EC 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, 250970,250971,250972,250973,250975,250976,250958,250959,250986,250989 250990,250991.
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 Essential Requirements Of The Council Directive 93/42/EEC, Annex I, of 14th June 1993 concerning medical devices, amended by Council Directive 2007/47/EC. All supporting documentation and Technical file are retained under the premises of the manufacturer (head of Quality department) and will be kept at disposal of the Notified Body and Competent Authorities.

We further declare that a suitable procedure is maintained which grants the application of the post-marketing surveillance procedure required by the above mentioned Directive.

General applicable directive(s): Council Directive 93/42/EEC concerning Medical devices, updated by Directive 2007/47/EC of the EP and the council of 5th September 2007.

Device Classification: Class I, non-sterile (in accordance with Annex IX, Rule 1)

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

Authorized European Representative: Medico Electrodes Ltd.
Warwick, CV34 6LX, UK
www.medicoelectrodes.com

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

For Medico Electrodes International Ltd.,

for,

Signed
Authorized Signatory.
Date: 27-02-2020

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

CE