

MEIL CONFIDENTIAL ISSUED TO GPS PRAHA
EU DECLARATION OF CONFORMITY

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: MSGLT-09, MSGLT-09RT, MSGST-07, MSGST-07RT, MLGLT-14, MLGLT-15K,
MSGST-27, MSGLT-03GRT.

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: **12-09-2024**
Place: NOIDA, U.P., INDIA

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

