PROCEDURE APPROVALS

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

Name	Function	Signature	Date
Jaimie Woodruff	Regulatory	jwoodruff	02/09/2021

Digitally signed by Șarco Alexandru
Date: 2022.08.01 16:22:09 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:	Surgical Instruments and Accessories

Reference Number	Product Description	Date 1st CE Marked
3-1003	DetachaTip III Shaft, Multiple Use Scissors, Curved Metzenbaum, 5mm x 33cm	October 2012
3-1004	DetachaTip III Shaft, Multiple Use Scissors, Curved Mini-Metzenbaum, 5mm x 33cm	October 2012
3-1005	DetachaTip III Shaft, Multiple Use Grasper, Babcock, 5mm x 33cm	October 2012
3-1006	DetachaTip III Shaft, Multiple Use Grasper, Straight Long Fenestrated, 5mm x 33cm	October 2012
3-1008	DetachaTip III Shaft, Multiple Use Grasper, Straight Fenestrated (Duckbill), 5mm x 33cm	October 2012
3-1009	DetachaTip III Shaft, Multiple Use Dissector, Curved (Maryland), 5mm x 33cm	October 2012
3-1010	DetachaTip III Handle, Multiple Use Handle, Standard with Ratchet	October 2012
3-1011	DetachaTip III Shaft, Multiple Use Grasper, Claw, 5mm x 33cm	October 2012
3-1012	DetachaTip III Shaft, Multiple Use Dissector, Blunt, 5mm x 33cm	October 2012
3-1017	DetachaTip III Shaft, Multiple Use Dissector, Right Angle Meeker, 5mm x 33cm	October 2012
3-1018	DetachaTip III Shaft, Multiple Use Dissector, Tapered (Dolphin), 5mm x 33cm	October 2012
3-1019	DetachaTip III Shaft, Multiple Use Grasper, Allis, 5mm x 33cm	October 2012
3-1028	DetachaTip III Shaft, Multiple Use Grasper, Endoweave, 5mm x 33cm	October 2012
3-4301	DetachaTip III Shaft, Multiple Use Scissors, Curved Metzenbaum, 5mm x 43cm	October 2012
3-4304	DetachaTip III Shaft, Multiple Use Scissors, Curved Mini-Metzenbaum, 5mm x 43cm	October 2012

Reference Number	Product Description	Date 1st CE Marked
3-4305	DetachaTip III Shaft, Multiple Use Grasper, Babcock, 5mm x 43cm	October 2012
3-4306	DetachaTip III Shaft, Multiple Use Grasper, Straight Long Fenestrated, 5mm x 43cm	October 2012
3-4307	DetachaTip III Shaft, Multiple Use Grasper, Straight Fenestrated (Duckbill), 5mm x 43cm	October 2012
3-4308	DetachaTip III Shaft, Multiple Use Dissector, Curved (Maryland), 5mm x 43cm	October 2012
3-4311	DetachaTip III Shaft, Multiple Use Grasper, Claw, 5mm x 43cm	October 2012
3-4312	DetachaTip III Shaft, Multiple Use Dissector, Blunt, 5mm x 43cm	October 2012
3-4317	DetachaTip III Shaft, Multiple Use Dissector, Right Angle Meeker, 5mm x 43cm	October 2012
3-4318	DetachaTip III Shaft, Multiple Use Dissector, Tapered (Dolphin), 5mm x 43cm	October 2012
3-4319	DetachaTip III Shaft, Multiple Use Grasper, Allis, 5mm x 43cm	October 2012
3-4328	DetachaTip III Shaft, Multiple Use Grasper, Endoweave, 5mm x 43cm	October 2012

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 Information supplied by the manufacturer with medical devices

EN 1707:1996 Conical fittings with 6% (Luer) taper for syringes, needles, and certain other medical equipment – Lock fittings

EN 20594-1:1993/A1:1997 Conical fittings with 6% (Luer) taper for syringes, needles, and certain other medical equipment – Part 1: General requirements

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

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

EN ISO 11135-1:2014 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 11607-1:2009 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

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 14971:2012 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
22Jan2021	A	Initial release; moved 3-XXXX products from DOC TF-32-1 due to Notified Body change from BSI UK to BSI Netherlands	LBA