

# 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):



Albert Roossien, Regulatory Lead

First Issued: **2012-07-31**Date: **2019-03-04**Expiry Date: **2023-06-18****...making excellence a habit.™**

Page 1 of 2

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.

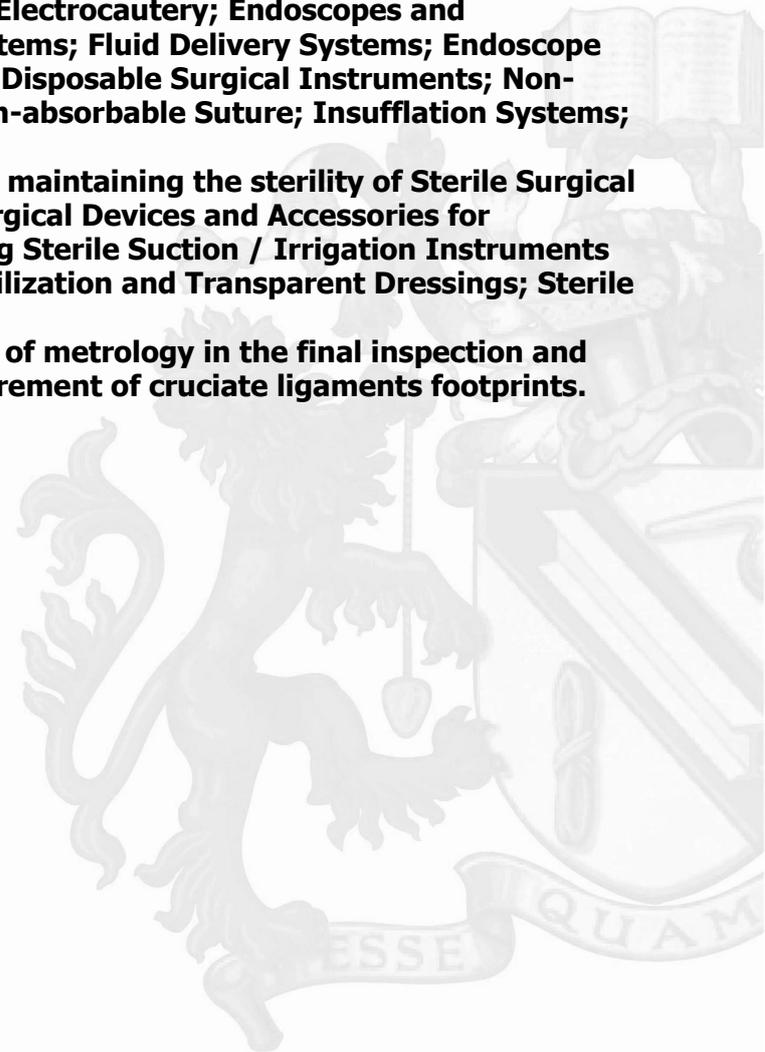
Certificate No: CE 587783

## 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; Non-absorbable 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 Laparoscopic 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.**

First Issued: **2012-07-31**Date: **2019-03-04**Expiry Date: **2023-06-18**

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## List of Significant Subcontractors

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

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**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
AB Medica SAS Les Petities Quarterées Mery sur Cher 18100 France	<b>Finished Device Supplier</b>
Anchor Products Company, Inc. 52 Official Road Addison Illinois 60101 USA	<b>Manufacture</b>
ATC Technologies 30-B Upton Drive Wilmington Massachusetts 01887 USA	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Buffalo Filter 5900 Genesee Street Lancaster New York 14086 USA	<b>Manufacture</b>
Conmed Coporation 134 Flanders Road Westborough Massachusetts 01581 USA	<b>Design Regulatory Compliance</b>
Consolidated Medical Equipment Co. Ave. Alejandro Dumas No. 11321 Complejo Industrial Chihuahua CP 31136 Mexico	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Corbion Arkelsedijk 46 Gorinchem, NL-4200 AA The Netherlands	<b>Crucial Supplier</b>
Greenwald Surgical Co., Inc 2688 DeKalb Street Lake Station Indiana 46405 USA	<b>Manufacture</b>
Henke-Sass Wolf GmbH Keltenstrasse 1 D-78532 Tuttlingen Germany	<b>Finished Device Supplier</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
International Sterilization Laboratories (ISL) 217 Sampey Road Groveland Florida 34736 USA	<b>ETO Sterilization</b>
Isomedix Operations, Inc. 4405 Marketing Place Groveport Ohio 43125 USA	<b>Gamma Sterilization</b>
Isomedix Operations, Inc. 1435 Isomedix Place El Paso Texas 79936 USA	<b>Gamma Sterilization</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Katecho, Inc. 4020 Gannett Avenue Des Moines Iowa 50321 USA	<b>Manufacture</b>
KLS Martin GmbH + Co. KG Am Flughafen 18 79108 Freiburg Germany	<b>Manufacture</b>
Lacey Manufacturing Company LLC 1146 Barnum Avenue Bridgeport Connecticut 06610 USA	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Lake Region Medical 68 Mill Lane Road Brimfield Massachusetts 01010 USA	<b>Manufacture</b>
Lake Region Medical 200 South Yorkshire Street Salem VA 24153 USA	<b>Manufacture</b>
Linvatec Corporation also trading as ConMed Linvatec 11311 Concept Blvd. Largo Florida 33773 USA	<b>Design</b> <b>Manufacture</b> <b>Regulatory Compliance</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
MDSS (Medical Device Safety Service GmbH) Schiffgraben 41 30175 Hanover Germany	<b>EU Representative</b>
MedBio Inc. 5346 36th Street SE Grand Rapids Michigan 49512 USA	<b>Crucial Supplier</b>
Micro-Tech (Nanjing) Co., Ltd No.10 Gaoke Third Road, Nanjing National Hi-Tech. Industrial Development Zone, 210061 Nanjing, Jiangsu Province, China	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Modern Medical Equipment Manufacturing Ltd Unit F, 5th Floor, Gold King Ind. Bldg., Nos. 35-41 Tai Lin Pai Rd Kwai Chung N.T., Hong Kong	<b>Finished Device Supplier</b>
Riverpoint Medical LLC 825 NE 25th Avenue Portland Oregon 97232 USA	<b>Finished Device Supplier</b>
Sequel Special Products 1 Hillside Drive Wolcott Connecticut 06716 USA	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Spectrum Labs Inc 3400 Royalty Row Irving Texas 75062 USA	<b>Manufacture</b>
Sterigenics U.S., LLC 305 Enterprise Drive Westerville Ohio 43081 USA	<b>Gamma Sterilization</b>
Sterigenics U.S., LLC 502 Prairie Mine Rd Mulberry Florida 33860 USA	<b>Gamma Sterilization</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	<b>ETO Sterilization</b>
Sterigenics US, LLC 2973 Olympic Industrial Drive Smyrna Georgia 30080 USA	<b>ETO Sterilization</b>
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	<b>ETO Sterilization</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Sterigenics US, LLC 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	<b>Gamma Sterilization</b>
Sterigenics US, LLC 3125 Wichita Court Fort Worth Texas 76140 USA	<b>Gamma Sterilization</b>
Sterigenics US, LLC 1700 College Blvd West Memphis Arkansas 72301 USA	<b>Gamma Sterilization</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Sterilization Services of Georgia 6005 Boatrock Boulevard Atlanta Georgia 30336 USA	<b>ETO Sterilization</b>
Surgical Specialties México, S. de R.L. de C.V. Corredor 2000 Tijuana-Rosarito No. 24702-B Ejido Francisco Villa Tijuana Baja California Mexico	<b>Manufacture</b>
SurgiQuest Inc. 488 Wheelers Farm Road Milford Connecticut 06461 USA	<b>Design</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Teleflex Medica de México S. de R.L. de C.V. Ave. Industrials No 5954 Parque Industrial Finsa Nuevo Laredo 88275 Mexico	<b>Manufacture</b>
Venusa de Mexico S.A. de C.V. an Accellent Company Calle Hertz 1525-6 Parque Industrial J. Bermudez Ciudad Juarez Chihuahua 32470 Mexico	<b>Manufacture</b>

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**USA**

**Subcontractor:**

**Service(s) supplied**

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Vesta, Inc  
9900 South 57th Street  
Franklin  
Wisconsin  
53132  
USA

**Manufacture**

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W.O.M. World of Medicine GmbH  
Salzufer 8  
10587 Berlin  
Germany

**Manufacture**

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Date	Reference Number	Action
31 July 2012	7843294	First issue, transfer from another notified body.
11 February 2013	7945784	Transfer of Active Devices from another notified body. Addition of, 'Venusa de Mexico S.A. de C.V., Calle Hertz 1525-6, Parque Industrial J. Bermudez, Ciudad Juarez, Chihuahua, Mexico 32470', for Manufacture. Addition of, 'Accellent, Inc., 68 Mill Lane Rd., Brimfield, MA 01010, USA', for Manufacture. Addition of, 'Ethox International MMC Sterilization Services Group, 2205 East 33rd Street, Erie, Pennsylvania, 16510, USA', for Packaging and Sterilization - ETO. Addition of, 'Conmed Electrosurgery, 14603 E. Fremont Avenue, Centennial, Co 80112, USA', for Design and Manufacture. Addition of, 'Sterilization Services of Georgia, 6005 Boatrock Road, Atlanta, GA 30336, USA' for Sterilization. Addition of, 'STERIS Isomedix Services, 1435 Isomedix Place, El Paso, TX 79936, USA' for Sterilization – Gamma.
30 April 2013	7974024	Certificate Renewal. Consolidated Medical Equipment Ltd, sterilization service removed.
06 December 2013	8083499	Addition of Design, development and manufacture of Powered Surgical Instruments to scope of certificate. Addition of Linvatec Corporation, also trading as ConMed Linvatec, 11311 Concept Blvd., Largo, Florida 33773, USA

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Date	Reference Number	Action
23 May 2014	8150311	<p>Scope extension to incorporate the scopes of Linvatec Corporation also trading as ConMed Linvatec CE 574219 - (Design and Manufacture of Powered Surgical Instruments; Pneumatic Surgical Instrument Systems; Fluid Delivery Systems; Endoscope Systems; Endoscopic Electrosurgical Instruments; Disposable Surgical Instruments; Non-absorbable 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), CE 587786 - (Those aspects of Annex V related to securing and maintaining sterility in the manufacture of: Sterile A accessories for Endoscopy; Sterile Electrosurgical Devices and Accessories for Conventional and Laparoscopic Procedures including Sterile Suction / Irrigation Instruments and Tubing; Sterile Electrodes; Sterile Cables; Sterile Leadwires; IV Stabilization and Transparent Dressings; Sterile Electrosurgical Accessories), CE 578763 (Those aspects of Annex VI relating to the accuracy of metrology in the final inspection and testing of Reusable surgical devices for the measurement of cruciate ligaments footprints.) and Vision Systems Group, A Division of Viking Systems, Inc., CE 596762 - (The design and manufacture of Endoscopes and Laparoscopes).</p> <p>Addition of subcontractors:</p> <ul style="list-style-type: none"> <li>• Vision Systems Group for design, manufacture and regulatory activities</li> <li>• BBF Sterillisation Service GMBH for Gamma Sterilization</li> <li>• FTSI for Gamma Sterilization</li> <li>• International Sterilization Laboratories (ISL) for ETO Sterilization</li> </ul>

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Date	Reference Number	Action
		<ul style="list-style-type: none"> <li>• Katecho Inc. for Manufacture</li> <li>• Sterigenics US, LLC, Charlotte NC for Gamma Sterilization</li> <li>• Sterigenics, Westerville OH for Sterilization</li> </ul>
23 September 2015	8408567	Addition of 'Sterile Surgical Procedure Kits' to scope. Removal of Ethox International as a significant sub-contractor. Change of address of significant sub-contractor KLS Martin GmbH + Co. KG. Change of significant sub-contractor legal entity from Vision Systems to Conmed Corp. Removal of 'Manufacture' activity type from Conmed Corp. Addition of significant sub-contractors: Spectrum Labs Inc for manufacture and Steris Isomedix Services (Groveport, OH) for sterilization. Removal of United States Endoscopy Group Inc from the list of subcontractors

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Date	Reference Number	Action
10 October 2016	8578016	Addition of '-5994' suffix to zip code of legal manufacturer address. Addition of critical subcontractors AB Medica SAS, ATC Technologies, Buffalo Filter, Greenwald Surgical, Henke-Sass, Kirwan Surgical Products LLC, Lacey Manufacturing Company LLC, Lake Region Medical, Modern Medical Equipment Manufacturing Ltd., Neometrics Inc., Olsen Medical LLC, Sequel Special Products, Surgical Specialities, Tecno Instruments Pvt. Ltd., Teleflex Medical de México, Vesta Inc. and W.O.M. World of Medicine GmbH for manufacture. Addition of critical subcontractor SurgiQuest Inc. for design. Addition of crucial suppliers Corbion, MedBio Inc. and Riverpoint Medical LLC. Removal of critical subcontractors BBF Sterilisations Service GmbH and ConMed Electrosurgery. Change of company name for 'FTSI' to 'Sterigenics U.S., LLC'.
01 March 2017	8467986	Addition of 'manufacture' to Riverpoint Medical, LLC (825 NE 25th Avenue, Portland, Oregon, 97232, USA) supplied services.

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Date	Reference Number	Action
23 February 2018	8868365	Addition of critical subcontractor: Anchor Products Company for manufacture activities. Change from manufacture to finished device supplier activities for critical subcontractors: AB Medica, Henke-Sass, Modern Medical and Riverpoint Medical. Removal of critical subcontractors: Kirwan Surgical, Medivators, Neometrics, Olsen Medical and Tecno Instruments. Clarification of subcontractor Activity type from 'Sterilization' to 'ETO Sterilization' for Sterigenics US, LLC (Georgia), Sterigenics US, LLC (New York), and Sterilization Services of Georgia. Clarification of subcontractor Activity type from 'Sterilization' to 'Gamma Sterilization' for Sterigenics (Ohio), and Steris Isomedix Services.

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Date	Reference Number	Action
14 June 2018	8923064	Certificate renewal. Reduction in scope to remove 'Patient Monitoring Devices and Accessories'. Addition of Sterigenics sites 1700 College Blvd, West Memphis, Arkansas and 3125 Wichita Court, Fort Worth, Texas for Gamma Sterilization activities. Change in company name for subcontractor 'Accelent, Inc.' to 'Lake Region Medical'. Change in address for subcontractor Surgical Specialties Corporation. Change in company name for 'Sterigenics' 305 Enterprise Drive to 'Sterigenics US, LLC'. Change in company name for 'STERIS Isomedix Services' El Paso and Groveport to 'Isomedix Operations, Inc.'
Current	8752171	Traceable to NB 0086.