



Declaration of Conformity

Technical File: **KSE-04**

The undersigned declares that the products named and listed on this certificate meet the provisions of the European Communities Council Directive 93/42/EEC, as amended by Directive 2007/47/EC, and the Essential Principles and classification rules according to Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002, which apply to them and the CE mark may be affixed.

General Product Name: **Electrodes**

Manufacturer: **Cardinal Health 200, LLC
3651 Birchwood Drive
Waukegan, IL 60085 USA**

EC Representative: **Cardinal Health Ireland Manufacturing Limited,
Tullamore Business and Technology Park,
Tullamore, County Offaly, R35 H903, Ireland**

Intended Use: The ECG electrodes for long term monitoring, the Liquid Gel Electrodes for short term use and the Universal ECG electrodes are designed for passive collection of bioelectric signals from the undamaged skin (also usable for passive collection of body signals like EMG and respiration). The Neonatal ARBO* Kiddy clear gel electrodes and the ARBO* Goldy Karaya gel electrodes serve for collection and leading bioelectric signals from the undamaged skin of infants and neonates. Chest wall suction electrodes consist of a suction ball that produces a vacuum after compression and release by which the chest suction electrodes will adhere to the thorax.

Sterility: No *Refer to Attached Table*

Measuring Function: No

Directive Classification: I (non-sterile/non-measuring)

In Accordance with Annex: VII

The manufacturer has exclusive responsibility for this Declaration of Conformity.

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principals, the classification rules at each stage, from the design of the device until its final inspection before being supplied, in accordance with clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

If this Declaration of Conformity contains Class I, non-sterile, non-measurement devices, it is noted that they are not regulated by TÜV SÜD P.S. and follow conformity assessment procedures set out in Annex VII, in accordance with clause 6.6 of Schedule 3 Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Date CE Marking Approved: *Refer to Attached Table*

EC Certificate(s): *Refer to Attached Table*

Reorder codes/GMDN Codes: *Refer to Attached Table*

Notified Body Name: TÜV SÜD Product Service GmbH Identification Number: 0123
Ridlerstraße 65
D-80339 München, Germany

Signature:

Maria Rao

Maria Rao, Regulatory Affairs Manager

Manfield, MA

May 27, 2020

Date



Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: <i>Self Certified</i>						
Class	I (non-sterile/non-measuring)	Annex VII				
2011000300	Meditec Adult ECG Limb Clamp Electrode Set	No	Non	Electrocardiographic electrode, single-use [35035]	1	
2062000324	Meditec ECG Chest Suction Electrode	No	Non	Electrocardiographic electrode, single-use [35035]	1	
31.1245.21	Kendall™ H124SG ECG Electrodes Foam, Hydrogel 30 x 24 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1992
31.1345.21	Kendall™ H34LG ECG Electrodes Foam, Wet Gel, Stress 50 x 45 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1998
31.1355.21	Kendall™ H135SG ECG Electrodes Foam, Hydrogel 43 x 35 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1992
31.1355.31	Kendall ECG Electrodes, H135SG Stemple 35 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	
31.1355821	Kendall™ H135TSG ECG Electrodes Foam, Hydrogel Radiolucent 43 x 35 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1995



Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: <i>Self Certified</i>						
Class	I (non-sterile/non-measuring)	Annex VII				
31.1413.21	Kendall™ H135LG ECG Electrodes Foam, Wet Gel 40 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/13/2009
31.1414.21	Kendall™ H1354LG ECG Electrodes Foam, Wet Gel, 4 mm Banana Adapter 40 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/13/2009
31.1663.21	Kendall™ H66LG ECG Electrodes Foam, Wet Gel 55 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1998
31.1664.21	Kendall™ H664LG ECG Electrodes Foam, Wet Gel, 4 mm Banana Adapter 55 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/2008
31.1705.21	Kendall™ H70LG ECG Electrodes Non-woven, Wet Gel 70 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/2008
31.1715.21	Kendall™ H71SG ECG Electrodes Foam, Hydrogel 58 x 51 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1998
31.1914.21	Kendall™ H914SG ECG Electrodes Foam, Hydrogel 4 mm Banana Adapter 57 x 34 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1995



Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: <i>Self Certified</i>						
Class	I (non-sterile/non-measuring)	Annex VII				
31.1914821	Kendall™ H914TSG ECG Electrodes Foam, Hydrogel 4 mm Banana Adapter, Radiolucent 57 x 34 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1995
31.1915821	Kendall™ H91TSG ECG Electrodes Foam, Hydrogel, Radiolucent 57 x 34 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1995
31.1917.21	Kendall™ H91SSG ECG Electrodes Foam, Hydrogel, Stress 57 x 34 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1995
31.1925.21	Kendall™ H92SG ECG Electrodes Foam, Hydrogel, 57 x 34 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1992
31.1925.30	Kendall™ H92SG ECG Electrodes Foam, Hydrogel 57x34 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	05/27/2020
31.1935.21	Kendall™ H93SG ECG Electrodes Foam, Hydrogel, 42 x 24 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1992
31.1946.21	Kendall™ H34SG ECG Electrodes Foam, Hydrogel, Stress, Radiolucent 50 x 45 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1995



Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: <i>Self Certified</i>						
Class	I (non-sterile/non-measuring)	Annex VII				
31.1985.21	Kendall™ H98LG ECG Electrodes Non-woven, Wet Gel 55 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1998
31.1986.21	Kendall™ H98SG ECG Electrodes Non-woven, Hydrogel 55 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1998
31.1995.21	Kendall™ H99LG ECG Electrodes Cloth, Wet Gel 55 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1998
31.1996.21	Kendall™ H99SG ECG Electrodes Cloth, Hydrogel 55 mm	No	Non	Electrocardiographic electrode, single-use [35035]	1	12/31/1998
31.3076.26	Kendall™ H207H Neonatal ECG Electrodes Non-woven, Hydrogel, 1,5 mm DIN Connector 22 x 30 mm	No	Non	Neonatal electrocardiographic electrode [17460]	1	12/31/2005
31.3276.03	Kendall™ H27H/F Neonatal ECG Electrodes Non-woven, Hydrogel, 1,5 mm DIN Connector 24 mm	No	Non	Neonatal electrocardiographic electrode [17460]	1	12/31/2005
31.3870.24	Kendall™ H87V Neonatal ECG Electrodes Non-woven, Karaya Gel, 1,5 mm DIN Connector 30 mm	No	Non	Neonatal electrocardiographic electrode [17460]	1	12/31/2016



Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: <i>Self Certified</i>						
Class	I (non-sterile/non-measuring)	Annex VII				
31.3873.25	Kendall™ H87V/F Neonatal ECG Electrodes Non-woven, Karaya Gel, 1,5 mm DIN Connector 30 mm	No	Non	Neonatal electrocardiographic electrode [17460]	1	12/31/2016
31.3876.04	Kendall™ H87H/F Neonatal ECG Electrodes Non-woven, Hydrogel, 1,5 mm DIN Connector 30 mm	No	Non	Neonatal electrocardiographic electrode [17460]	1	12/31/2005
31.5032.26	Kendall™ H203PG Neonatal ECG Electrodes Non-woven, Clear Gel, 4 mm Socket 22 x 30 mm	No	Non	Neonatal electrocardiographic electrode [17460]	1	12/31/1999
31.5033.26	Kendall™ H203PGK Neonatal ECG Electrodes Non-woven, Clear Gel, 4 mm Socket 22 x 30 mm	No	Non	Neonatal electrocardiographic electrode [17460]	1	12/31/1999
31.5039124	Kendall™ H203PGT Neonatal ECG Electrodes Non-woven, Clear Gel, 4 mm Socket, Radiolucent 22 x 30 mm	No	Non	Neonatal electrocardiographic electrode [17460]	1	12/31/1999
31.5072.03	Kendall™ H207PG/F Neonatal ECG Electrodes Non-woven, Clear Gel, 1,5 mm DIN Connector 22 x 30 mm	No	Non	Neonatal electrocardiographic electrode [17460]	1	12/31/1999
31.5072.26	Kendall™ H207PGN Sleep Laboratory Electrodes Non-woven, Clear Gel, 1,5 mm DIN Connector 22 x 30 mm	No	Non	Analytical scalp electrode, single-use [11440]	1	12/31/1997



Products Covered By This Certificate

Reorder Code	Description	Measuring Function	Sterilization Method	GMDN Code	Rule	Date Approved for CE
EC Certificate: <i>Self Certified</i>						
Class	I (non-sterile/non-measuring)	Annex VII				
31.5072824	Kendall™ H207PGT Neonatal ECG Electrodes, Non-woven, Clear Gel, 1,5 mm DIN Connector, Radiolucent 22 x 30 mm	No	Non	Neonatal electrocardiographic electrode [17460]	1	12/31/1999
31.5872.04	Kendall™ H87PG/F Neonatal ECG Electrodes Non-woven, Clear Gel, 1,5 mm DIN Connector 30 mm	No	Non	Neonatal electrocardiographic electrode [17460]	1	12/31/1999
31.6071.26	Kendall™ H207LG/F60 Sleep Laboratory Electrodes Foam, Wet Gel, 1,5 mm DIN Connector 33 x 24 mm	No	Non	Analytical scalp electrode, single-use [11440]	1	12/31/2015
31.6072.26	Kendall™ H207LGN Sleep Laboratory Electrodes Foam, Wet Gel, 1,5 mm DIN Connector 33 x 24 mm	No	Non	Analytical scalp electrode, single-use [11440]	1	12/31/2013
31.6073.26	Kendall™ H207LG/F150 Sleep Laboratory Electrodes Foam, Wet Gel, 1,5 mm DIN Connector 33 x 24 mm	No	Non	Analytical scalp electrode, single-use [11440]	1	12/31/2015
31.6074.26	Kendall™ H207LG/F200 Sleep Laboratory Electrodes Foam, Wet Gel, 1,5 mm DIN Connector 33 x 24 mm	No	Non	Analytical scalp electrode, single-use [11440]	1	12/31/2015