



EC Certificate - Full Quality Assurance System

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

No. CE 587783

Issued To: ConMed Corporation

525 French Road

Utica New York 13502-5994

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 2797):

Gary E Slack, Senior Vice President Medical Devices

Gay C Stade

First Issued: **2012-07-31** Date: **2021-04-28** Expiry Date: **2023-06-18**

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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 587783

Certificate Scope:

Design, development and manufacture of Endoscopic Surgical Instruments and Accessories; Powered Surgical Instruments; Active and Non Active Surgical Devices and Accessories for Conventional and Laparoscopic Procedures including Stapling/Suturing Devices and Surgical Instruments; Pressure Infusors; Patient Monitoring Devices and Accessories; Gynecological/Obstetrical Devices; Electrosurgical Generators and Accessories; Electrocautery Units; and Surgical Handpieces for Electrocautery; Endoscopes and Laparoscopes; Pneumatic Surgical Instrument Systems; Fluid Delivery Systems; Endoscope Systems; Endoscopic Electrosurgical Instruments; Disposable Surgical Instruments; Nonabsorbable Implants; Bioabsorbable Implants; Non-absorbable Suture; Insufflation Systems; Computer Interface

Those aspects of Annex II relating to securing and maintaining the sterility of Sterile Surgical Instruments, Accessories for Endoscopy; electrosurgical Devices and Accessories for Conventional and Laproscopic Procedures including Sterile Suction / Irrigation Instruments and Tubing; Electrodes; cables; Leadwires; IV Stabilization and Transparent Dressings; Sterile Surgical Procedure Kits.

Those aspects of Annex II relating to the accuracy of metrology in the final inspection and testing of Reusable surgical devices for the measurement of cruciate ligaments footprints.

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