PROCEDURE APPROVALS

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

Name	Function	Signature	Date
Kathy Reddig	Regulatory	kreddig	06/02/2021

Digitally signed by Șarco Alexandru
Date: 2022.08.01 16:29:19 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 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:	Rule 9
Product Family:	Electrosurgical Accessories

Reference Number	Product Description	Date 1st CE Marked
130316	Electrosurgical handpiece, Rocker Switch, Blade Electrode, 10' Cord, Reusable, Sterile	July 1979
130316-15NS	Electrosurgical handpiece, Rocker Switch, Blade Electrode, 15' Cord, Reusable, Non-sterile	August 2003
130317	Electrosurgical handpiece, Push Button, Blade Electrode, 10' Cord, Reusable, Sterile	July 1979
130317-10NS	Electrosurgical handpiece, Push Button, Blade Electrode, 10' Cord, Reusable, Non-sterile	February 2000
130317-15	Electrosurgical handpiece, Push Button, Blade Electrode, 15'Cord, Reusable, Sterile	July 1979

List of Applied Harmonized Standards and years

EN 556-1:2001/AC:2006 Sterilization of medical devices – Requirements for medical devices to be designated "Sterile" – Part 1: Requirements for terminally sterilized medical devices

EN 1041:2008/A1:2013 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 60601-2-2:2009/A11:2011 - Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment and high frequency surgical accessories

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

EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

EN ISO 10993-10:2013 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity

EN ISO 10993-11:2018 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

EN ISO 11137-1:2015 – Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 11137-2:2015 – Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose

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 of the processing of resterilizable medical devices

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
02 June 2021	A	Initial release; moved product from DOC TF-78-1 due to Notified Body change from BSI UK to BSI Netherlands	LBA