PROCEDURE APPROVALS

Note: Date of last approval will serve as the Approval Date for this document.

Name	Function	Signature	Date
Kathy Reddig	Regulatory	kreddig	05/27/2021

Digitally signed by Şarco Alexandru
Date: 2022.08.01 16:23:41 EEST
Reason: MoldSign Signature
Location: Moldova

Declaration of Conformity

Manufacturer: **Address:**	CONMED Corporation 525 French Road Utica, New York 13502 USA
European Auth. Rep.:	MDSS GmbH Schiffgraben 41 D-30175 Hannover Germany
Notified Body **Address:**	British Standards Institute (BSI) Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands
NB Identification #:	2797
Conformity Assessment:	Annex II, Sections 1-3 and 5, of the Directive 93/42/EEC on Medical Devices
EC Certificate Number:	CE587783
Device Classification:	Class IIb
Rule per Annex IX:	9
Product Family:	Surgical Instruments and Accessories

Reference Number	Product Description	Date 1st CE Marked
CD871	CORE 5mm Electrosurgical Suction/Irrigation Electrode Probe, Spatula with Sheath, Reusable	April 2003
CD872	CORE 5mm Electrosurgical Suction/Irrigation Electrode Probe, L-Hook with Sheath, Reusable	April 2003
CD873	CORE 5mm Electrosurgical Suction/Irrigation Electrode Probe, J-Hook with Sheath, Reusable	April 2003
CD874	CORE 5mm Electrosurgical Suction/Irrigation Electrode Sheath, Replacement Part, Reusable	April 2003
CD878	CORE 5mm Electrosurgical Suction/Irrigation Electrode Probe, Needle with Sheath, Reusable	April 2003

List of Applied Harmonized Standards and years

EN 1041:2008 Information supplied by the manufacturer with medical devices

EN 60601-1:2006/A1:2013 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance

EN 60601-1-6:2010 Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance– Usability

EN 60601-2-2:2009 Medical electrical equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment and high frequency surgical accessories

EN 62366:2008 Medical devices Application of usability engineering to medical devices

EN ISO 10993-1:2009/AC:2010 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 14155:2011/AC:2011 Clinical investigation of medical devices for human subjects – Part 1: General requirements

EN ISO 14971:2019 Medical devices – Application of risk management to medical devices

EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

EN ISO 17664:2004 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices

EN 60601-2-18:2015 Medical Electrical Equipment – Part 2-18: Particular requirements for basic safety and essential performance of endoscopic equipment

We, the manufacturer, hereby declare that the medical devices listed on this declaration conform with the applicable provisions of EC Directive 93/42/EEC of 14June1993 concerning medical devices.

DOC Change History

Date	Rev.	Description of Change	Initials
31 Dec 2020	A	Initial release; moved CD872 and CD873 from DOC TF-13-2 due to labeling update for Notified Body change from BSI UK to BSI Netherlands	LBA
20 Jan 2021	B	Moved CD871, CD874, and CD878 from DOC TF-13-2 due to Notified Body change from BSI UK to BSI Netherlands	LBA
05/27/2021	C	Updated EN ISO 14971:2012 to EN ISO 14971:2019 per ECN27437.	TLH