

## EU DECLARATION OF CONFORMITY

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

Medical Device: Disposable ECG Electrodes

Model Name/Type: 849760, 849755, 849751, 849750, 849758, 849996, 849759, 849765, 849763, 849753,  
849757, 849998, 849752, 849923, 849922, 849980, 849981, 849924, 849925, 849754,  
849720, 849721, 849722, 849756, 849901, 849902, 849903, 849904, 849905, 849906,  
849907, 849723, 849726, 849909, 849767, 849768, 849644, 849645, 849647, 849648,  
849649, 849766 & 849745.

UDI-DI: 8906035280000

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

Packaging: Various

GMDN Code: 35035 (Single Use ECG Electrode), 17460 (Electrode, Electrocardiograph, Neonatal)

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.  
Warwick, CV34 6LX, UK  
SRN: **EUDAMED is inactive**  
[www.medicoelectrodes.com](http://www.medicoelectrodes.com)

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



Signed  
For Medico Electrodes International Ltd.,  
Authorized Signatory.

Date: **26-06-2020**  
Place: NOIDA, U.P., INDIA

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

