

PROCEDURE APPROVALS

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

Name	Function	Signature	Date
Jaimie Woodruff	Regulatory	jwoodruff	06/01/2021

Declaration of Conformity

Manufacturer: CONMED Corporation
Address: 525 French Road
 Utica, New York 13502 USA

Single Registration Number: TBD

European Auth. Rep.: MDSS GmbH
 Schiffgraben 41
 D-30175 Hannover
 Germany

Notified Body
Address: BSI Group The Netherlands B.V.
 Say Building, John M. Keynesplein 9, 1066EP
 Amsterdam
 Netherlands

NB Identification #: N/A

Conformity Assessment: Annex II and III, of the Regulation (EU) 2017/745 on Medical Devices

EC Certificate Number: Self-Certified

Device / Risk Classification: Class I

Rule per Annex VIII: Rule 1

Product Family: Electrosurgical Accessories

Devices:

Reference Number	Product Description	Date 1 st CE Marked	Basic UDI-DI	Technical Document #
Cables for Reusable Electrodes:				
60-0137-001	Reusable Electrode Cable	06/22/1998	30653405008143	AS-NEA-005
60-5806-001	Reusable Electrode Cable	06/22/1998	30653405011266	AS-NEA-005
Adapters:				
A228	ConMed TDS Adapters	06/22/1998	30653405015691	AS-NEA-005
A238	ConMed TDS Adapters	06/22/1998	30653405015721	AS-NEA-005
B204	Molded Adapter Assembly	06/22/1998	30653405015912	AS-NEA-005
B205	Molded Adapter Assembly	06/22/1998	30653405015936	AS-NEA-005
B210	Molded Adapter Assembly	06/22/1998	30653405015974	AS-NEA-005
B210R	Dispersive Electrode Adapters	06/22/1998	30653405015974	AS-NEA-005
B227	Molded Adapter Assembly	06/22/1998	30653405016025	AS-NEA-005
B230	Adapter – Dual Dispersive Electrode Adapter	06/22/1998	30653405016025	AS-NEA-005

Reference Number	Product Description	Date 1 st CE Marked	Basic UDI-DI	Technical Document #
B260	Adapter: Mech Plug; B To A	06/22/1998	30653405016063	AS-NEA-005
B261	Adapter: Mech Plug; B To A	06/22/1998	30653405016070	AS-NEA-005
60-8031-001	Dispersive Electrode Adapter	08/01/2003	20653405043840	AS-NEA-005
Cables for Single Use Electrodes:				
T205	Grounding Cable: 10ft, Phone Plug	06/22/1998	30653405030939	AS-NEA-005
T210	Grounding Cable: 10ft, Phone Plug	06/22/1998	30653405030977	AS-NEA-005
T228	Macrolite Cable: 10ft, Receptacle	06/22/1998	30653405031035	AS-NEA-005
T229	Surefit Cable: 10ft, Pin/Recept	06/22/1998	30653405031059	AS-NEA-005
T-229-5M	Grounding Cable: 5m, Pin/Recept	06/22/1998	30653405031066	AS-NEA-005
T235	Grounding Cable: 10ft, Receptacle	06/22/1998	30653405031073	AS-NEA-005
T238	Grounding Cable: 10ft, Pin/Receptacle	06/22/1998	30653405031080	AS-NEA-005

This declaration is issued under the sole responsibility of the manufacturer.

We, the manufacturer, hereby declare that the medical devices listed on this declaration conform with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices.

Place of issue of the DoC:

ConMed Corporation
525 French Road
Utica, NY- 13502
USA

Date of issue of the DoC:

See Windchill approver Coversheet

Revision History

Revision #	Reason for Change
A	Initial MDR release