EU DECLARATION OF CONFORMITY

Manufacturer:	Medico Electrodes International Ltd. Plot 142A/11, 12, 27, 28 & 29 Noida Special Economic Zone, Noida 201305, UP, India
Medical Device:	Disposable ECG Electrodes
Model Name/Type:	250960,250961,250962,250963,250964,250965,250966,250967,250968,250969, 250970,250971,250972,250973,250274,250975,250976,250958,250959,250986, 250989, 250990 and 250991
Device Classification:	Class I (in accordance with Annex VIII, Rule 1- Non-invasive devices of EU MDR 2017/745)
Packaging:	Various
GMDN Code:	35035 (Electrocardiographic electrode, single Use) 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. Blvd. Saint-Michel 65/6 1040 Brussels, Belgium SRN: **EUDAMED is inactive** www.medicoelectrodes.com

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

For Medico Electrodes International Ltd.,

Signed
Authorized Signatory.
Date: 31-12-2020

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

CE