

EC DECLARATION OF CONFORMITY

Product:	ECG Electrode Belts
Manufacturer:	LevMed Ltd. Hanarkis 9/3 Zikhron Ya'akov 3093320 Israel
Classification rule:	Class I in accordance with Rule 1 of Annex VIII of the Regulation (EU) 2017/ 745 of European Parliament and of the council of 5 April 2017 on medical devices.
European Authorized Representative:	Kinesis Medical B.V. Sprangseweg 13 5144 NV Waalwijk The Netherlands

We hereby declare that the following products:

Catalogue #*	Product Description
11001-YY	6U Universal ECG Electrode Belt with Handles
11002n-YY	6U Universal ECG Electrode Belt with Straps
11005/h-YY	AllBrand ECG Electrode Belt with Handles
11005/s-YY	AllBrand ECG Electrode Belt with Straps
1106X/h-YY	Dedicated ECG Electrode Belt with Handles
1106X/s-YY	Dedicated ECG Electrode Belt with Straps
11051/h-YY	10U Universal ECG Belt with Handles
11054	Pediatric ECG Electrodes belt

*YY = logo applied on product.

meet the provisions of the Regulation (EU) 2017/ 745 of European Parliament and of the council of 5 April 2017 on medical devices.

All devices have been verified as conforming to the general safety and performance requirements relating to the EC Declaration of Conformity as set out in Annex I of the Regulation (EU) 2017 /745.

This declaration is based on the conformity assessment of products to the requirements of Annex II of the Regulation (EU) 2017/ 745.



June 29th , 2021

Yuval Zuk, CEO, LevMed Ltd.

Date