

PROCEDURE APPROVALS

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

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

Declaration of Conformity

Manufacturer: CONMED Corporation
Address: 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 1 st 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 14 June 1993 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