

EC Certificate - Full Quality Assurance System

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

No. CE 586997
Issued To: Symmetry Surgical, Inc.
3034 Owen Drive
Antioch
Tennessee
37013
USA

In respect of:

The design and manufacture of sterile and non-sterile manual non-powered surgical instruments for general, plastic, and laparoscopic surgery.

The design and manufacture of electrosurgical laparoscopic surgical instruments and accessories.

Those aspects of Annex II concerned with the maintenance of the accuracy of Class I measuring instruments.

Those aspects of Annex II concerned with securing and maintaining sterile conditions of single use Class I instruments.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2012-08-22**

Date: **2021-04-27**

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

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Page 1 of 3

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

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Supplementary Information to CE 586997

Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIb		
GMDN 62061	VersaGrip™ inserts	Surgical instruments used to grasp, manipulate and cut or dissect tissue or objects during laparoscopic surgical procedures.
	Dissectors and accessories connected to an active device	
Class IIa		
MD 0106	Knives and rongeurs	---
	Vein strippers	---
	Sponges & dissectors	---
	Clamps	---
	Retractors, spreaders, blades	---
	Suction tubes	---
	Trocars, cannulas, needles	---
Class Is		
MDS 7006	Sterile surgical accessories	---

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

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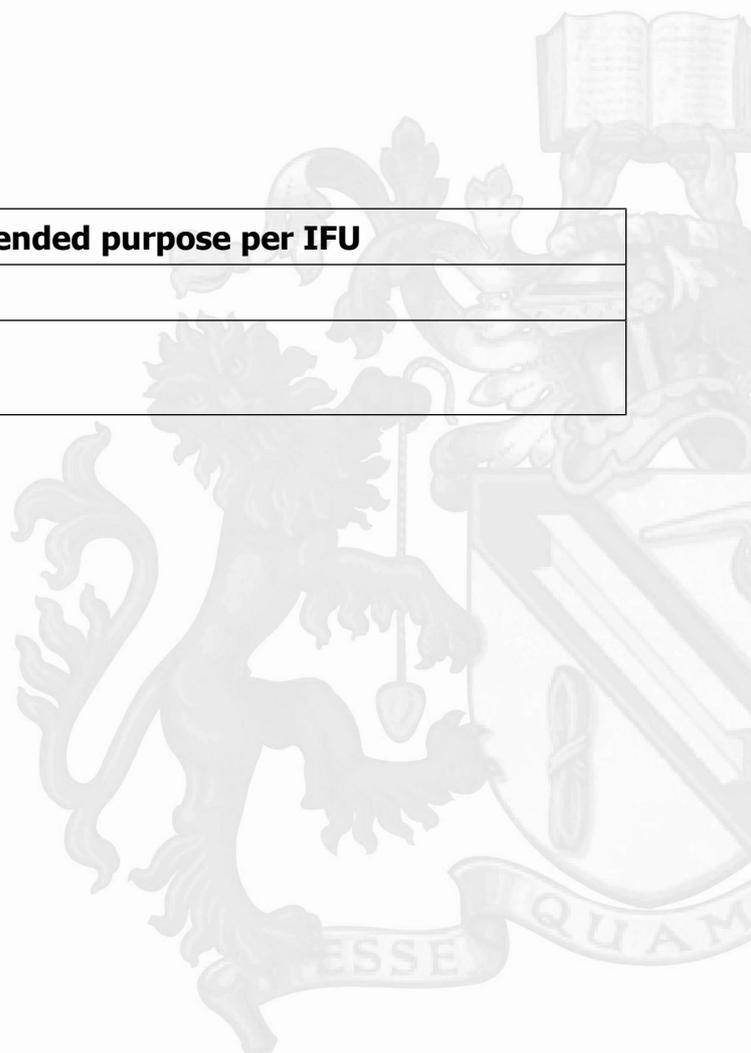
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Number	Device Name	Intended purpose per IFU
Class Im		
MD 0104	Surgical measuring instruments	---



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List of Significant Subcontractors

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Subcontractor:	Service(s) supplied
August Reuchlen GmbH Junkersstrasse 8 Tuttlingen 78532 Germany	Final Inspection Manufacture
Carwild Corporation 3 State Pier Road New London Connecticut 06320 USA	Manufacture Packaging
Contech Medical, Inc 99 Hartford Avenue Providence RI 02909 USA	Assembly Packaging

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Subcontractor:	Service(s) supplied
Faulhaber Pinzetten OHG Daimlerstrasse 1 Frittlingen 78665 Germany	Manufacture
Fetzer Surgical LLC 1019 W Wise Rd Ste 201 Schaumburg 60193 USA	Final Inspection Manufacture
Geister Medizintechnik GmbH Föhrenstrasse 2 Tuttlingen 78532 Germany	Manufacture

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Subcontractor:	Service(s) supplied
HEBUmedical GmbH Badstrasse 8 Tuttlingen 78532 Germany	Manufacture
Instrumed GmbH dba Avalign German Speciality Instruments Unter Buchsteig 3 D-78532 Tuttlingen Germany	Final Inspection Manufacture
Integra York PA, Inc. 589 Davies Drive York Pennsylvania 17402 USA	Final Inspection Manufacture

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Subcontractor:

Service(s) supplied

Isomedix Operations, Inc.
 435 Whitney Street
 Northborough
 Massachusetts
 01532
 USA

ETO Sterilization
Radiation (Gamma Sterilization)

Isomedix Operations, Inc.
 3459 South Clinton Avenue
 South Plainfield
 New Jersey
 07080
 USA

ETO Sterilization

JakuTec Medizintechnik GmbH & Co. KG
 Auf der Höhe 15
 78576 Emmingen-Liptingen
 Germany

Manufacture

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Josef Betzler Surgical Instruments e.K. Hohnerstrasse 15 Seitingen-Oberflacht 78606 Germany	Final Inspection Manufacture
Koscher & Würtz GmbH Einsteinstrasse 7 Spaichingen 78549 Germany	Final Inspection Manufacture
Max Hauser Süddeutsche Chirurgiemechnik GmbH Föhrenstrasse 33 Tuttlingen 78532 Germany	Manufacture

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Subcontractor:	Service(s) supplied
Medicon eG Gänsäcker 15 Tuttlingen 78532 Germany	Manufacture
Phoenix Instruments Inc. 2368 Corporate Lane, Suite 106 Naperville Illinois 60563 USA	Final Inspection Manufacture
QSA Surgical (Pvt.) Ltd P.O. Box 1094 Ghuinke Daska Road Siaklot Pakistan	Final Inspection Manufacture

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Subcontractor:	Service(s) supplied
Rebstock Instruments GmbH In Weiheracker 7 Durbheim 78589 Germany	Final Inspection Manufacture
Rudischhauser Surgical Instruments Manufacturing GmbH Gansacker 28 78532 Tuttlingen Germany	Manufacture
RUDOLF STORZ GmbH Friedrich-Wöhler-Str. 13 Emmingen 78576 Germany	Manufacture

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Subcontractor:	Service(s) supplied
Shanghai Medical Instruments (Group) Ltd Corp No. 351 Yue Xiu Road Shanghai 20072 China	Manufacture
Shanghai ShuNeng Irradiation Technology Co., LTD. Building 5, No.255, Maoyuan Road Fengxian District Shanghai City 201401 People's Republic of China	Radiation (E Beam Sterilization)
Symmetry Medical Manufacturing, Inc. dba Tecomet 3724 North State Road 15 Warsaw Indiana 46582 USA	Final Inspection Manufacture

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Subcontractor:	Service(s) supplied
Symmetry Surgical GmbH Maybachstraße 10 Tuttlingen 78532 Germany	EU Representative Final Inspection Packaging
Technimark LLC 149 Devereux Drive Latrobe Pennsylvania 15650 USA	Manufacture Packaging
Tecomet Inc. 5307 95th Avenue Kenosha Wisconsin 53144 USA	Manufacture

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Subcontractor:

Service(s) supplied

Trokamed GmbH
Kleine Breite 17
78187 Geisingen
Germany

Final Inspection
Manufacture

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Date	Reference Number	Action
22 August 2012	7832143	First Issue
28 February 2013	7959367	Addition to scope of 'sterile and non sterile' to all instruments,high speed saw systems,surgical procedure kits, general, plastic surgery and Ophthalmic instruments, sterile and non sterile instruments for connection to active devices. Addition of 'packaging' to the service supplied by Carwild.
21 March 2013	7904215	Addition of neurosurgical instruments to the scope combined with the issue of Design Examination certificate CE 591483.
19 December 2013	8082469	Clarification of EU Rep name and address and Removal of "Codman & Shurtleff" as significant sub contractor.

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04 April 2017	8690000	Clarification of scope to remove 'development'. Modification of scope to include 'The design and manufacture of Access Electrosurgical Endoscopic Surgical Instruments' Clarification of scope to include 'Instruments' in the aspects of manufacturing of Class I sterile and Class I Measuring instruments' Clarification of scope to include "Those aspects of Annex II concerned with the design and manufacture of Class I measuring instruments. Those aspects of Annex II concerned with securing and maintaining sterile conditions of single use Class I instruments." Addition of significant subcontractor; 'Tecomet Inc., Kenosha, Wisconsin, USA' for the activity of 'Manufacture' Removal of significant subcontractor: Symmetry Medical, New Bedford. Change of EU Representative from Symmetry Medical Sheffield, Beulah Road, Sheffield, S6 2AN, UK to Symmetry Surgical GmbH, Maybachstraße 10, 78532 Tuttlingen, Germany. Addition of Final Inspection and Packaging activities to the significant subcontractor Symmetry Surgical GmbH.
11 August 2017	8744633	Certificate renewal. Removal of high speed drill/saw systems and surgical procedure kits from scope.

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Date	Reference Number	Action
		Change of name for subcontractor Classic Industries, Inc. to Technimark LLC. Correction of addresses for Stoerk Instrumente GmbH and Tuttlinger Instrumenten Manufaktur GmbH (TIM). Addition of critical subcontractor Medsorb Dominicana, S.A. for manufacturing activities.
28 February 2019	7843001	Administrative Subcontractor Service wording update from "Sterilization" to "ETO Sterilization" and "Gamma Sterilization" for Steris Isomedix Services, Massachusetts 01532. Traceable to NB 0086.

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Date	Reference Number	Action
Current	3150607	<p>Certificate renewal.</p> <p>Removal of scope elements "neurosurgical instruments" and "Orthopaedic, dental, ophthalmic, ear, nose and throat, obstetrics and endoscopic instruments".</p> <p>Clarification of scope to amend "electrosurgical endoscopic surgical instruments" to "electrosurgical laparoscopic surgical instruments".</p> <p>Clarification of scope to remove "Access" from "electrosurgical laparoscopic surgical instruments".</p> <p>Clarification of scope to remove "Sterile and non sterile instruments for connection to active devices" and include "accessories" with "The design and manufacture of Access electrosurgical laparoscopic surgical instruments".</p> <p>Clarification of scope from "Those aspects of Annex II concerned with the design and manufacture of Class I measuring instruments" to "Those aspects of Annex II concerned with the maintenance of the accuracy of Class I measuring instruments".</p> <p>Addition of device table to the certificate.</p> <p>Removal of critical subcontractors "HGR Instrumente GmbH", "Medsorb Dominicana S.A.", "Stephan Schilling GmbH", "Erchinger MedTechnology GmbH", "Stoerk Instrumente GmbH" and "Tuttlinger Instrumenten Manufaktur GmbH" for the activity of "manufacture".</p>

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Date	Reference Number	Action
		Addition of the following critical subcontractors for the activities of "Final inspection" and "manufacture": "August Reuchlen GmbH, Junkersstrasse 8, Tuttlingen, 78532, Germany" "Fetzer Surgical LLC, 1019 W Wise Rd Ste 201, Schaumburg, 60010, USA" "Instrumed GmbH dba Avalign German Speciality Instruments, Unter Buchsteig 3, D-78532, Tuttlingen, Germany" "Integra York PA Inc, 589 Davies Drive, York, PA 17402 USA" "Josef Betzler Surgical Instruments e.K., Hohnerstrasse 15, Seitingen-Oberflacht, D-78606, Germany" "Koscher & Wurtz GmbH, Einsteinstrasse 7, Spaichingen, 78549, Germany" "Phoenix Instruments, 2368 Corporate Lane, Suite 106, Naperville, Illinois, 60563, USA" "QSA Surgical (Pvt.) Ltd, P.O. Box 1094, Ghuinke, Daska Rd, Siaklot, Pakistan" "Rebstock Instruments GmbH, In Weiheracker 7, Durbheim, 78589, Germany" "Symmetry Medical Manufacturing, Inc. dba Tecomet, 3724 North State Road 15, Warsaw, Indiana, 46582, USA" "Trokamed GmbH, Kleine Breite 17, 78187 Geisingen, Germany"

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Date	Reference Number	Action
		<p>Addition of critical subcontractor "Shanghai ShuNen Irradiation Technology Co., LTD. Building 5, No.255, Maoyuan Road, Fengxian District, 201401 Shanghai City, People's Republic of China" for the activity of "Radiation (E Beam sterilization)".</p> <p>Addition of critical subcontractor "Isomedix Operations, Inc., 3459 South Clinton Avenue, South Plainfield, New Jersey, 07080, USA" for the activity of "ETO Sterilization".</p> <p>Name correction for the following critical subcontractors: From "EGON faulhaber" to "Faulhaber Pinzetten OHG" From "HEBU MEDICAL GmbH" to "HEBUmedical GmbH"</p> <p>Name and address correction for "Steris Isomedix Services, 453 Whitney Street, Box 457, Northborough, Massachusetts, 01532, USA" to "Isomedix Operations Inc, 453 Whitney Street, Northborough, Massachusetts, 01532, USA".</p> <p>Name and address correction for "RUDISCHHAUSER GmbH, Trossinger Strasse 13, Tuttlingen, 78532, Germany" to "Rudischhauser Surgical Instruments Manufacturing GmbH, Gansacker 28, 78532, Tuttlingen, Germany".</p> <p>Name and address correction for "Shanghai Multi-med Union Co., Ltd., 2018 No. 1958 Zhong Shang North Rd, Putuo District, Shanghai, 200063, China" to "Shanghai Medical Instruments (Group) Ltd Corp, No. 351 Yue Xiu Road, Shanghai, 20072, China".</p>

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Date	Reference Number	Action
		Name change and address correction for "Jakoubek Medizintechnik GmbH, Auf der Höhe 15, Liptingen, 78576, Germany" to "JakuTec Medizintechnik GmbH & Co. KG, Auf der Höhe 15, Emmingen-Liptingen, 78576, Germany". Address change for "Max Hauser Süddeutsche Chirurgiemechnik GmbH" from "Kettlerstrasse 44-46, Tuttlingen, 78532, Germany" to "Föhrenstrasse 33, Tuttlingen, 78532, Germany".