

DOC. TITLE: RE00189740 Declaration of Conformity (MDR) - Electrophysiology (ECG) Electrodes (CAH)

DOCUMENT NO:	RE00189740	REVISION:	5

DECLARATION OF CONFORMITY



We, Cardinal Health 200 LLC, declare that the products covered in this EU Declaration of Conformity meet the provision of the Medical Device Regulation (EU) 2017/745.

Declaration of Conformity Number	RE00189740
Technical Documentation Number	RE00168520
Manufacturer's Name	Cardinal Health 200, LLC also trading as Cardinal Health
Manufacturer's Address	3651 Birchwood Drive Waukegan, IL 60085 USA
Single Registration Number	US-MF-000006765
Authorized Representative's Name and Address	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Notified body's Name and Identification Number	N/A
CE Certificate Number	N/A
Product Category	Biomedical Electrodes
Basic UDI-DI	Refer to Attachment 1.
EMDN	ECG Electrodes [C020501] EEG Extracranic Electrodes [N01010202] Electromyographic Electrodes [N010101]
Product Code, Trade name and Description	Refer to Attachment 1.
Intended Purpose	(1) Electrocardiogram (ECG) electrodes are used to transmit the electrical activity produced by the heart via attached lead wires to an ECG monitor. (2) For use in passive sensing of bio-electric signals (such as ECG, EEG, EMG, and respiration from the intact skin).
Classification and Rule	Class I, Rule 1.
Common Specifications	N/A
Where appropriate, add applicable Union legislation	N/A
Conformity assessment	Self Declared

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SIGNATURE SECTION			
This EU Declaration of Conformity is issued for and on behalf of and under the sole responsibility of the Legal Manufacturer identified above.			
Place of Issue	Waukegan, IL 60085 USA		
Signature	 Electronically signed by: Patricia Beja Reason: Approved Date: Sep 21, 2023 20:28 EDT	Date	Sep 21, 2023
Name and Function	Patty Beja, Regulatory Affairs		

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ATTACHMENT 1

Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
22300	Kendall™ 300 Foam Electrodes, Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
22450	Kendall™ 450 Foam Electrodes, Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
22453	Kendall™ 453 Foam Electrodes, Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
22455	Kendall™ 455 Foam Electrodes, Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
22500	Kendall™ 500 Foam Electrodes, Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
22850	Kendall™ 850 Foam Electrodes, Conductive Adhesive Hydrogel, Radiolucent	063014000000000000003296T	C020501	Class I, Rule I
22853	Kendall™ 853 Foam Electrodes, Conductive Adhesive Hydrogel, Radiolucent	063014000000000000003296T	C020501	Class I, Rule I
22855	Kendall™ 855 Foam Electrodes, Conductive Adhesive Hydrogel, Radiolucent	063014000000000000003296T	C020501	Class I, Rule I
22930	Kendall™ 930 Foam Electrodes, Conductive Adhesive Hydrogel, Radiolucent	063014000000000000003296T	C020501	Class I, Rule I
22933	Kendall™ 933 Foam Electrodes, Conductive Adhesive Hydrogel, Radiolucent	063014000000000000003296T	C020501	Class I, Rule I
22935	Kendall™ 935 Foam Electrodes, Conductive Adhesive Hydrogel, Radiolucent	063014000000000000003296T	C020501	Class I, Rule I
222002	Kendall™ Neonatal-Pediatric Monitoring Electrode, Prewired, Square, Reflective Backing, Radiolucent	063014000000000000003196Q	C020501	Class I, Rule I
222002A	Kendall™ Neonatal-Pediatric Monitoring Electrode with Aloe, Prewired, Square, Reflective Backing, Radiolucent	063014000000000000003186N	C020501	Class I, Rule I
2293003	Kendall™ Adult 930 Foam Electrodes, Prewired, 3 Lead, Conductive Adhesive Hydrogel, Radiolucent	063014000000000000003326G	C020501	Class I, Rule I

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Product Code List

Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
2293005	Kendall™ Adult 930 Foam Electrodes, Prewired, 5 Lead, Conductive Adhesive Hydrogel, Radiolucent	063014000000000000003326G	C020501	Class I, Rule I
30710001	Kendall™ Neonatal Electrodes, Foam, Hydrogel, 1.5mm Socket, Monitoring	063014000000000000003176L	C020501	Class I, Rule I
30807732	Kendall™ 5500 Diagnostic Tab Electrodes	063014000000000000003336J	C020501	Class I, Rule I
31013926	Kendall™ 530 Foam Electrodes, Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
31043055	Kendall™ Cloth Electrodes, 7665 Conductive Adhesive Hydrogel	063014000000000000003356N	C020501	Class I, Rule I
31043063	Kendall™ Cloth Electrodes, 7663 Conductive Adhesive Hydrogel	063014000000000000003356N	C020501	Class I, Rule I
31043170	Kendall™ 7605 Cloth Electrodes, Conductive Adhesive Hydrogel	063014000000000000003356N	C020501	Class I, Rule I
31050522	Kendall™ 200 Foam Electrodes, Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
31078135	Kendall™ 230 Foam Electrodes, Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
31112496	Kendall™ 130 Foam Electrodes, Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
31115788	Kendall™ Electrodes, 535 Foam Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
31115796	Kendall™ Electrodes, 533 Foam Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
31118733	Kendall™ 100 Foam Electrodes, Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
31424719	Kendall™ 1053NPSM Neonatal Electrodes, Prewired, Large Cloth, Radiolucent	063014000000000000003276P	C020501	Class I, Rule I
31424743	Kendall™ 1051NPSM Neonatal Electrodes, Prewired, Small Cloth, Radiolucent	063014000000000000003276P	C020501	Class I, Rule I
31424768	Kendall™ 1050NPSM Neonatal Electrodes, Prewired, Small Cloth	063014000000000000003226D	C020501	Class I, Rule I
31424780	Kendall™ 1041PTS Neonatal Electrodes, Prewired, Round, Clear Tape Radiolucent	063014000000000000003256K	C020501	Class I, Rule I
31424785	Kendall™ 1042PTS Neonatal Electrodes, Prewired, Square, Clear Tape Radiolucent	063014000000000000003256K	C020501	Class I, Rule I
31424786	Kendall™ 1042PTS54 Neonatal Electrodes, Prewired, Square, Clear	063014000000000000003256K	C020501	Class I, Rule I

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Product Code List

Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
	Tape, Radiolucent			
31433538	Kendall™ 5400 Diagnostic Tab Electrodes	063014000000000000003336J	C020501	Class I, Rule I
31439725	Kendall™ 133 Foam Electrodes, Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
31439766	Kendall™ 135 Foam Electrodes, Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
31447793	Kendall™ CA610 Diagnostic Tab Electrodes	063014000000000000003336J	C020501	Class I, Rule I
31452389	Kendall™ SF3040.50 Foam Electrodes, Conductive Adhesive Hydrogel, Radiolucent	063014000000000000003296T	C020501	Class I, Rule I
31478368	Kendall™ 233 Foam Electrodes, Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
31478376	Kendall™ 235 Foam Electrodes, Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
40000003	Kendall™ 630 Foam Electrodes, Conductive Adhesive Hydrogel, Radiolucent	063014000000000000003296T	C020501	Class I, Rule I
40000013	Kendall™ 600 Foam Electrodes, Conductive Adhesive Hydrogel, Radiolucent	063014000000000000003296T	C020501	Class I, Rule I
50007305	Kendall™ 7305 Foam Electrodes, Conductive Adhesive Hydrogel	063014000000000000003286R	C020501	Class I, Rule I
31.1245.21	Kendall™ H124SG ECG Electrodes Foam, Hydrogel 30 x 24 mm	063014000000000000003386U	C020501	Class I, Rule I
31.1345.21	Kendall™ H34LG ECG Electrodes Foam, Wet Gel, Stress 50 x 45 mm	063014000000000000003446P	C020501	Class I, Rule I
31.1355.21	Kendall™ H135SG ECG Electrodes Foam, Hydrogel 43 x 35 mm	063014000000000000003386U	C020501	Class I, Rule I
31.1663.21	Kendall™ H66LG ECG Electrodes Foam, Wet Gel 55 mm	063014000000000000003446P	C020501	Class I, Rule I
31.1914.21	Kendall™ H914SG ECG Electrodes Foam, Hydrogel 4 mm Banana Adapter 57 x 34 mm	063014000000000000003426K	C020501	Class I, Rule I
31.1917.21	Kendall™ H91SSG ECG Electrodes Foam, Hydrogel, Stress 57 x 34 mm	063014000000000000003386U	C020501	Class I, Rule I
31.1925.21	Kendall™ H92SG ECG Electrodes Foam, Hydrogel, 57 x 34 mm	063014000000000000003386U	C020501	Class I, Rule I
31.1925.30	Kendall™ H92SG ECG Electrodes Foam, Hydrogel 57x34 mm	0630140000000000000035872	C020501	Class I, Rule I

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Product Code List

Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
31.1935.21	Kendall™ H93SG ECG Electrodes Foam, Hydrogel, 42 x 24 mm	063014000000000000003386U	C020501	Class I, Rule I
31.1946.21	Kendall™ H34SG ECG Electrodes Foam, Hydrogel, Stress, Radiolucent 50 x 45 mm	063014000000000000003406F	C020501	Class I, Rule I
31.1985.21	Kendall™ H98LG ECG Electrodes Non-woven, Wet Gel 55 mm	063014000000000000003566W	C020501	Class I, Rule I
31.1986.21	Kendall™ H98SG ECG Electrodes Non-woven, Hydrogel 55 mm	063014000000000000003546S	C020501	Class I, Rule I
31.1995.21	Kendall™ H99LG ECG Electrodes Cloth, Wet Gel 55 mm	063014000000000000003476V	C020501	Class I, Rule I
31.1996.21	Kendall™ H99SG ECG Electrodes Cloth, Hydrogel 55 mm	063014000000000000003466T	C020501	Class I, Rule I
31.3076.26	Kendall™ H207H Neonatal ECG Electrodes Non-woven, Hydrogel, 1,5 mm DIN Connector 22 x 30 mm	063014000000000000003556U	C020501	Class I, Rule I
31.3276.03	Kendall™ H27H/F Neonatal ECG Electrodes Non-woven, Hydrogel, 1,5 mm DIN Connector 24 mm	063014000000000000003496Z	C020501	Class I, Rule I
31.3872.02	Neonatal ECG Electrodes Non-woven, Clear Gel, 1,5 mm DIN Connector 30 mm	063014000000000000003556U	C020501	Class I, Rule I
31.3876.04	Kendall™ H87H/F Neonatal ECG Electrodes Non-woven, Hydrogel, 1,5 mm DIN Connector 30 mm	063014000000000000003556U	C020501	Class I, Rule I
31.5032.26	Kendall™ H203PG Neonatal ECG Electrodes Non-woven, Clear Gel, 4 mm Socket 22 x 30 mm	063014000000000000003536Q	C020501	Class I, Rule I
31.5033.26	Kendall™ H203PGK Neonatal ECG Electrodes Non-woven, Clear Gel, 4 mm Socket 22 x 30 mm	063014000000000000003526N	C020501	Class I, Rule I
31.5072.03	Kendall™ H207PG/F Neonatal ECG Electrodes Non-woven, Clear Gel, 1,5 mm DIN Connector 22 x 30 mm	063014000000000000003486X	C020501	Class I, Rule I
31.5872.04	Kendall™ H87PG/F Neonatal ECG Electrodes Non-woven, Clear Gel, 1,5 mm DIN Connector 30 mm	063014000000000000003556U	C020501	Class I, Rule I
31.6071.26	Kendall™ H207LG/F60 Sleep Laboratory Electrodes Foam, Wet Gel, 1,5 mm DIN Connector 33 x 24 mm	063014000000000000003576Y	N01010202 and N010101	Class I, Rule I
31.6072.26	Kendall™ H207LGN Sleep Laboratory Electrodes Foam, Wet Gel, 1,5 mm DIN Connector 33 x 24 mm	063014000000000000003576Y	N01010202 and N010101	Class I, Rule I

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Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
31.6073.26	Kendall™ H207LG/F150 Sleep Laboratory Electrodes Foam, Wet Gel, 1,5 mm DIN Connector 33 x 24 mm	063014000000000000003576Y	N01010202 and N010101	Class I, Rule I
31.6074.26	Kendall™ H207LG/F200 Sleep Laboratory Electrodes Foam, Wet Gel, 1,5 mm DIN Connector 33 x 24 mm	063014000000000000003576Y	N01010202 and N010101	Class I, Rule I
31.6075.03	Sleep Laboratory Electrodes Foam, Wet Gel, 1,5 mm DIN Connector 33 x 24 mm	063014000000000000003576Y	N01010202 and N010101	Class I, Rule I
31.6076.03	Sleep Laboratory Electrodes Foam, Wet Gel, 1,5 mm DIN Connector 33 x 24 mm	063014000000000000003576Y	N01010202 and N010101	Class I, Rule I
31.1355821	Kendall™ H135TSG ECG Electrodes Foam, Hydrogel Radiolucent 43 x 35 mm	063014000000000000003416H	C020501	Class I, Rule I
31.1914821	Kendall™ H914TSG ECG Electrodes Foam, Hydrogel 4 mm Banana Adapter, Radiolucent 57 x 34 mm	063014000000000000003436M	C020501	Class I, Rule I
31.1915821	Kendall™ H91TSG ECG Electrodes Foam, Hydrogel, Radiolucent 57 x 34 mm	063014000000000000003416H	C020501	Class I, Rule I
31.5039124	Kendall™ H203PGT Neonatal ECG Electrodes Non-woven, Clear Gel, 4 mm Socket, Radiolucent 22 x 30 mm	063014000000000000003516L	C020501	Class I, Rule I
31.5072824	Kendall™ H207PGT Neonatal ECG Electrodes, Non-woven, Clear Gel, 1,5 mm DIN Connector, Radiolucent 22 x 30 mm	063014000000000000003496Z	C020501	Class I, Rule I
EF00066	Kendall™ CA310 Diagnostic Tab Electrodes	063014000000000000003336J	C020501	Class I, Rule I
EF00149	Kendall™ CA510 Diagnostic Tab Electrodes	063014000000000000003336J	C020501	Class I, Rule I
EP00779	Kendall™ 1050NPSMR40 Neonatal Electrodes, Prewired, Small Cloth, 40" RWBL	063014000000000000003246H	C020501	Class I, Rule I
EP30016	Kendall™ L36-LB Cloth Limb Band Neonatal Electrodes, Prewired	063014000000000000003266M	C020501	Class I, Rule I
ER88007	Kendall™ Nutab Diagnostic Tab Electrodes	063014000000000000003346L	C020501	Class I, Rule I
ES40030	Kendall™ H49P Cloth Electrodes, Repositionable Conductive Adhesive Hydrogel	063014000000000000003366Q	C020501	Class I, Rule I

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Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
ES40036	Kendall™ 1093 Cloth Electrodes, Repositionable, Conductive Adhesive Hydrogel	063014000000000000003366Q	C020501	Class I, Rule I
ES40076	Kendall™ H59P Cloth Electrodes, Repositionable Conductive Adhesive Hydrogel	063014000000000000003366Q	C020501	Class I, Rule I
ES40281	Kendall™ H69P Cloth Electrodes, Repositionable Conductive Adhesive Hydrogel	063014000000000000003366Q	C020501	Class I, Rule I
RR3305	Kendall™ Radiolucent Repositionable Cloth Electrodes, Conductive Adhesive Hydrogel	063014000000000000003376S	C020501	Class I, Rule I

RE00189740_EU Declaration of Conformity

Final Audit Report

2023-09-22

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