

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. CE 56021
Issued To: **Codman & Shurtleff, Inc.**
325 Paramount Drive
Raynham
Massachusetts
02767-0350
USA

In respect of:

those aspects of Annex V related to securing and maintaining sterility in the manufacture of disposable towel clamps, disposable marking pens, cranial hand drills, disposable replacement tubing and bags used with cranial fluid drainage systems and disposable cords

the manufacture of high speed drill systems

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **28 September 2000**

Date: **24 June 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.

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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
DePuy Inc 50 Scotland Boulevard Bridgewater MA-02324 USA	Distribution Final Inspection Packaging
Ethicon Inc Route 22 West Somerville NJ 08876-0151 USA	Sterilization
Gebr. Brasseler GmbH & Co. KG (KOMET MEDICAL) Trophagener Weg 25 32657 Lemgo Germany	Manufacture
Rotomed AG Allmendstrasse 4 CH-4512 Bellach Switzerland	Manufacture

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Subcontractor:	Service(s) supplied
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 Verviers B-4800 Belgium	Sterilization
STERIS Isomedix Services 435 Whitney Street Northborough Massachusetts 01532 USA	Sterilization
STERIS Isomedix Services 9 Apollo Drive Whippany New Jersey 07981 USA	Sterilization

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Date	Reference Number	Action
28 September 2000		First Issue
15 March 2002		Codman & Shurtleff Inc (Norton) removed from sub-contractors listing
01 November 2002		Minor adjustment to Codman & Shurtleff Inc's address
18 September 2003		Steris Isomedix (Whippany) sterilizer and DePuy Inc (Bridgewater) added to the list of sub-contractors
06 February 2006		Certificate renewal (renewal date in line with client main QMS certificate CE 00484)
24 February 2010	7462461	Certificate renewal

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Date	Reference Number	Action
14 September 2011	7456909	Extension of scope to include the manufacture of high speed drill systems. Addition of Rotomed, Gebr Brasseler and Protomedical as subcontractors for the manufacture of high speed drill systems.
11 June 2014	8154020	Addition of contract sterilizer Sterigenics in Petit-Rechain
04 February 2015	8281852	Certificate Renewal Removal of Protomedical GmbH
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)