wire loop electrode, Ø 10 mm, 132 mm, insulated shaft 2.4 mm	IIb	9	11-499	44683
530-035	Ball electrode, d=6 mm, angled, 128 mm, insulated shaft 2.4 mm	IIb	9	11-499	44683
530-070	Electrode extension, 195 mm, shaft 2.4 mm	IIb	9	11-499	44683
530-122	Needle electrode, angled, 136 mm, insulated shaft 2.4 mm	IIb	9	11-499	44683
530-123	Knife electrode, angled, rhombic, 146 mm, insulated shaft 2.4 mm	IIb	9	11-499	44683
530-124	Needle electrode, angled, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683

REF	Product description	Class	Rule	UMDNS	GMDN
530-125	Lancet electrode, angled, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683
530-126	Lancet electrode, straight, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683
530-127	Knife electrode, thin, straight, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683
530-130	Ball electrode, Ø 2 mm, angled, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683
530-132	Loop electrode, 20 x 20 mm, 142 mm, insulated shaft 2.4 mm	IIb	9	11-499	44683
530-133	Loop electrode, 20 x 15 mm, 137 mm, insulated shaft 2.4 mm	IIb	9	11-499	44683
530-134	Loop electrode, 10 x 10 mm, 132 mm, insulated shaft 2.4 mm	IIb	9	11-499	44683
530-135	Loop electrode, 15 x 15 mm, 137 mm, insulated shaft 2,4 mm	IIb	9	11-499	44683
530-136	Loop electrode, 25 x 25 mm, 147 mm, insulated shaft 2,4 mm	IIb	9	11-499	44683
530-150	Electrode extension, 175 mm, shaft 2.4 mm	IIb	9	11-499	44683
530-207	Knife electrode, straight, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683
530-211	Needle electrode, straight, shaft 2.4 mm (5 pcs.)	IIb	9	11-499	44683
530-224	Knife electrode, rhombic, 146 mm, insulated shaft 2.4 mm	IIb	9	11-499	44683
530-225	Needle electrode ENT, angled, 124 mm, insulated shaft 2.4 mm	IIb	9	11-499	44683
605-001	Bipolar forceps, angled, 195 mm, 8 mm x 1 mm	IIb	9	11-502	44683
605-002	Bipolar forceps, bayonet, 195 mm, 6 mm x 1 mm	IIb	9	11-502	44683
605-007	Bipolar forceps, angled, 195 mm, 8 mm x 2 mm	IIb	9	11-502	44683
605-011	Bipolar forceps, straight, 160 mm, 6 mm x needle	IIb	9	11-502	44683
605-013	Bipolar forceps, angled, 160 mm, 6 mm x 0.5 mm	IIb	9	11-502	44683
605-014	Bipolar forceps, angled, 160 mm, 6 mm x 1 mm	IIb	9	11-502	44683
605-018	Bipolar forceps, bayonet, 165 mm, 6 mm x 1 mm	IIb	9	11-502	44683
605-019	Bipolar forceps, straight, 110 mm, 6 mm x needle	IIb	9	11-502	44683
605-020	Bipolar forceps, straight, 110 mm, 6 mm x 0.5 mm	IIb	9	11-502	44683
605-021	Bipolar forceps, angled, 110 mm, 6 mm x 0.5 mm	IIb	9	11-502	44683
605-023	Bipolar forceps, angled, 110 mm, 6 mm x needle	IIb	9	11-502	44683
605-024	Bipolar forceps, angled, 220 mm, 8 mm x 1 mm	IIb	9	11-502	44683
605-027	Bipolar forceps, straight, 160 mm, 8 mm x 2 mm	IIb	9	11-502	44683
605-029	Bipolar forceps, straight, 195 mm, 8 mm x 2 mm	IIb	9	11-502	44683
605-030	Bipolar forceps, straight, 220 mm, 8 mm x 2 mm	IIb	9	11-502	44683
605-031	Bipolar forceps, bayonet, 220 mm, 6 mm x 0.5 mm	IIb	9	11-502	44683
605-033	Bipolar forceps, bayonet, 165 mm, 6 mm x 0.5 mm	IIb	9	11-502	44683
605-034	Bipolar forceps, bayonet, 195 mm, 8 mm x 2 mm	IIb	9	11-502	44683
605-036	Bipolar forceps, angled, 160 mm, 6 mm x needle	IIb	9	11-502	44683
605-039	Bipolar forceps, straight, 160 mm, 8 mm x 1 mm	IIb	9	11-502	44683
605-040	Bipolar forceps, straight, 195 mm, 8 mm x 1 mm	IIb	9	11-502	44683
605-041	Bipolar forceps, straight, 220 mm, 8 mm x 1 mm	IIb	9	11-502	44683
605-057	Bipolar forceps, straight, 195 mm, 8 mm x 2 mm, square riffle	IIb	9	11-502	44683
605-058	Bipolar forceps, angled, 195 mm, 8 mm x 2 mm, square riffle	IIb	9	11-502	44683
605-059	Bipolar forceps, bayonet, 195 mm, 8 mm x 2 mm, square riffle	IIb	9	11-502	44683
605-063	Bipolar forceps, bayonet, angled, 220 mm, 6 mm x 1 mm	IIb	9	11-502	44683
605-070	Bipolar forceps, straight, 300 mm, 8 mm x 2 mm	IIb	9	11-502	44683
605-080	Bipolar forceps, straight, 270 mm, 8 mm x 2 mm	IIb	9	11-502	44683
607-001	Bipolar forceps, NON-Stick-Gold, angled, 195 mm, 8 mm x 1 mm	IIb	9	11-502	44683
607-002	Bipolar forceps, NON-Stick-Gold, bayonet, 195 mm, 6 mm x 1 mm	IIb	9	11-502	44683
607-007	Bipolar forceps, NON-Stick-Gold, angled, 195 mm, 8 mm x 2 mm	IIb	9	11-502	44683

REF	Product description	Class	Rule	UMDNS	GMDN
607-014	Bipolar forceps, NON-Stick-Gold, angled, 160 mm, 6 mm x 1 mm	IIb	9	11-502	44683
607-020	Bipolar forceps, NON-Stick-Gold, straight, 110 mm, 6 mm x 0,5 mm	IIb	9	11-502	44683
607-021	Bipolar forceps, NON-Stick-Gold, angled, 110 mm, 6 mm x 0,5 mm	IIb	9	11-502	44683
607-027	Bipolar forceps, NON-Stick-Gold, straight, 160 mm, 8 mm x 2 mm	IIb	9	11-502	44683
607-029	Bipolar forceps, NON-Stick-Gold, straight, 195 mm, 8 mm x 2 mm	IIb	9	11-502	44683
607-030	Bipolar forceps, NON-Stick-Gold, straight, 220 mm, 8 mm x 2 mm	IIb	9	11-502	44683
607-039	Bipolar forceps, NON-Stick-Gold, straight, 160 mm, 8 mm x 1 mm	IIb	9	11-502	44683
607-040	Bipolar forceps, NON-Stick-Gold, straight, 195 mm, 8 mm x 1 mm	IIb	9	11-502	44683
607-080	Bipolar forceps, NON-Stick-Gold, straight, 270 mm, 8 mm x 2 mm	IIb	9	11-502	44683
607-100	Bipo. forceps, NON-Stick-Gold, bayonet, 160 mm, 0,3 mm	IIb	9	11-502	44683
607-101	Bipolar forceps, NON-Stick-Gold, bayonet, 180 mm, 0,3 mm	IIb	9	11-502	44683
607-102	Bipolar forceps, NON-Stick-Gold, bayonet, 200 mm, 0,3 mm	IIb	9	11-502	44683
607-103	Bipolar forceps, NON-Stick-Gold, bayonet, 220 mm, 0,3 mm	IIb	9	11-502	44683
607-105	Bipo. forceps, NON-Stick-Gold, bayonet, 160 mm, 0,6 mm	IIb	9	11-502	44683
607-106	Bipo. forceps, NON-Stick-Gold, bayonet, 180 mm, 0,6 mm	IIb	9	11-502	44683
607-107	Bipo. forceps, NON-Stick-Gold, bayonet, 200 mm, 0,6 mm	IIb	9	11-502	44683
607-108	Bipo. forceps, NON-Stick-Gold, bayonet, 220 mm, 0,6 mm	IIb	9	11-502	44683
607-110	Bipolar forceps, NON-Stick-Gold, bayonet, 180 mm, 1,0 mm	IIb	9	11-502	44683
607-111	Bipolar forceps, NON-Stick-Gold, bayonet, 200 mm, 1,0 mm	IIb	9	11-502	44683
607-112	Bipo. forceps, NON-Stick-Gold, bayonet, 220 mm, 1 mm	IIb	9	11-502	44683
607-113	Bipo. forceps, NON-Stick-Gold, bayonet, 240 mm, 1 mm	IIb	9	11-502	44683
607-115	Bipo. forceps, NON-Stick-Gold, bayonet, 200 mm, 2 mm	IIb	9	11-502	44683
607-116	Bipo. forceps, NON-Stick-Gold, bayonet, 220 mm, 2 mm	IIb	9	11-502	44683
607-120	Bipo. forceps, NON-Stick-Gold, bayonet, angled up, 200 mm, 1 mm	IIb	9	11-502	44683
607-121	Bipo. forceps, NON-Stick-Gold, bayonet, angled up, 220 mm, 1 mm	IIb	9	11-502	44683
607-122	Bipo. forceps, NON-Stick-Gold, bayonet, angled down, 200 mm, 1 mm	IIb	9	11-502	44683
607-123	Bipo. forceps, NON-Stick-Gold, bayonet, angled down, 220 mm, 1 mm	IIb	9	11-502	44683
607-130	Bipolar forceps, NON-Stick-Gold, straight, 220 mm, 0,3 mm	IIb	9	11-502	44683
607-140	Bipo. forceps, NON-Stick-Gold, round handle, bayonet, 180 mm, 0,3 mm	IIb	9	11-502	44683
607-141	Bipo. forceps, NON-Stick-Gold, round handle, bayonet, 200 mm, 0,3 mm	IIb	9	11-502	44683
607-145	Bipo. forceps, NON-Stick-Gold, round handle, bayonet, 180 mm, 0,6 mm	IIb	9	11-502	44683
607-146	Bipo. forceps, NON-Stick-Gold, round handle, bayonet, 200 mm, 0,6 mm	IIb	9	11-502	44683
607-147	Bipo. forceps, NON-Stick-Gold, round handle, bayonet, 225 mm, 0,6 mm	IIb	9	11-502	44683
607-150	Bipo. forceps, NON-Stick-Gold, round handle, bayonet, 180 mm, 1 mm	IIb	9	11-502	44683
607-151	Bipo. forceps, NON-Stick-Gold, round handle, bayonet, 200 mm, 1 mm	IIb	9	11-502	44683
607-152	Bipo. forceps, NON-Stick-Gold, round handle, bayonet, 225 mm, 1 mm	IIb	9	11-502	44683
607-153	Bipo. forceps, NON-Stick-Gold, round handle, bayonet, 250 mm, 1 mm	IIb	9	11-502	44683
607-170	Bipo. forceps, NON-Stick-Gold, round handle, straight, 155 mm, 0,3 mm	IIb	9	11-502	44683
607-171	Bipo. forceps, NON-Stick-Gold, round handle, straight, 180 mm, 0,3 mm	IIb	9	11-502	44683
607-175	Bipo. forceps, NON-Stick-Gold, round handle, straight, 155 mm, 0,6 mm	IIb	9	11-502	44683
607-176	Bipo. forceps, NON-Stick-Gold, round handle, straight, 180 mm, 0,6 mm	IIb	9	11-502	44683
607-177	Bipo. forceps, NON-Stick-Gold, round handle, straight, 200 mm, 0,6 mm	IIb	9	11-502	44683
607-180	Bipo. forceps, NON-Stick-Gold, round handle, straight, 180 mm, 1 mm	IIb	9	11-502	44683
607-181	Bipo. forceps, NON-Stick-Gold, round handle, straight, 200 mm, 1 mm	IIb	9	11-502	44683
607-182	Bipo. forceps, NON-Stick-Gold, round handle, straight, 225 mm, 1 mm	IIb	9	11-502	44683

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen | Germany
Telefon +49 (0) 7072-6002-0
Telefax +49 (0) 7072-6002-33
info@bowa.de | bowa.de
Registergericht: Stuttgart HRA 381478
Geschäftsführer: Jens Kröber
Martin Heinrich

BOWA
EINFACH SICHER

REF	Product description	Class	Rule	UMDNS	GMDN
607-185	Bipo. forceps, NON-Stick-Gold, round handle, straight, 200 mm, 2 mm	IIb	9	11-502	44683
607-186	Bipo. forceps, NON-Stick-Gold, round handle, straight, 225 mm, 2 mm	IIb	9	11-502	44683
607-190	Bipolar forceps, NON-Stick-Gold, round handle, angled, 225 mm, 1,0 mm	IIb	9	11-502	44683
610-016	Monopolar forceps, bayonet, 195 mm, 8 mm x 2 mm	IIb	9	11-502	44683
610-017	Monopolar forceps, straight, 195 mm, 8 mm x 2 mm	IIb	9	11-502	44683
610-018	Monopolar forceps, straight, 195 mm, 8 mm x 1 mm	IIb	9	11-502	44683
610-019	Monopolar forceps, straight, 220 mm, 8 mm x 2 mm	IIb	9	11-502	44683
610-021	Monopolar forceps, straight, 220 mm, 8 mm x 1 mm	IIb	9	11-502	44683
610-025	Monopolar forceps, straight , 270 mm, 8 mm x 2 mm	IIb	9	11-502	44683
612-018	Monopolar forceps, anatomic, 180 mm, 18 mm x 2 mm	IIb	9	11-502	44683
612-021	Monopolar forceps, anatomic, 200 mm, 18 mm x 2,2 mm	IIb	9	11-502	44683
612-025	Monopolar forceps, anatomic, 250 mm, 18 mm x 2,4 mm	IIb	9	11-502	44683
612-118	Monopolar forceps, surgical, 180 mm, 18 mm x 2 mm	IIb	9	11-502	44683
612-121	Monopolar forceps, surgical, 200 mm, 18 mm x 2,2 mm	IIb	9	11-502	44683
612-125	Monopolar forecps, surgical, 250 mm, 18 mm x 2,4 mm	IIb	9	11-502	44683
700-003	LAP electrode, spatula, 360 mm	IIb	9	16-206	44683
700-004	LAP electrode, strong hook, 360 mm	IIb	9	16-206	44683
700-005	LAP electrode, thin hook, 360 mm	IIb	9	16-206	44683
700-006	LAP electrode, needle, 360 mm	IIb	9	16-206	44683
710-003	LAP electrode, spatula, suction / irrigation tube, sealing cap, 360 mm	IIb	9	16-206	44683
710-004	LAP electr., strong hook, suct. / irrigation tube, sealing cap, 360 mm	IIb	9	16-206	44683
710-005	LAP electr., thin hook, suction / irrigation tube, sealing cap, 360 mm	IIb	9	16-206	44683
710-006	LAP electrode, needle, suction / irrigation tube, sealing cap, 360 mm	IIb	9	16-206	44683
720-000	ErgoLAP MONOPOLAR, handle	IIb	9	11-502	42553
721-301	ErgoLAP MONOPOLAR, jaw, forceps, 360 mm	IIb	9	11-502	42553
721-302	ErgoLAP MONOPOLAR, jaw, DeBakey, 360 mm	IIb	9	11-502	42553
721-303	ErgoLAP MONOPOLAR, jaw, Babcock, 360 mm	IIb	9	11-502	42553
721-304	ErgoLAP MONOPOLAR, jaw, Metzenbaum, 360 mm	IIb	9	11-502	42553
721-306	ErgoLAP MONOPOLAR, jaw, hook scissors, 360 mm	IIb	9	11-502	42553
721-307	ErgoLAP MONOPOLAR, jaw, Dorsey, 360 mm	IIb	9	11-502	42553
721-308	ErgoLAP MONOPOLAR, jaw, Fundus, 360 mm	IIb	9	11-502	42553
721-309	ErgoLAP MONOPOLAR, jaw, Maryland, 360 mm	IIb	9	11-502	42553
721-310	ErgoLAP MONOPOLAR, jaw, Alligator, 360 mm	IIb	9	11-502	42553
722-530	ErgoLAP MONOPOLAR, shaft tube, 360 mm	IIb	9	11-502	42553
736-005	ErgoLAP MONO., handle, shaft tube, sealing spare parts, 360 mm	IIb	9	11-502	42553
741-100	ERGO 320R, handle, COMFORT, cable, 4,5 m	IIb	9	11-502	61873
741-101	ERGO 320R, handle	IIb	9	11-502	61873
741-234	ERGO 320R, shaft tube, ø 5 mm, 340 mm	IIb	9	11-502	61873
741-812	ERGO 320R Set, atraumatic grasping forceps, 340 mm, COMFORT	IIb	9	11-502	61873
741-814	ERGO 320R Set, atraumatic grasping forceps, 340 mm	IIb	9	11-502	61873
741-822	ERGO 320R Set, grasping forceps, fenestrated, curved, 340 mm, COMFORT	IIb	9	11-502	61873
741-823	ERGO 320R Set, grasping forceps, fenestrated, curved, 340 mm	IIb	9	11-502	61873
741-827	ERGO 320R Set, grasping forceps with 2x3 teeth, 340 mm, COMFORT	IIb	9	11-502	61873
741-828	ERGO 320R Set, grasping forceps with 2x3 teeth, 340 mm	IIb	9	11-502	61873

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen | Germany
Telefon +49 (0) 7072-6002-0
Telefax +49 (0) 7072-6002-33
info@bowa.de | bowa.de
Registergericht: Stuttgart HRA 381478
Geschäftsführer: Jens Kröber
Martin Heinrich

REF	Product description	Class	Rule	UMDNS	GMDN
741-832	ERGO 320R Set, Metzenbaum scissors, 340 mm, COMFORT	IIb	9	11-502	61873
741-833	ERGO 320R Set, Metzenbaum scissors, 340 mm	IIb	9	11-502	61873
741-842	ERGO 320R Set, Maryland dissector, 340 mm, COMFORT	IIb	9	11-502	61873
741-843	ERGO 320R Set, Maryland dissector, 340 mm	IIb	9	11-502	61873
742-106	ERGO 325R, handle, rotatable, with lock	IIb	9	11-502	61873
742-234	ERGO 325R, shaft tube, ø 5 mm, 340 mm	IIb	9	11-502	61873
742-310	ERGO 320R/325R, jaw atraumatic grasping forceps, fenestrated, 340 mm	IIb	9	11-502	61873
742-320	ERGO 320R/325R, jaw grasping forceps, fenestrated, curved, 340 mm	IIb	9	11-502	61873
742-330	ERGO 320R/325R, jaw Metzenbaum scissors, 340 mm	IIb	9	11-502	61873
742-340	ERGO 320R/325R, jaw Maryland dissector, 340 mm	IIb	9	11-502	61873
742-350	ERGO 320R/325R, jaw grasping forceps with 2x3 teeth, 340 mm	IIb	9	11-502	61873
742-816	ERGO 325R Set, atraumatic grasping forceps, 340 mm, rotatable, with lock	IIb	9	11-502	61873
742-826	ERGO 325R Set, grasp. forceps, fenes., curved, 340 mm, rotatable, with lock	IIb	9	11-502	61873
742-829	ERGO 325R Set, grasp. forceps with 2x3 teeth, 340 mm, rotatable, with lock	IIb	9	11-502	61873
742-836	ERGO 325R Set, Metzenbaum scissors, 340 mm, rotatable, with lock	IIb	9	11-502	61873
742-846	ERGO 325R Set, Maryland dissector, 340 mm, rotatable, with lock	IIb	9	11-502	61873
743-100	ERGO 330R, handle, COMFORT, cable, 4.5 m	IIb	9	11-502	61873
743-101	ERGO 330R, handle	IIb	9	11-502	61873
743-225	ERGO 330R, shaft tube, ø 5 mm, 250 mm	IIb	9	11-502	61873
743-234	ERGO 330R, shaft tube, ø 5 mm, 340 mm	IIb	9	11-502	61873
743-325	ERGO 330R, jaw, 250 mm	IIb	9	11-502	61873
743-334	ERGO 330R, jaw, 340 mm	IIb	9	11-502	61873
743-425	ERGO 330R, drive rod, 250 mm	IIb	9	11-502	61873
743-434	ERGO 330R, drive rod, 340 mm	IIb	9	11-502	61873
743-525	ERGO 330R, blade holding tube, 250 mm	IIb	9	11-502	61873
743-534	ERGO 330R, blade holding tube, 340 mm	IIb	9	11-502	61873
743-851	ERGO 330R Set, coagulation forceps with cutting blade, 340 mm, COMFORT	IIb	9	11-502	61873
743-852	ERGO 330R Set, coagulation forceps with cutting blade, 340 mm	IIb	9	11-502	61873
743-853	ERGO 330R Set, coagulation forceps with cutting blade, 340 mm	IIb	9	11-502	61873
743-854	ERGO 330R Set, coagulation forceps with cutting blade, 250 mm	IIb	9	11-502	61873
743-999	ERGO 330R, blade, sterile (20 pcs.)	IIb	9	11-502	61873
744-100	ERGO 335R, handle, COMFORT, cable, 4.5 m	IIb	9	11-502	61873
744-101	ERGO 335R, handle	IIb	9	11-502	61873
744-220	ERGO 335R, Schaftrohr, ø 3 mm, 200 mm	IIb	9	11-502	61873
744-229	ERGO 335R, shaft tube, ø 3 mm, 290 mm	IIb	9	11-502	61873
744-312	ERGO 335R, jaw atraumatic grasping forceps, fenestrated, 200 mm	IIb	9	11-502	61873
744-313	ERGO 335R, jaw atraumatic grasping forceps, fenestrated, 290 mm	IIb	9	11-502	61873
744-342	ERGO 335R, jaw Maryland dissector, 200 mm	IIb	9	11-502	61873
744-343	ERGO 335R, jaw Maryland dissector, 290 mm	IIb	9	11-502	61873
744-812	ERGO 335R Set, atraumatic grasping forceps, ø 3 mm, 290 mm, COMFORT	IIb	9	11-502	61873
744-813	ERGO 335R Set, atraumatic grasping forceps, ø 3 mm, 200 mm, COMFORT	IIb	9	11-502	61873
744-815	ERGO 335R Set, atraumatic grasping forceps, ø 3 mm, 290 mm	IIb	9	11-502	61873
744-816	ERGO 335R Set, atraumatic grasping forceps, ø 3 mm, 200 mm	IIb	9	11-502	61873
744-844	ERGO 335R Set, Maryland dissector, ø 3 mm, 290 mm, COMFORT	IIb	9	11-502	61873
744-845	ERGO 335R Set, Maryland dissector, ø 3 mm, 200 mm, COMFORT	IIb	9	11-502	61873

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Straße 4-10
72810 Gomaringen | Germany
Telefon +49 (0) 7072-6002-0
Telefax +49 (0) 7072-6002-33
info@bowa.de | bowa.de
Registergericht: Stuttgart HRA 381478
Geschäftsführer: Jens Kröber
Martin Heinrich

BOWA
EINFACH SICHER

REF	Product description	Class	Rule	UMDNS	GMDN
744-847	ERGO 335R Set, Maryland dissector, ø 3 mm, 290 mm	IIb	9	11-502	61873
744-848	ERGO 335R Set, Maryland dissector, ø 3 mm, 200 mm	IIb	9	11-502	61873
745-100	Trocar sleeve, metal tube, smooth, insuflation stopcock, ø 3,4 mm, 100mm	IIa	7	14-154	37148
745-120	Silikon valve for trocar sleeve (5 pcs.)	IIa	7	14-154	37148
745-130	Sealing for trocar sleeve (5 pcs.)	IIa	7	14-154	37148
745-200	Trocar, phyramid-shaped, 145 mm	IIa	7	14-154	37148
750-000	ErgoLAP BIPOLAR, handle	IIb	9	11-502	42553
750-033	ErgoLAP BIPOLAR, handle, shaft tube, sealing spare parts, 330 mm	IIb	9	11-502	42553
751-033	ErgoLAP BIPOLAR, jaw, Hirsch, 330 mm	IIb	9	11-502	42553
752-033	ErgoLAP BIPOLAR, jaw, Kleppinger, 330 mm	IIb	9	11-502	42553
753-033	ErgoLAP BIPOLAR, jaw, tweezers, 330 mm	IIb	9	11-502	42553
754-033	ErgoLAP BIPOLAR, jaw, micro-tweezers, 330 mm	IIb	9	11-502	42553
755-033	ErgoLAP BIPOLAR, outer shaft tube, 330 mm	IIb	9	11-502	42553
756-033	ErgoLAP BIPOLAR, inner shaft tube, 330 mm	IIb	9	11-502	42553
760-033	ErgoLAP BIPOLAR, jaw, NON-Stick CUT, knife-shaped, 330 mm	IIb	9	11-502	42553
760-119	TissueSeal PLUS, 190 mm	IIb	9	11-502	42553
760-123	TissueSeal PLUS, 230 mm	IIb	9	11-502	42553
760-128	TissueSeal PLUS, 280 mm	IIb	9	11-502	42553
760-216	TissueSeal PLUS COMFORT, 160 mm, cable 4.5 m	IIb	9	11-502	42553
760-219	TissueSeal PLUS COMFORT, 190 mm, cable 4.5 m	IIb	9	11-502	42553
760-223	TissueSeal PLUS COMFORT, 230 mm, cable 4.5 m	IIb	9	11-502	42553
760-228	TissueSeal PLUS COMFORT, 280 mm, cable 4.5 m	IIb	9	11-502	42553
760-319	TissueSeal handle, COMFORT 190 mm, cable 4.5 m	IIb	9	11-502	42553
760-323	TissueSeal handle, COMFORT 230 mm, cable 4.5 m	IIb	9	11-502	42553
760-328	TissueSeal handle, COMFORT 280 mm, cable 4.5 m	IIb	9	11-502	42553
761-033	ErgoLAP BIPOLAR, jaw, NON-Stick CUT, wedge-shaped, 330 mm	IIb	9	11-502	42553
770-000	NightKNIFE + LIGATOR, handle, COMFORT, cable 4.5 m	IIb	9	11-502	42553
770-036	LIGATOR, handle, shaft tube, sealing spare parts, 360 mm, COMFORT	IIb	9	11-502	42553
770-200	NightKNIFE set, 200 mm, COMFORT	IIb	9	11-502	42553
770-201	NightKNIFE set, exchangeable knife, 200 mm, COMFORT	IIb	9	11-502	42553
770-211	LIGATOR, shaft tube, 110 mm	IIb	9	11-502	42553
770-236	LIGATOR, shaft tube, 360 mm	IIb	9	11-502	42553
770-300	NightKNIFE set, 360 mm, COMFORT	IIb	9	11-502	42553
770-301	NightKNIFE set, exchangeable knife, 360 mm, COMFORT	IIb	9	11-502	42553
770-320	NightKNIFE, shaft tube, 200 mm	IIb	9	11-502	42553
770-336	NightKNIFE, shaft tube, 360 mm	IIb	9	11-502	42553
770-999	NightKNIFE, blade (5 pcs.)	IIb	9	11-502	42553
771-011	LIGATOR, jaw, straight, 110 mm	IIb	9	11-502	42553
771-036	LIGATOR, jaw, straight, 360 mm	IIb	9	11-502	42553
771-120	NightKNIFE, jaw, 200 mm	IIb	9	11-502	42553
771-121	NightKNIFE, jaw, exchangeable knife, 200 mm	IIb	9	11-502	42553
771-136	NightKNIFE, jaw, 360 mm	IIb	9	11-502	42553
771-137	NightKNIFE, jaw, exchangeable knife, 360 mm	IIb	9	11-502	42553
772-011	LIGATOR, jaw, Maryland, 110 mm	IIb	9	11-502	42553
772-036	LIGATOR, jaw, Maryland, 360 mm	IIb	9	11-502	42553

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Straße 4-10
72810 Gomaringen | Germany
Telefon +49 (0) 7072-6002-0
Telefax +49 (0) 7072-6002-33
info@bowa.de | bowa.de
Registergericht: Stuttgart HRA 381478
Geschäftsführer: Jens Kröber
Martin Heinrich

REF	Product description	Class	Rule	UMDNS	GMDN
773-000	NightKNIFE + LIGATOR set, COMFORT	IIb	9	11-502	42553
773-001	NightKNIFE + LIGATOR set, exchangeable knife, COMFORT	IIb	9	11-502	42553
775-000	ERGO 310D, Laparoscopic vessel sealer, Ø 5 mm, 340 mm	IIb	9	11-502	44684
795-145	BiZZER, bipolar scissors, 145 mm, curved, needle tip	IIb	9	13-484	44683
795-180	BiZZER, bipolar scissors, 180 mm, curved, needle tip	IIb	9	13-484	44683
795-545	BiZZER, bip. scissors, 145 mm, curved, needle tip, COMFORT, cable 4.5m	IIb	9	13-484	44683
795-580	BiZZER, bip. scissors, 180 mm, curved, needle tip, COMFORT, cable 4.5m	IIb	9	13-484	44683
796-170	BiZZER, bipolar scissors, 170 mm, curved	IIb	9	13-484	44683
796-570	BiZZER, bipolar scissors, 170 mm, curved, COMFORT, cable 4.5 m	IIb	9	13-484	44683
797-180	BiZZER, bipolar scissors, 180 mm, curved, slight	IIb	9	13-484	44683
797-230	BiZZER, bipolar scissors, 230 mm, curved, slight	IIb	9	13-484	44683
797-280	BiZZER, bipolar scissors, 280 mm, curved, slight	IIb	9	13-484	44683
797-580	BiZZER, bipolar scissors, 180 mm, curved, slight, COMFORT, cable 4.5 m	IIb	9	13-484	44683
797-630	BiZZER, bipolar scissors, 230 mm, curved, slight, COMFORT, cable 4.5 m	IIb	9	13-484	44683
797-680	BiZZER, bipolar scissors, 280 mm, curved, slight, COMFORT, cable 4.5 m	IIb	9	13-484	44683
798-145	BiZZER, bipolar scissors, 145 mm, curved, fine	IIb	9	13-484	44683
798-180	BiZZER, bipolar scissors, 180 mm, curved, fine	IIb	9	13-484	44683
798-230	BiZZER, bipolar scissors, 230 mm, curved, fine	IIb	9	13-484	44683
798-280	BiZZER, bipolar scissors, 280 mm, curved, fine	IIb	9	13-484	44683
798-545	BiZZER, bipolar scissors, 145 mm, curved, fine, COMFORT, cable 4.5 m	IIb	9	13-484	44683
798-580	BiZZER, bipolar scissors, 180 mm, curved, fine, COMFORT, cable 4.5 m	IIb	9	13-484	44683
798-630	BiZZER, bipolar scissors, 230 mm, curved, fine, COMFORT, cable 4.5 m	IIb	9	13-484	44683
798-680	BiZZER, bipolar scissors, 280 mm, curved, fine, COMFORT, cable 4.5 m	IIb	9	13-484	44683
800-000	Tip cleaner, single-use, sterile (50 pcs.)	Is	1	15-271	44684
800-001	NON-Stick knife electrode, shaft 2.4 mm, single-use, sterile (10 pcs.)	IIb	9	11-499	44684
800-002	NON-Stick needle electrode, shaft 2.4 mm, single-use, ster. (10 pcs.)	IIb	9	11-499	44684
800-003	NON-Stick ball electrode, shaft 2.4 mm, single-use, sterile (10 pcs.)	IIb	9	11-499	44684
800-004	NON-Stick knife el., 152 mm, shaft 2.4 mm, single-use, ster. (10 pcs.)	IIb	9	11-499	44684
800-005	NON-Stick ball el., 134 mm, shaft 2.4 mm, single-use, ster. (10 pcs.)	IIb	9	11-499	44684
800-006	Safety holster, single-use, sterile (100 pcs.)	Is	1	16-349	44684
800-007	Knife electrode, shaft 2.4 mm, single-use, sterile (5 pcs.)	IIb	9	11-499	44684
800-011	Needle electrode, shaft 2.4 mm, single-use, sterile (5 pcs.)	IIb	9	11-499	44684
800-021	Ball electrode, shaft 2.4 mm, single-use, sterile (5 pcs.)	IIb	9	11-499	44684
800-028	Knife electrode, 152 mm, shaft 2.4 mm, single-use, sterile (5 pcs.)	IIb	9	11-499	44684
800-030	Ball electrode, 136 mm, shaft 2.4 mm, single-use, sterile (10 pcs.)	IIb	9	11-499	44684
801-030	Handle, 1 sw., knife, Ø 2.4 mm, 3-pin, 3 m, s-u, sterile (50 pcs.)	IIb	9	11-494	44681
802-030	Handle, 2 sw., knife, Ø 2.4 mm, 3-pin, 3 m, s-u, sterile (50 pcs.)	IIb	9	11-494	44681
802-032	SHE SHA Handle, 2 sw., knife, 3 m, s-u, sterile (10 pcs.)	IIb	9	11-494	44681
803-030	Handle, no sw., knife, Ø 2.4 mm, 3 m, single-use, ster. (10 pcs.)	IIa	6	11-494	44678
815-040	Neutral electrode, 40 cm², non-split (100 pcs)	IIb	9	11-500	11500
815-070	Neutral electrode, 70 cm², non-split (100 pcs)	IIb	9	11-500	11500
815-110	Neutral electrode, 110 cm², non-split (100 pcs)	IIb	9	11-500	11500
815-140	Neutral electrode, 140 cm², non-split (100 pcs)	IIb	9	11-500	11500
816-042	Neutral electrode, 40 cm², split, EASY (100 pcs)	IIb	9	11-500	11500
816-071	Neutral electrode, 70 cm², split (100 pcs)	IIb	9	11-500	11500

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen | Germany
Telefon +49 (0) 7072-6002-0
Telefax +49 (0) 7072-6002-33
info@bowa.de | bowa.de
Registergericht: Stuttgart HRA 381478
Geschäftsführer: Jens Kröber
Martin Heinrich

BOWA
EINFACH SICHER

REF	Product description	Class	Rule	UMDNS	GMDN
816-072	Neutral electrode, 70 cm², split, EASY (100 pcs)	IIb	9	11-500	11500
816-092	Neutral electrode, 90 cm², split, EASY (100 pcs)	IIb	9	11-500	11500
816-112	Neutral electrode, 110 cm², split, EASY (100 pcs)	IIb	9	11-500	11500
816-141	Neutral electrode, 140 cm², split (100 pcs)	IIb	9	11-500	11500
816-161	Neutral electrode, 160 cm², split (100 pcs)	IIb	9	11-500	11500
816-162	Neutral electrode, 160 cm², split, EASY (100 pcs)	IIb	9	11-500	11500
817-040	Neutral electrode, 40 cm², non-split, with cable 3 m (15 pcs)	IIb	9	11-500	11500
817-070	Neutral electrode, 70 cm², non-split, with cable 3 m (15 pcs)	IIb	9	11-500	11500
817-110	Neutral electrode, 110 cm², non-split, with cable 3 m (15 pcs)	IIb	9	11-500	11500
817-140	Neutral electrode, 140 cm², non-split, with cable 3 m (15 pcs)	IIb	9	11-500	11500
818-042	Neutral electrode, 40 cm², split, with cable 3 m, EASY (15 pcs)	IIb	9	11-500	11500
818-071	Neutral electrode, 70 cm², split, with cable 3 m (15 pcs)	IIb	9	11-500	11500
818-072	Neutral electrode, 70 cm², split, with cable 3 m, EASY (15 pcs)	IIb	9	11-500	11500
818-092	Neutral electrode, 90 cm², split, with cable 3 m, EASY (15 pcs)	IIb	9	11-500	11500
818-112	Neutral electrode, 110 cm², split, with cable 3 m, EASY (15 pcs)	IIb	9	11-500	11500
818-141	Neutral electrode, 140 cm², split, with cable 3 m (15 pcs)	IIb	9	11-500	11500
818-161	Neutral electrode, 160 cm², split, with cable 3 m (15 pcs)	IIb	9	11-500	11500
818-162	Neutral electrode, 160 cm², split, with cable 3 m, EASY (15 pcs)	IIb	9	11-500	11500
830-000	TissueSeal, electrode tips, straight, toothed, s-u, sterile (5 sets)	IIb	9	11-499	44684
830-001	TissueSeal, electrode tips, straight, single-use, sterile (5 sets)	IIb	9	11-499	44684
830-010	TissueSeal, electrode tips, angled, toothed, s-u, sterile (5 sets)	IIb	9	11-499	44684
830-011	TissueSeal, electrode tips, angled, single-use, sterile (5 sets)	IIb	9	11-499	44684
830-050	ARC PLUS filter set, single-use, sterile (50 pcs.)	IIa	2	11-494	44678
900-000	ARC PLUS Argon coagulation unit for ARC 250 / 303 / 350 (REF 900-350)	IIa	11	17-738	36154
900-001	ARC PLUS Argon coagulation unit, for ARC 400 / 350 (REF 900-351)	IIa	11	17-738	36154
900-030	Equipotential bonding, 0.5 m	I	1	11-496	16902
900-031	Equipotential bonding, 5 m	I	1	11-496	16902
900-035	Equipotential bonding, 1.5 m	I	1	11-496	16902
900-100	Electrosurgical unit ARC 100	IIb	9	11-490	11490
900-250	Electrosurgical unit ARC 250	IIb	9	11-490	11490
900-303	Electrosurgical unit ARC 303	IIb	9	11-490	11490
900-350	Electrosurgical unit ARC 350 (REF 900-350)	IIb	9	11-490	11490
900-351	Electrosurgical unit ARC 350 (REF 900-351)	IIb	9	11-490	11490
900-390	Option LIGATION, for ARC 350 (REF 900-350)	IIb	9	11-490	11490
900-391	Option GastroCut, for ARC 350 (REF 900-351)	IIb	9	11-490	11490
900-392	Option Argon / GastroCut, for ARC 250 / 303	IIb	9	11-490	11490
900-395	Option Bipolar Resection, for ARC 400 / 350 (REF 900-351)	IIb	9	11-490	11490
900-396	Option LIGATION, for ARC 400 / 350 (REF 900-351)	IIb	9	11-490	11490
900-397	Europe Option ARC 303 (ERBE/MARTIN via adapter)	IIb	9	11-490	11490
900-398	Europe Option ARC 250 (ERBE/MARTIN via adapter)	IIb	9	11-490	11490
900-399	Option BipolarSimCOAG, for ARC 400	IIb	9	11-490	11490
900-400	Electrosurgical unit ARC 400	IIb	9	11-490	11490
900-901	Pressure reducer, for ARC PLUS (REF 900-000), DIN 477 no. 6	IIb	9	13-323	37025
900-902	Pressure reducer, for ARC PLUS (REF 900-000), DIN 477 no. 10	IIb	9	13-323	37025
900-903	Pressure reducer, for ARC PLUS (REF 900-000), CGA 580	IIb	9	13-323	37025

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen | Germany
Telefon +49 (0) 7072-6002-0
Telefax +49 (0) 7072-6002-33
info@bowa.de | bowa.de
Registergericht: Stuttgart HRA 381478
Geschäftsführer: Jens Kröber
Martin Heinrich

REF	Product description	Class	Rule	UMDNS	GMDN
900-904	Pressure reducer, for ARC PLUS (REF 900-000), BS 341 no. 3	IIb	9	13-323	37025
900-906	Pressure reducer, for ARC PLUS (REF 900-001) and ARC 400, DIN 477 no. 6	IIb	9	13-323	37025
900-907	Pressure reducer, for ARC PLUS (REF 900-001) and ARC 400, DIN 477 no. 10	IIb	9	13-323	37025
900-908	Pressure reducer, for ARC PLUS (REF 900-001) and ARC 400, CGA 580	IIb	9	13-323	37025
900-909	Pressure reducer, for ARC PLUS (REF 900-001) and ARC 400, BS 341 no. 3	IIb	9	13-323	37025
900-911	Mains cable, plug type F, 5 m	I	1	11-496	16902
900-912	Mains cable, plug type G, 5 m	I	1	11-496	16902
900-913	Mains cable, plug type K, 5 m	I	1	11-496	16902
900-914	Mains cable, plug type L, 5 m	I	1	11-496	16902
900-915	Mains cable, plug type N, 5 m	I	1	11-496	16902
900-916	Mains cable, plug type B, 5 m	I	1	11-496	16902
900-917	Mains cable, plug type I, 5 m	I	1	11-496	16902
901-011	Single-pedal footswitch, with switch, cable 4 m	IIb	9	11-009	36336
901-012	Single-pedal footswitch for ARC 100, cable 4 m	IIb	9	11-009	36336
901-021	Double-pedal footswitch, cable 4 m	IIb	9	11-009	36336
901-031	Double-pedal footswitch with switch, cable 4 m	IIb	9	11-009	36336
901-032	Double-pedal footswitch with switch and clip, cable 4 m	IIb	9	11-009	36336
901-045	Interface with fibre optics, for ARC 350, for ARC PLUS (REF 900-000)	I	1	11-496	16902
901-050	Fibre optics, for ARC PLUS (REF 900-000 silver)	I	1	11-496	16902
901-051	Fibre optics, for ARC PLUS (REF 900-001)	I	1	11-496	16902
901-052	Fibre optics, for ARC PLUS (REF 900-000)	I	1	11-496	16902
901-124	Accessory set, 2.4 mm	IIb	9	15-895	44683
901-125	ARC 100 set, 2.4 mm	IIb	9	15-895	44683
901-126	ARC 100 accessory set, 2.4 mm	IIb	9	15-895	44683
901-140	Accessory set, 4 mm	IIb	9	15-895	44683
901-210	Adapter bipolar, Erbe, for BOWA ARC	I	1	16-490	35041
901-220	Adapter bipolar, Martin, for BOWA ARC	I	1	16-490	35041
901-250	Adapter monopolar, Erbe, for BOWA ARC	I	1	16-490	35041
901-270	Adapter monopolar, Martin, for BOWA ARC	I	1	16-490	35041
932-031	Rigid Argon coagulation electrode, 75 mm	IIb	9	11-499	44683
932-032	Rigid Argon coagulation electrode, 150 mm	IIb	9	11-499	44683
932-034	Rigid Argon coagulation electrode, 370 mm	IIb	9	11-499	44683
932-035	Rigid Argon needle cutting and coagulation electrode, 100 mm	IIb	9	11-499	44683
932-036	Rigid Argon needle cutting and coagulation electrode, 150 mm	IIb	9	11-499	44683
932-042	Argon handle COMFORT, cable 3.5 m	IIb	9	11-494	44680
932-045	Cable for flexible Argon probe, round plug, 2.5 m	IIa	2	11-493	35042
932-048	Flexible Argon probe, round pin plug, Ø 1.5 mm, 1.5 m	IIb	9	16-206	44683
932-049	Flexible Argon probe, round pin plug, Ø 2.3 mm, 2.2 m	IIb	9	16-206	44683
932-050	Flexible Argon probe, round pin plug, Ø 3.2 mm, 2.2 m	IIb	9	16-206	44683
932-051	Flexible Argon probe, round pin plug, Ø 1.5 mm, 3 m	IIb	9	16-206	44683
932-052	Flexible Argon probe, round pin plug, Ø 2.3 mm, 3 m	IIb	9	16-206	44683
932-055	Rigid Argon knife cutting and coagulation electrode, 100 mm	IIb	9	11-499	44683
932-058	Rigid Argon knife cutting and coagulation electrode, 150 mm	IIb	9	11-499	44683
932-059	Rigid Argon knife cutting and coagulation electrode, 370 mm	IIb	9	11-499	44683
932-060	Argon coagulation electrode, bendable 170 mm	IIb	9	11-499	44683

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen | Germany
Telefon +49 (0) 7072-6002-0
Telefax +49 (0) 7072-6002-33
info@bowa.de | bowa.de
Registergericht: Stuttgart HRA 381478
Geschäftsführer: Jens Kröber
Martin Heinrich

BOWA
EINFACH SICHER

REF	Product description	Class	Rule	UMDNS	GMDN
932-061	Argon coagulation electrode, bendable 250 mm	IIb	9	11-499	44683
932-062	Argon coagulation electrode, bendable 370 mm	IIb	9	11-499	44683
932-118	Flexible Argon probe, round pin plug, Ø 2.3 mm, 1 m	IIb	9	16-206	44683
932-146	Cable for flexible Argon probe COMFORT, 2.5 m	IIa	2	11-493	35042
932-148	Flexible Argon probe, Ø 1.5 mm, 1.5 m	IIb	9	16-206	44683
932-149	Flexible Argon probe, Ø 2.3 mm, 2.2 m	IIb	9	16-206	44683
932-150	Flexible Argon probe, Ø 3.2 mm, 2.2 m	IIb	9	16-206	44683
932-151	Flexible Argon probe, Ø 1.5 mm, 3.0 m	IIb	9	16-206	44683
932-152	Flexible Argon probe, Ø 2.3 mm, 3.0 m	IIb	9	16-206	44683
932-153	Flexible Argon probe, 90°, Ø 2.3 mm, 2.2 m	IIb	9	16-206	44683
932-154	Flexible Argon probe, Ø 2.3 mm, 1 m	IIb	9	16-206	44683
932-248	Flexible Argon probe, Ø 1.5 mm, 1.5 m, single-use, sterile (10 pcs.)	IIb	9	11-499	44684
932-249	Flexible Argon probe, Ø 2.3 mm, 2.2 m, single-use, sterile (10 pcs.)	IIb	9	11-499	44684
932-250	Flexible Argon probe, Ø 3.2 mm, 2.2 m, single-use, sterile (10 pcs.)	IIb	9	11-499	44684
932-251	Flexible Argon probe, Ø 1.5 mm, 3 m, single-use, sterile (10 pcs.)	IIb	9	11-499	44684
932-252	Flexible Argon probe, Ø 2.3 mm, 3 m, single-use, sterile (10 pcs.)	IIb	9	11-499	44684
932-253	Flexible Argon probe, 90°, Ø 2.3 mm, 2.2 m, single-use, sterile (10 pcs.)	IIb	9	11-499	44684
952-001	SHE SHA, Hose, for handle, single-use, sterile (10 pcs.)	Is	1	16-262	46483

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen | Germany
Telefon +49 (0) 7072-6002-0
Telefax +49 (0) 7072-6002-33
info@bowa.de | bowa.de
Registergericht: Stuttgart HRA 381478
Geschäftsführer: Jens Kröber
Martin Heinrich

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 16 02 16316 018

Holder of Certificate: **BOWA-electronic GmbH & Co. KG**
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen
GERMANY

Facility(ies):
BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10, 72810 Gomaringen,
GERMANY

BOWA Polska Sp. zo. o.
Zlotkowo, ul. Obornicka 10, 60-002 Suchy Las,
POLAND

Certification Mark:

Scope of Certificate:
Design and development, production and distribution of
- Electrosurgical Units and accessories,
- Argon Coagulation Units and accessories,
- electrode handles,
- active electrodes and instruments,
- monopolar and bipolar forceps,
- endoscopic and laparoscopic instruments,
- Instruments for vessel sealing,
- neutral electrodes,
- bipolar scissors

Applied Standard(s):
EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713076068
Valid from: 2016-03-03
Valid until: 2019-02-28

Date, 2016-03-03

Stefan Preiß

Page 1 of 1

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

Zertifiziervertrag

Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:

– Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:

– Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.

– Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract

Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.

On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuev-sued.de/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:

– Validity of the quoted test standard(s)

In addition for certificates with the right to use a certification mark and for QM certificates:

– Conditions for an adequate manufacturing are maintained

– Regular surveillance of the facility is performed

Akkreditierungen / Benennungen (Status 14.10.2013) /
Accreditations / notifications (as of 2013-10-14)

Deutschland / Germany

Produktsicherheitsgesetz (ProdSG) /
Product Safety Act (ProdSG)

Europa / Europe

- Niederspannungsrichtlinie 2006/95/EG
- Spielzeugrichtlinie 2009/48/EG
- Richtlinie für aktive medizinische Implantate 90/385/EWG
- Richtlinie für Medizinprodukte 93/42/EWG
- Richtlinie für In-vitro-Diagnostika 98/79/EG
- Richtlinie für Gasverbrauchseinrichtungen 2009/142/EG
- Richtlinie für persönliche Schutzausrüstungen 89/686/EWG
- EMV-Richtlinie 2004/108/EG
- Richtlinie für Sportboote 94/25/EG + 2003/44/EG
- Richtlinie für Maschinen 2006/42/EG
- Richtlinie für Ex-Schutz Geräte 94/9/EG

- Low Voltage Directive 2006/95/EC
- Toys Directive 2009/48/EC
- Directive for Active Implantable Medical Devices 90/385/EEC
- Directive for Medical Devices 93/42/EEC
- Directive on In Vitro Diagnostic Medical Devices 98/79/EC
- Directive for Gas Appliances 2009/142/EC
- Directive for Personal Protective Equipment 89/686/EEC
- EMC Directive 2004/108/EC
- Directive for Recreational Craft 94/25/EC + 2003/44/EC
- Directive for Machinery 2006/42/EC
- Directive for Ex Safe Equipment 94/9/EC

- ENEC Agreement for luminaires, household and IT equipment

USA

- Nationally Recognized Testing Laboratory (NRTL) to 29 CFR 1910.7 by OSHA
- Accredited for FDA 510(k) Third Party Review
- Conformity Assessment Body to the MRA for Medical Devices; FDA QSReg Inspections, FDA 510(k) Third Party Review

Asien-Pazifik Region / Asia Pacific

- Recognized Certification Body to Electrical Products (Safety) Regulation; Hong Kong
- Konformitätsbewertungsstelle / Conformity Assessment Body to the MRA for Medical Devices; Australien / Australia
- Konformitätsbewertungsstelle / Conformity Assessment Body to the MRA for Medical Devices; Neuseeland / New Zealand

Weltweit / Worldwide

- NCB im CB-Scheme des IECEE / NCB in the CB Scheme of IECEE
- ExCB im IECEx-Scheme des IECEE / ExCB in the IECEx Scheme of IECEE
- Zertifizierstellen durch DAkkS akkreditiert DE-ZE-11321-01, DE-ZM-11321-09 und DE-ZM-11321-01. Certification Bodies accredited by DAkkS DE-ZE-11321-01, DE-ZM-11321-09 and DE-ZM-11321-01.

Zertifizierstelle für Produkte / Certification Body for Products · e-mail ps-zert@tuev-sued.de
Zertifizierstelle für Medizinprodukte / Certification Body for Medical Devices · e-mail: medical devices@tuev-sued.de
Kundenservice / Clients Services · Phone +49/89/50 08-42 61 · Fax +49/89/50 08-42 30 · e-mail ps-zert@tuev-sued.de

СИСТЕМА СЕРТИФИКАЦИИ ГОСТ Р

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

СЕРТИФИКАТ СООТВЕТСТВИЯ

№ РОСС RU.ИМ02.Н17809

Срок действия с 18.07.2016г. по 18.07.2019г.

№ 1758756

ОРГАН ПО СЕРТИФИКАЦИИ № RA. RU.11ИМ02
МЕДИЦИНСКИХ ИЗДЕЛИЙ АНО «ВНИИИМТ»
129301, г. Москва, ул. Касаткина, д.3 тел. (495) 683-97-92, факс (499)187-89-54,
e-mail: im02@bk.ru

ПРОДУКЦИЯ Материал упаковочный для стерилизации:
рулоны комбинированные плоские и со складками «СтериТ®»,
(см. приложение на 1 листе)
ТУ 9398-083-11764404-2011
Серийный выпуск.

код ОК 005 (ОКП): 93 9800

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ НОРМАТИВНЫХ ДОКУМЕНТОВ
ГОСТ ISO 11607-2011,
ГОСТ Р 50444-92

код ТН ВЭД России: 3822 00 000 0

ИЗГОТОВИТЕЛЬ Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»), 105094, г. Москва, Госпитальный вал, д.5, стр.7А, пом.VIII ИНН 5023001024,
Место производства - см. приложение

СЕРТИФИКАТ ВЫДАН Обществу с ограниченной ответственностью «Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»)
Россия, 105094, г. Москва, Госпитальный вал, д.5, стр.7А, пом.VIII
тел./факс (495) 988-76-67

НА ОСНОВАНИИ протокола испытаний № 16-865 от 11.07.2016г. ИЦ МИ АНО «ВНИИИМТ» (№ RA.RU.21ИМ04).

Регистрационное удостоверение № РЗН 2013/110 от 04 апреля 2016г. Федеральной службы по надзору в сфере здравоохранения (РОСЗДРАВНАДЗОР)

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ Маркирование продукции производится знаком соответствия Системы сертификации ГОСТ Р при добровольной сертификации продукции

М.П. **Руководитель органа** Е. И. Полянская
(подпись) (инициалы, фамилия)

Эксперт В.В. Русова
(подпись) (инициалы, фамилия)

Сертификат не применяется при обязательной сертификации

СИСТЕМА СЕРТИФИКАЦИЙ ГОСТ Р

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

№ 0936352

ПРИЛОЖЕНИЕ

К сертификату соответствия № РОСС RU.ИМ02.Н17809

Перечень конкретной продукции, на которую распространяется действие сертификата соответствия

код ОК 005 (ОКП) / код ТН ВЭД России	Наименование и обозначение продукции, ее изготовитель	Обозначение документации, по которой выпускается продукция
93 9800 3822 00 000 0	**Материал упаковочный для стерилизации:** **рулоны комбинированные плоские и со складками «СтериТ®» по ТУ 9398-083-11764404-2011:** 1. Размеры рулонов комбинированных плоских: Ширина рулона, 30-600 мм; Длина рулона, 10-200 м. 2. Размеры рулонов комбинированных со складками: Ширина рулона, 50-600 мм; Ширина боковой складки,10-100 мм; Длина рулона, 10-200 м. Место производства - 152020, Ярославская область, г. Переславль-Залесский, ул. Большая Протечная, д.51б	Лист 1

М.П. **Руководитель органа** Е.И. Полянская
(подпись) (инициалы, фамилия)

Эксперт В.В. Русова
(подпись) (инициалы, фамилия)