

**MEIL CONFIDENTIAL**  
**EU DECLARATION OF CONFORMITY**

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Manufacturer: Medico Electrodes International Ltd.  
Plot 142A/11, 12, 27, 28 & 29, Noida Special Economic Zone, Noida,  
Uttar Pradesh, 201305, India.

SRN: IN-MF-000021002

Medical Device: Disposable ECG Electrodes / Electrocardiograph Electrodes (ECG Electrodes)

Model Name/Type: Various (Appendix\_01\_List of Product References)

Intended Purpose: An electrocardiograph electrode is the electrical conductor, which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or a vector cardiogram.

Basic UDI-DI: 89060352820210101DL

Device Classification: Class I (in accordance with Annex VIII, Rule 1- Non-invasive devices of EU MDR 2017/745)

Packaging: Various

GMDN Code: 35035

We Herewith Declare In Our Own Responsibility that The Above-Mentioned Products Meet The General Safety and Performance Requirements, Annex I, of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices. All supporting documentation and Technical file is retained under the premises of the manufacturer (Head of Quality Department) & Authorized European Representative and will be kept at disposal of the Notified Body and Competent Authorities for a period of ten years from the production date of the device.


We further declare that a suitable procedure is maintained which grants the application of the post-marketing surveillance procedure required by EU MDR 2017/745.

General applicable regulation(s): Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices

Referenced standard(s): ANSI/AAMI EC12:2000

Authorized European Representative: Medico Electrodes Ltd.  
Blvd. Saint-Michel 65/6  
1040 Brussels, Belgium  
SRN: BE-AR-000020093  
www.medicoelectrodes.com

Person keeping the technical documentation: Amit Seth, Vice-President.

  
Signed  
For Medico Electrodes International Ltd.,  
Authorized Signatory.

Date: **06-04-2023**  
Place: NOIDA, U.P., INDIA

On the basis of this declaration, the product packaging will bear the following marking:



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<b>Appendix 01 List of Product References</b>		
<b>S.No.</b>	<b>Halbach References</b>	<b>Medico References</b>
1.	849760	MSGLT-08GRT
2.	849755	MSGST-12
3.	849751	MSGLT-08G
4.	849750	MSGLT-15GK
5.	849758	MSGLT-8G4
6.	849996	MSGLT-01G
7.	849759	MSGST-35M
8.	849765	MSGLT-15DC
9.	849763	MSGST-12C
10.	849753	MSGLT-05MGRT
11.	849757	MSGST-35MRT
12.	849998	MSGST-12RT
13.	849752	MSGLT-05MG
14.	849980	REP4032RT-3
15.	849981	REP4032RT-5
16.	849754	MSGLT-05MGRT
17.	849720	MLGLT-14
18.	849721	MLGLT-024
19.	849722	MLGLT-15DC
20.	849756	MSGST-64RT
21.	849901	MSGLT-05MG
22.	849902	MSGLT-05MGRT
23.	849903	MSGLT-08G
24.	849904	MSGLT-08GRT
25.	849905	MSGST-124
26.	849906	MLGLT-02
27.	849907	MLGST-07
28.	849723	MLGLT-14RT
29.	849726	MLGLT-11
30.	849909	MSGLT-05MGRT
31.	849745	3521MED
32.	849767	OTL-5235-S60
33.	849768	OTL-4227-S42
34.	849644	OTL-5235-S
35.	849645	OTL-5235-S4
36.	849647	OTL-4227-S
37.	849648	OTL-4227-S4
38.	849649	OTL-4227
39.	849766	OTL-4227-S50