

EC Certificate - Full Quality Assurance System

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

No. **CE 00484**
Issued To: **Codman & Shurtleff, Inc.**
325 Paramount Drive
Raynham
Massachusetts
02767-0350
USA

In respect of:

See certificate scope page.

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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **01 February 1995**

Date: **15 December 2016**

Expiry Date: **31 January 2020**

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

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

Certificate No: CE 00484

Certificate Scope:

The design, development and manufacture of non-powered surgical instruments, aneurysm clips, surgical patties, cranial fluid drainage/monitoring systems, endoscopes/electrodes, spinal fixation devices, neuro-catheters, absorbable fixation systems, surgical single use sterile devices and sterile kits, intracranial pressure monitors, electrosurgical generators, electro-surgical products, dural substitutes and related sterile and non-sterile accessories; vascular access ports (Class III) and related accessories (Class IIa), disposable tunnelers, infusion/microcatheters and intermediate catheters, steerable guidewires, guiding catheters, balloon catheters, thrombectomy devices, intracranial vascular stents and vascular occlusion devices.

First Issued: **01 February 1995**Date: **15 December 2016**Expiry Date: **31 January 2020**

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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Atrion Medical Products, Inc 1426 Curt Francis Road Arab Alabama 35016 USA	Manufacture
B. Braun Medical, Inc. 824 Twelfth Avenue Bethlehem Pennsylvania 18018 USA	Manufacture
Codman & Shurtleff, Inc. 6303 Blue Lagoon Drive, Suite 315 Miami FL 33126 USA	Design

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Subcontractor:	Service(s) supplied
Codman & Shurtleff, Inc. Calle Circuito Interior Norte #1820 Parque Industrial Salvarcar Ciudad Juarez, C.P. 32574 Mexico	Manufacture
Concert Medical, LLC 77 Accord Park Drive Norwell MA 02061 USA	Manufacture
Contech Medical, Inc 99 Hartford Avenue Providence RI 02909 USA	Assembly Packaging

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Subcontractor:	Service(s) supplied
Cordis Corporation 14201 North West 60th Avenue Miami Lakes Florida 33014 USA	Manufacture
Cordis de Mexico S.A. de C.V. Calle Circuito Interior Norte #1820 Parque Industrial Salvarcar Ciudad Juarez Chihuahua, CP 32574 Mexico	Manufacture
Datascope Corporation 1300 MacArthur Boulevard Mawah NJ 07430-0605 USA	Animal substances Manufacture

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Subcontractor:	Service(s) supplied
DePuy Inc 50 Scotland Boulevard Bridgewater MA-02324 USA	Distribution Final Inspection Packaging
DePuy Orthopaedics, Inc. 325 Paramount Drive Raynham Massachusetts 02767 USA	Manufacture
Günter Bissinger Medizintechnik GmbH Hans-Theisen-Str. 1 Teningen/Baden, 79331 Germany	Manufacture

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Subcontractor:	Service(s) supplied
Johnson & Johnson Medical Ltd Pinewood Campus Nine Mile Ride Wokingham RG40 3EW United Kingdom	EU Representative
Lake Region Medical 340 Lake Hazeltine Drive Chaska Minnesota 55318-1029 USA	Manufacture
Lyophilization Services of New England, Inc. One Sundial Avenue, Suite 112 Manchester NH 03103 USA	Animal substances Manufacture

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Subcontractor:	Service(s) supplied
Medos SARL Rue Girardet 29 Le Locle 2400 Switzerland	Control of Sterilization Design Final Inspection Manufacture Packaging
Medsorb Dominicana, SA Zona Franca Industrial San Pedro de Marcoris Dominican Republic	Manufacture Packaging
Micrus Endovascular, LLC 3260 Executive Way Miramar FL 33025-3930 USA	Final Inspection Manufacture
Micrus Endovascular, LLC 821 Fox Lane San Jose CA 95131-1601 USA	Distribution Final Inspection Manufacture

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Subcontractor:	Service(s) supplied
Millar Inc. 6001-A Gulf Freeway Houston Texas 77023 USA	Manufacture
Nitinol Device and Components, Inc. 47533 Westinghouse Drive Fremont California 94539 USA	Manufacture
Nutek Corporation 1001 Whipple Road Hayward California 94544 USA	E beam Sterilization

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Subcontractor:	Service(s) supplied
Professional Contract Sterilization Inc 40 Myles Standish Boulevard Taunton Massachusetts 02780-1026 USA	ETO Sterilization
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 Verviers B-4800 Belgium	Sterilization
Sterigenics US, LLC 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	Sterilization

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Subcontractor:	Service(s) supplied
Sterigenics Avenue de Lossburg 69480 Anse France	Sterilization
Sterilization Services of Georgia, Inc. 6005 Boat Rock Boulevard Atlanta Georgia 30336 USA	ETO Sterilization
Steris Isomedix Services, Inc. 9 Apollo Drive Whippany New Jersey 07981 USA	Sterilization

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Subcontractor:	Service(s) supplied
Steris Isomedix Services 1435 Isomedix Place El Paso Texas 79936 USA	Sterilization
Steris Isomedix Services 2072 Southport Road Spartanburg South Carolina 29306 USA	Sterilization
STERIS Isomedix Services 435 Whitney Street Northborough Massachusetts 01532 USA	Sterilization

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Subcontractor:	Service(s) supplied
Symmetry Medical Manufacturing, Inc. dba Tecomet 3724 North State Road 15 Warsaw Indiana 46582 USA	Manufacture Packaging
Symmetry Medical 61 John Vertente Boulevard New Bedford Industrial Park New Bedford, MA-02745 USA	Manufacture Packaging
Synergetics, Inc 3600 Horizon Drive King of Prussia Pennsylvania 19406 USA	Design Manufacture

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Subcontractor:	Service(s) supplied
Synergetics, Inc 3845 Corporation Centre Drive O'Fallon Missouri 63368 USA	Design Manufacture
Synergy Health AST, LLC 3200 Lakeville Highway #120 Petaluma CA 94954 USA	E beam Sterilization
Technimark 149 Devereux Drive Latrobe PA 15650 USA	Manufacture Packaging

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Date	Reference Number	Action
01 February 1995		First Issued
17 May 1996		Addition of Subcontractor, JJPI Canal St, Stamford
12 June 1996		Addition of Subcontractor, Cosmed
22 October 1996		Reissue in new format, Addition of Subcontractor, Removal of Subcontractor
26 February 1998		Addition of Subcontractor, Surgical Instruments, Removal of Subcontractors, J&J Randolph & Cosmed
08 July 1999		Not formally released at issue 6. Proposed changes incorporated into issue 7
14 October 1999		Name change from Johnson & Johnson Professional Inc to Codman & Shurtleff, Inc. Addition of Subcontractor, Maxxim Medical, Removal of Subcontractor Orthopaedic devices
29 August 2000		Removal of Subcontractor, Codman & Shurtleff, Kentucky
21 November 2000		Addition of Subcontractor, Ethicon GmbH
14 March 2002		Five year renewal, Extension to scope to include Absorbable Fixation Systems, Addition of Subcontractors, Professional Sterilization Inc & DePuy Inc, Bridgewater
29 August 2003		Extension to Scope, intracranial pressure monitors, electrosurgical generators and related sterile and non-sterile accessories, Reissue in new format

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09 September 2003		The word 'monitoring' was added after the word 'drainage' and the words 'soft wire' were removed from the scope. Electrosurgical products added to the scope Codman & Shurtleff Inc's (New Bedford) address details amended The activities of DePuy Inc (Bridgewater) changed to "inspection, packaging and distribution" Steris Isomedix, Inc (Whippany) added to the subcontractors listing.
02 January 2004		Sterigenics (Verviers, Belgium) added to list of sub-contract sterilizers
24 February 2004		Addition of subcontractors: Datascope Corp and LSNE as animal tissue subcontractors
14 October 2004		Addition of Sterigenics, France
15 April 2005		Dural substitute added to the scope Certificate renewal
16 May 2005		Vascular access ports (Class III) and accessories (Class IIa) added to scope from certificate CE 74338
01 August 2006		New controlled manufacturing area introduced at New Bedford facility Addition of Contech Packaging to the list of subcontractors

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15 August 2006		Valley Forge removed from the list of subcontractors and Synergetics added to the list of subcontractors
29 September 2006		Subcontractor name change from Codman & Shurtleff, Inc to DePuy and Ethicon GmbH to Codman. Medsorb Dominicana, SA and Classic Industries added to the list of subcontractors
17 June 2008	7225356	Change of subcontractor company name from DePuy to Symmetry Medical. Change of Subcontractor company address of Synergetics, Inc. from PA 19406 to Missouri 63368. Add subcontractors Codman Sarl and Medos Sarl, Switzerland for design, final inspection, manufacture and packaging.

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19 November 2008	7282434	Extension to scope to include the scope from Cordis Neurovascular, Inc. (CNV), Full Quality Assurance certificate CE 01496. Addition of Synergetics, Inc. PA 19406 for the activity of Design and Manufacture, Cordis Neurovascular (CNV) for the activity of Manufacture, Atrion Medical Products for the activity of Manufacture, B. Braun Medical, Inc for the activity of Manufacture, Lake Region Medical for the activity of Manufacture, Accellent Endoscopy for the activities of Development and Manufacture, Accellent Cardiology for the activities of Development and Manufacture, Cordis de Mexico S.A. de C.V. for the activity of Manufacture, Steris Corporation Isomedix Services (South Carolina) for the activity of Sterilization, Sterigenics for the activity of Sterilization, Steris Corporation Isomedix Services (El Paso) for the activity of Sterilization, Nitinol Device and Components, Inc for the activity of Manufacture and Accellent Inc for the activities of Distribution and Manufacture to the list of significant subcontractors. The removal of Ethicon Inc, NJ 08876-0151 and Steris Corporation, Ohio 44060.
24 February 2010	7462461	Certificate renewal
30 March 2010	7507276	Addition of Codman & Shurtleff in Miami Lakes, FL for the activity of Design and Manufacture. Addition of Codman & Shurtleff in Juarez, Mexico for the activity of Manufacture. Addition of Codman, a division of Johnson & Johnson Medical Ltd., as EU Authorized representative

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28 September 2010	7556838	Addition of HLL Lifecare Ltd, India for manufacture to the list of significant subcontractors.
13 October 2011	7686775	Addition of Günter Bissinger, Medizintechnik GmbH, Hans-Theisen-Str. 1 Teningen/Baden, 79331, Germany to the list of significant subcontractors for the activity of manufacture.
02 December 2011	7758006	Addition of two Micrus Facilities - San Jose for the activities of Design, Distribution, Manufacture and Final Inspection and Miramar FL for the activities of Design, Manufacture and Final Inspection. Addition of Sterilization Services of Georgia for the activity of Sterilization. Deletion of Cordis Neurovascular as a significant subcontractor.
27 January 2012	7792805	Addition of Disposable Tunnelers to the certificate scope (transferred from CE 74341 following clarification of intended purpose).
02 March 2012	7805341	Addition of Disposable Tunnelers to the certificate scope (transferred from CE 74341 following clarification of intended purpose).

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22 August 2012	7869233	Scope modification – removal of "Infusion Catheters, Intravascular Catheter, Steerable Guidewires, Disposable Tunnelers, Guiding Catheters, Intracranial Vascular Stents and Vascular Occlusion devices for peripheral, coronary and/or neurovascular use" and addition of "disposable tunnelers, infusion/microcatheters and intermediate catheters, steerable guidewires, guiding catheters, balloon catheters, thrombectomy devices, intracranial vascular stents and vascular occlusion devices." Company name change of Micrus Endovascular in the subcontractor listing to "Micrus Endovascular, LLC".
11 June 2014	8154020	Expansion of use and change of address of contract sterilizer Sterigenics in Petit-Rechain Removal of subcontractor Codman, Tuttlingen
12 January 2015	8225011	Change the zip code of "Codman & Shurtleff, Mexico" to 32574. Add "ETO" to service(s) supplied by "Sterilization Services of Georgia". Remove "Codman, a Division of" from EU representative information. Add a new subcontractor "Nutek Corporation".

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04 February 2015	8281851	Certificate renewal Removal of Codman & Shurtleff Inc. Miami Lakes location and HLL Lifecare Limited. Removal of Microtest Laboratories Inc. Addition of Millar Inc. for manufacture of microsensors.
30 June 2015	8294868	Added Codman & Shurtleff, Blue Lagoon site for services of Design. Removed Design services for Micrus Endovascular, Miramar.
10 March 2016	8500491	Added Synergy Health AST, LLC for services of E Beam Sterilization.
24 June 2016	8416579	Added ethylene oxide sterilization chamber, chamber #4, and modified sterilization protocol in chamber #3 to align with the protocol in chamber #4, for contract sterilizer Sterigenics Belgium (Petit Rechain)
06 October 2016	8596458	Removed all 3 Accellant subcontractors. Changed Classic Industries name to Technimark LLC. Added service of Control of Sterilization to Medos SARL. Removed service of Design from Micrus Endovascular (San Jose).
15 December 2016	8557413	Added Symmetry Medical, 3724 North State Road 15, Warsaw, For services of Manufacture, Packaging.