

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

List of Significant Subcontractors

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

Certificate No: **CE 56021**
 Date: **24 June 2016**
 Issued To: **Codman & Shurtleff, Inc.**
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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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Certificate History

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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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|-------------------|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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) |

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