PROCEDURE APPROVALS

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

Name	Function	Signature	Date
Jaimie Woodruff	Regulatory	jwoodruff	12/31/2020

Digitally signed by Şarco Alexandru
Date: 2022.08.01 16:26:15 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 IIa
Rule per Annex IX:	6
Product Family:	Surgical Instruments and Accessories

Reference Number	Product Description	Date 1st CE Marked
CD849	CORE Suction/Irrigation Cannula, 5mm Probe with Holes, 45cm length	August 2005
CD856	CORE Suction/Irrigation Cannula, 10mm Probe with Holes, 32cm length	August 2005
CD860	CORE Suction/Irrigation Cannula, 5mm Probe with Holes, 32cm length	August 2005
CD8185	CORE Suction/Irrigation Instrument, Core Trumpet, Single Solution Bag	August 2005
CD8190	CORE Suction/Irrigation Instrument, Core Trumpet, Single or Dual Solution Bags	August 2005
CD8300	CORE Suction/Irrigation Instrument, Core Reposable Trumpet, Single Solution Bag	August 2005
CD8302	CORE Suction/Irrigation Instrument, Core Reposable Trumpet, Single or Dual Solution Bag	August 2005
CD8400	CORE Suction/Irrigation Instrument, Core Trumpet, Handpiece Only, Single or Dual Solution Bags	August 2005
CD8450	CORE Suction/Irrigation Instrument, Core Trumpet, Handpiece only, Single or Dual Solution Bags	August 2005

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 15986:2011 Symbol for use in the labeling of medical devices – Requirements for labeling of medical devices containing phthalates

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 11135-1:2007 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 11607-2:2006 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes

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
31 Dec 2020	A	Initial release; moved CD8185, CD8190, CD8300, CD8302, CD8400, CD8450, CD849, CD856, CD860 from DOC TF-13-1 due to labeling update for Notified Body change from BSI UK to BSI Netherlands	LBA