PROCEDURE APPROVALS

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

Name	Function	Signature	Date
Kathy Reddig	Regulatory	kreddig	09/14/2021

Digitally signed by Şarco Alexandru
Date: 2022.08.01 16:14:36 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:	CE 587783
Device Classification:	Class IIb
Rule per Annex IX:	Rule 9
Product Family:	Electrosurgical Accessories

Reference Number	Product Description	Date 1st CE Marked
138008	¼" Medium (0.64cm) conization, reusable, non-sterile	August 1998
138010	3/8" (0.95cm) diameter, loop electrode for cutting and biopsies, reusable, non-sterile	August 1998
138011	¼" (0.64cm) diameter, loop electrode for cutting and biopsies, reusable, non-sterile	August 1998
138012	¾" (1.91cm) diameter, loop electrode for cutting and biopsies, reusable, non-sterile	August 1998
138025	6" ENT needle electrode with extended insulation, single use	November 1998
138026	5" (12.7cm), straight electrode extender, reusable, non-sterile	January 1997
138100	1" heavy flat blade electrode, single use	November 1998
138101	1" standard flat blade, single use	November 1998
138102	1" needle electrode, single use	November 1998
138103	1" ball electrode, single use	November 1998
138104	1" flat blade electrode, with extended insulation, single use	November 1998
138105	1" needle electrode with extended insulation, single use	November 1998
138107	6" flat blade electrode, single use	November 1998
138108	6" needle electrode, single use	November 1998
138110	6" needle electrode, with extended insulation, single use	November 1998
138112	4" flat blade electrode, single use	November 1998
138113	3 ½" flat blade electrode, single use	November 1998

Reference Number	Product Description	Date 1st CE Marked
139025EXT	6" UltraClean® needle electrode with extended insulation, single use	March 2000
139100	1" UltraClean® blade electrode, single use	March 2000
139102	1" UltraClean® needle electrode, single use	March 2000
139104EXT	1" UltraClean® blade electrode with extended insulation, single use	March 2000
139105EXT	1" UltraClean® needle electrode with extended insulation, single use	March 2000
139107	6" UltraClean® blade electrode, single use	March 2000
139108	6" UltraClean® needle electrode, single use	March 2000
139110EXT	6" UltraClean® blade electrode with extended insulation, single use	March 2000
139112	4" UltraClean® blade electrode, single use	March 2000
139112EXT	4" UltraClean® blade electrode with extended insulation, single use	August 2000
139321	1" UltraClean® blade electrode for ABC® Triple Option Handpiece, single use	March 2004
60-0860-001	Needle electrode, fine, reusable, non-sterile	November 2000
60-0869-001	1" (2.54cm), straight blade electrode, reusable, non-sterile	November 2000
60-5180-101	Loop Excision electrode, "T" Style, 12x8mm, single use	November 1998
60-5180-102	Loop Excision electrode, "T" Style, 15x10mm, single use	November 1998
60-5180-104	Loop Excision electrode, "T" Style, 20x10mm, single use	November 1998
60-5181-102	3mm diameter, ball electrode, 10cm shaft, single use	November 1998
60-5181-103	5mm diameter, ball electrode, 10cm shaft, single use	November 1998

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 60601-1-6:2010/A1:2015 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

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 10993-7:2008/AC:2009 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

EN ISO 11135:2014 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

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 for 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
05 Jan 2021	A	Initial release; moved 60-5180-101, -102, -104, 50-5181-102, -103 from TF-82-1 due to Notified Body change from BSI UK to BSI Netherlands	LBA
27 May 2021	B	Moved 60-0860-001, 138010, 60-0869-001, 138011, 138012, 138008 from TF-82-1 due to Notified Body change from BSI UK to BSI Netherlands; updated EN 1041 to 2008/A1:2013, EN 60601-1-6 to 2010/A1:2015, EN 60601-2-2 to 2009/A11:2011, and EN ISO 14971 to 2019.	SP/LBA
12July2021	C	Moved 138025, 139025EXT, 139100, 139102, 139104EXT, 139105EXT, 139107, 139108, 139110EXT, 139112, 139112EXT, 139321 from TF-82-1 due to Notified Body change from BSI UK to BSI Netherlands	LBA
14Sept2021	D	Moved 138026, 138100, 138101, 138102, 138103, 138104, 138105, 138107, 138108, 138110, 138112, 138113 from TF-82-1 due to Notified Body change from BSI UK to BSI Netherlands	LBA