

PROCEDURE APPROVALS

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

Name	Function	Signature	Date
Kathy Reddig	Regulatory	kriddig	05/06/2021

**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-certify

**Device / Risk Classification:** Class I

**Rule per Annex VIII:** Rule 1

**Product Family:** Electrodes (EEG)

**Intended Purpose:** An electrode is an electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor via leadwires and cables.

**Devices:**

Reference Number	Product Description	Date 1 <sup>st</sup> CE Marked	Basic UDI-DI	Technical Document #
01-3130	ECG Backpad Adult	2004	084585464928FD	AET-EEG-001
01-4130	ECG Backpad Infant	2004	084585464928FD	AET-EEG-001
38-402-1	ECG Stripper Adult, 5 Lead	2004	084585464928FD	AET-EEG-001
38-404-1	ECG Stripper Adult, 4 Lead	2004	084585464928FD	AET-EEG-001
090-2764	Thermal Probe Cover	2004	084585464928FD	AET-EEG-001
1500-001	DYNATRACE Adult ECG Electrode, 1/Pouch	2004	084585464928FD	AET-EEG-001
1500-003	DYNATRACE Adult ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
1500-004	DYNATRACE Adult ECG Electrode, 4/Pouch	2004	084585464928FD	AET-EEG-001
1500-005	DYNATRACE Adult ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
1500-030	DYNATRACE Adult ECG Electrode, 30/Pouch	2004	084585464928FD	AET-EEG-001

Reference Number	Product Description	Date 1 <sup>st</sup> CE Marked	Basic UDI-DI	Technical Document #
1510-001	EXACTRACE Adult ECG Electrode, 1/Pouch	2004	084585464928FD	AET-EEG-001
1510-003	EXACTRACE Adult ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
1510-005	EXACTRACE Adult ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
1510-030	EXACTRACE Adult ECG Electrode, 30/Pouch	2004	084585464928FD	AET-EEG-001
1550-005	DYNATRACE STRESS Adult Diagnostic ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
1555-005	DYNATRACE MINI Adult Diagnostic ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
1590-001	INSTATRACE Adult Diaphoretic ECG Electrode, 1/Pouch	2004	084585464928FD	AET-EEG-001
1590-003	INSTATRACE Adult Diaphoretic ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
1590-005	INSTATRACE Adult Diaphoretic ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
1590-030	INSTATRACE Adult Diaphoretic ECG Electrode, 30/Pouch	2004	084585464928FD	AET-EEG-001
1620-001	HUGGABLES Neonatal/Pediatric ECG Electrode, 1/Pouch	2004	084585464928FD	AET-EEG-001
1620-003	HUGGABLES Neonatal/Pediatric ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
1680-001	INVISATRACE Adult ECG Electrode, 1/Pouch	2004	084585464928FD	AET-EEG-001
1680-003	INVISATRACE Adult ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
1680-005	INVISATRACE Adult ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
1680-030	INVISATRACE Adult ECG Electrode, 30/Pouch	2004	084585464928FD	AET-EEG-001
1690-001	ULTRATRACE Adult ECG Electrode, 1/Pouch	2004	084585464928FD	AET-EEG-001
1690-003	ULTRATRACE Adult ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
1690-005	ULTRATRACE Adult ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
1690-030	ULTRATRACE Adult ECG Electrode, 30/Pouch	2004	084585464928FD	AET-EEG-001
1700-001	CLEARTRACE Adult ECG Electrode, 1/Pouch	2004	084585464928FD	AET-EEG-001
1700-003	CLEARTRACE Adult ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
1700-004	CLEARTRACE Adult ECG Electrode, 4/Pouch	2004	084585464928FD	AET-EEG-001
1700-005	CLEARTRACE Adult ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
1700-007	CLEARTRACE Adult ECG Electrode, 7/Pouch	2004	084585464928FD	AET-EEG-001
1700-010	CLEARTRACE Adult ECG Electrode, 10/Pouch	2012	084585464928FD	AET-EEG-001
1700-030	CLEARTRACE Adult ECG Electrode, 30/Pouch	2004	084585464928FD	AET-EEG-001

Reference Number	Product Description	Date 1 <sup>st</sup> CE Marked	Basic UDI-DI	Technical Document #
1700-050	CLEARTRACE Adult ECG Electrode, 50/Pouch	2004	084585464928FD	AET-EEG-001
1700C-003	CLEARTRACE RTL Adult ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
1700C-005	CLEARTRACE RTL Adult ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
1700C-010	CLEARTRACE RTL Adult ECG Electrode, 10/Pouch	2012	084585464928FD	AET-EEG-001
1700C-050	CLEARTRACE RTL Adult ECG Electrode, 50/Pouch	2004	084585464928FD	AET-EEG-001
1720-003	CLEARTRODE Repositionable ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
1720C-003	CLEARTRODE RTL Repositionable ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
1731-003	NEOTRODE Neonatal/Pediatric ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
1731C-003	NEOTRODE RTL Neonatal/Pediatric ECG Electrode, 3/Pouch	2014	084585464928FD	AET-EEG-001
1741-003	NEOTRODE II Neonatal/Pediatric ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
1741C-003	NEOTRODE II RTL Neonatal/Pediatric ECG Electrode, 3/Pouch	2014	084585464928FD	AET-EEG-001
1750-005	CLEARTRACE DIAGNOSTIC Adult Diagnostic ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
1750-030	CLEARTRACE DIAGNOSTIC Adult Diagnostic ECG Electrode, 30/Pouch	2004	084585464928FD	AET-EEG-001
1800-001	SURETRACE Adult ECG Electrode, 1/Pouch	2004	084585464928FD	AET-EEG-001
1800-003	SURETRACE Adult ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
1800-005	SURETRACE Adult ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
1800-030	SURETRACE Adult ECG Electrode, 30/Pouch	2004	084585464928FD	AET-EEG-001
1800-050	SURETRACE Adult ECG Electrode, 50/Pouch	2013	084585464928FD	AET-EEG-001
1800C-003	SURETRACE RTL Adult ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
1800C-005	SURETRACE RTL Adult ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
1800C-050	SURETRACE RTL Adult ECG Electrode, 50/Pouch	2004	084585464928FD	AET-EEG-001
1870-001	POSITRACE Adult Diaphoretic ECG Electrode, 1/Pouch	2004	084585464928FD	AET-EEG-001
1870-003	POSITRACE Adult Diaphoretic ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
1870-005	POSITRACE Adult Diaphoretic ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
1870-030	POSITRACE Adult Diaphoretic ECG Electrode, 30/Pouch	2004	084585464928FD	AET-EEG-001
1870-050	POSITRACE Adult Diaphoretic ECG Electrode, 50/Pouch	2013	084585464928FD	AET-EEG-001
1870C-003	POSITRACE RTL Adult Diaphoretic ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001

Reference Number	Product Description	Date 1 <sup>st</sup> CE Marked	Basic UDI-DI	Technical Document #
1870C-004	POSITRACE RTL Adult Diaphoretic ECG Electrode, 4/Pouch	2004	084585464928FD	AET-EEG-001
1870C-005	POSITRACE RTL Adult Diaphoretic ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
1870C-050	POSITRACE RTL Adult Diaphoretic ECG Electrode, 50/Pouch	2013	084585464928FD	AET-EEG-001
1915-100	FASTRACE 4 Adult Resting Tab ECG Electrode, 100/Pouch	2004	084585464928FD	AET-EEG-001
1920-050	SNAPTRACE Adult Resting Snap ECG Electrode, 50/Pouch	2004	084585464928FD	AET-EEG-001
1925-100	HEARTBEAT Resting Tab ECG Electrode, 100/Pouch	2004	084585464928FD	AET-EEG-001
1935-100	V-TRACE Adult Resting Tab ECG Electrode, 100/Pouch	2004	084585464928FD	AET-EEG-001
2310-003	SOFTRACE Limb Band Neonatal/Pediatric ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
2320-003	SOFTRACE Small Repositionable ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
2320C-003	SOFTRACE RTL Small Repositionable ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
2321-003	SOFTRACE Neonatal/Pediatric ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
2321C-003	SOFTRACE RTL Neonatal/Pediatric ECG Electrode, 3/Pouch	2014	084585464928FD	AET-EEG-001
2330-003	SOFTRACE Medium Repositionable ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
2330C-003	SOFTRACE RTL MEDIUM REPOSITIONABLE ECG ELECTRODE, 3/PCH	2004	084585464928FD	AET-EEG-001
2331-003	SOFTRACE Neonatal/Pediatric ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
2331C-003	SOFTRACE RTL Neonatal/Pediatric ECG Electrode, 3/Pouch	2014	084585464928FD	AET-EEG-001
2350-003	SOFTRACE Large Repositionable ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
2350C-003	SOFTRACE RTL Large Repositionable ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
2350-005	SOFTRACE Large Repositionable ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
2350C-005	SOFTRACE RTL Large Repositionable ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
2700-001	CLEARTRACE2 Adult ECG Electrode, 1/Pouch	2004	084585464928FD	AET-EEG-001
2700-003	CLEARTRACE2 Adult ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001
2700-005	CLEARTRACE2 Adult ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
2700-030	CLEARTRACE2 Adult ECG Electrode, 30/Pouch	2004	084585464928FD	AET-EEG-001
2710-001	CLEARTRACE2 LT Adult ECG Electrode, 1/Pouch	2004	084585464928FD	AET-EEG-001
2710-003	CLEARTRACE2 LT Adult ECG Electrode, 3/Pouch	2004	084585464928FD	AET-EEG-001

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2710-005	CLEARTRACE2 LT Adult ECG Electrode, 5/Pouch	2004	084585464928FD	AET-EEG-001
2710-030	CLEARTRACE2 LT Adult ECG Electrode, 30/Pouch	2004	084585464928FD	AET-EEG-001
3600-003	OMNITRACE FOAM Adult ECG Electrode, 3/Pouch	2014	084585464928FD	AET-EEG-001
3600-005	OMNITRACE FOAM Adult ECG Electrode, 5/Pouch	2014	084585464928FD	AET-EEG-001
3600-050	OMNITRACE FOAM Adult ECG Electrode, 50/Pouch	2014	084585464928FD	AET-EEG-001
3600C-003	OMNITRACE RTL Adult ECG Electrode, 3/Pouch	2014	084585464928FD	AET-EEG-001
3600C-005	OMNITRACE RTL Adult ECG Electrode, 5/Pouch	2014	084585464928FD	AET-EEG-001
3600C-050	OMNITRACE RTL Adult ECG Electrode, 50/Pouch	2014	084585464928FD	AET-EEG-001

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

<b>Revision #</b>	<b>Reason for Change</b>
A	Initial release of EU MDR Declaration of Conformity.
B	Revised to remove catalog numbers 1690-010, 1921-100, 2100-100, 2500-050 and 3500-050.