



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ConMed Corporation 525 French Road

Utica New York 13502 USA

Holds Certificate No:

FM 587617

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Please see scope page.

Gay C Stade

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2012-07-19 Latest Revision Date: 2021-02-25 Effective Date: 2021-03-16 Expiry Date: 2024-03-15

Page: 1 of 4

bsi.



...making excellence a habit."

Certificate No: FM 587617

Registered Scope:

Design and Development, Production and Distribution of Sterile and Non Sterile, Active and Non Active Surgical Devices and Accessories for Conventional and Laproscopic Procedures including Clip Appliers and Implantable Clips; Suction / Irrigation Instruments and Tubing; Electrodes, Cables, Lead Wires and Gels; IV Stabilization Dressings; TENS / NMES / PNS Electrodes; Defibrillation Pads; Uterine Manipulators; Pressure Infusers; Pulse Oximeters and Accessories; Electrosurgical Generators and Accessories; Sterile Surgical Handpiece for Electrocautery; Electrocautery Unit; Sterile and Nonsterile Endoscopic Papillitome, ERCP Cannula, Guidewires, Retrieval Devices, Enteral Feeding Devices, Electrosurgical Forceps, Transbronchial Aspiration Needles, Insufflation Systems, Snares, Brushes, Probes, Needles, Balloon Catheters, Balloon Dilators, Biliary balloons, Dilatation devices, Overtubes, Ligators, Biopsy Forceps. Service of Endotracheal Cardiac Output Monitors, Electrosurgical Generators and Electrocautery Units.

Design, development, manufacturing, service and distribution of Powered Surgical Instruments; Pneumatic Surgical Instrument Systems; Fluid Delivery Systems; Endoscope Systems; Endoscopic Electrosurgical Instruments; Non-absorbable Implants; Bioabsorbable Implants; Non-absorbable Sutures; Insufflation Systems; Disposable Surgical Instruments; Re-usable Manual Surgical Instruments; Metal Implants; Computer Interfaces; Visualization Systems; Video Cameras; Camera Controllers and other equipment and accessories for surgical and medical applications.

Original Registration Date: 2012-07-19 Effective Date: 2021-03-16 Latest Revision Date: 2021-02-25 Expiry Date: 2024-03-15

Page: 2 of 4

Certificate No: **FM 587617**

Location

33773

USA

Linvatec Corporation also trading as ConMed Linvatec 11311 Concept Blvd. Largo Florida

ConMed Corporation 525 French Road Utica New York 13502 USA

Registered Activities

Design, development, manufacturing, service and distribution of sterile and non-sterile powered surgical instruments; pneumatic surgical instrument systems; fluid delivery systems; endoscope systems, endoscopic electrosurgical instruments; non-absorbable implants; bioabsorbable implants; non-absorbable sutures; insufflation systems; disposable surgical instruments; re-usable manual surgical instruments; metal implants; computer interfaces. Design and development of sterile and non-sterile active and non-active surgical devices and accessories for conventional and laparoscopic procedures; electrosurgical generators and accessories, electrocautery units, and sterile surgical handpieces for electrocautery. Servicing of electrosurgical generators and accessories and electrocautery units.

Design and Development, Production and Distribution of Sterile and Non Sterile, Active and Non Active Surgical Devices and Accessories for Conventional and Laproscopic Procedures including Clip Appliers and Implantable Clips; Suction / Irrigation Instruments and Tubing; Electrodes, Cables, Lead Wires and Gels; IV Stabilization Dressings; TENS / NMES / PNS Electrodes; Defibrillation Pads; Uterine Manipulators; Pressure Infusers; Pulse Oximeters and Accessories; Electrosurgical Generators and Accessories; Sterile Surgical Handpiece for Electrocautery; Electrocautery Unit; Sterile and Nonsterile Endoscopic Papillitome, ERCP Cannula, Guidewires, Retrieval Devices, Enteral Feeding Devices, Electrosurgical Forceps, Transbronchial Aspiration Needles, Insufflation Systems, Snares, Brushes, Probes, Needles, Balloon Catheters, Balloon Dilators, Biliary balloons, Dilatation devices, Overtubes, Ligators, Biopsy Forceps. Service of Endotracheal Cardiac Output Monitors, Electrosurgical Generators and Electrocautery Units.

Design, development, manufacturing, service and distribution of Powered Surgical Instruments; Pneumatic Surgical Instrument Systems; Fluid Delivery Systems; Endoscope Systems; Endoscopic Electrosurgical Instruments; Nonabsorbable Implants; Bioabsorbable Implants; Nonabsorbable Sutures; Insufflation Systems; Disposable Surgical Instruments; Re-usable Manual Surgical Instruments; Metal Implants; Computer Interfaces; Visualization Systems; Video Cameras; Camera Controllers and other equipment and accessories for surgical and medical applications.

Original Registration Date: 2012-07-19 Effective Date: 2021-03-16 Latest Revision Date: 2021-02-25 Expiry Date: 2024-03-15

Page: 3 of 4

This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

Certificate No: FM 587617

USA

Location Registered Activities **CONMED Corporation** Distribution of Sterile and Non-Sterile, Active and Non-active Surgical Devices and Accessories for Conventional, 1250 Terminus Dr. Endoscopic and Laparoscopic Procedures including Lithia Springs electrodes, electrosurgical generators and related Georgia accessories, endoscopic devices and related accessories, 30122 gynecological and obstetrical devices, lead wires and cables, **USA** patient monitoring devices and related accessories, pressure infusers, stapling and suturing devices and related accessories, surgical instruments and related accessories, power surgical instruments, pneumatic surgical instrument systems, fluid delivery systems, endoscope systems, endoscopic electrosurgical instruments, non-absorbable implants, bioabsorbable implants, non-absorbable sutures, insufflation systems, enteral feed devices, sterile surgical handpiece use with power source and powered surgical instruments. Design and Development of: - Sterile and Non Sterile, Active **CONMED Corporation** and Non Active Surgical Devices and Accessories for 6455 S Yosemite Street Conventional and Laproscopic Procedure including Clip Greenwood Village Appliers and Implantable Clips - Suction/Irrigation Colorado Instruments and Tubing - Electrodes - Uterine Manipulators -80111 Pressure Infusers - Electrosurgical Generators and **USA** Accessories - Sterile Surgical Handpiece for Electrocautery -Electrocautery Unit - Insufflation Systems. Design of endoscopes, visualization systems, video cameras, ConMed Corporation camera controllers, and other equipment and accessories for 134 Flanders Road surgical and medical applications. Westborough Massachusetts 01581

Original Registration Date: 2012-07-19 Effective Date: 2021-03-16 Latest Revision Date: 2021-02-25 Expiry Date: 2024-03-15

Page: 4 of 4