

EC DECLARATION OF CONFORMITY

Product:	ECG Electrode Belts
Manufacturer:	LevMed Ltd. Hanarkis 9/3 Zikhron Ya'akov 3093320 Israel SRN : IL-MF-000008545
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. Nies van der Schansstraat 9 5161 CE Sprang-Capelle The Netherlands +31853034974 SRN: NL-AR-000000432

We hereby declare that the following products:

Catalogue #*	Product Description
11001-YY	6U Universal ECG Electrode Belt with Handles The 6U Universal ECG Electrode Belt with Handles is a reusable accessory intended to be used with ECG devices for short-term 12-lead rest ECG recordings for adults and pediatrics Basic UDI -Di 7290016423ECGB6Uh5F
11002n-YY	6U Universal ECG Electrode Belt with Straps The 6U Universal ECG Electrode Belt with Straps is a reusable accessory intended to be used with ECG devices for short-term 12-lead rest ECG recordings for adults and pediatrics Basic UDI-DI 7290016423ECGB6Us65
11005/h-YY	AllBrand ECG Electrode Belt with Handles The AllBrand ECG Electrode Belt with Handles is a reusable accessory intended to be used with ECG devices for short-term 12-lead rest ECG recordings for adults and pediatrics. Basic UDI-DI 7290016423ECGBALBhF3
A-11005/s-YY	AllBrand ECG Electrode Belt with Straps The AllBrand ECG Electrode Belt with Straps is a reusable accessory intended to be used with ECG devices for short-term 12-lead rest ECG recordings for adults and pediatrics Basic UDI-DI 7290016423ECGBALBsFR
1106X/h-YY	Dedicated ECG Electrode Belt with Handles The Dedicated ECG Electrode Belt with Handles is a reusable accessory intended to be used with ECG devices for short-term 12-lead rest ECG recordings for adults and pediatrics Basic UDI-DI 7290016423ECGBDDh5V
1106X/s-YY	Dedicated ECG Electrode Belt with Straps



	<p>The Dedicated ECG Electrode Belt with Straps is a reusable accessory intended to be used with ECG devices for short-term 12-lead rest ECG recordings for adults and pediatrics Basic UDI-DI 7290016423ECGBDDs6K</p>
11051/h-YY	<p>10U Universal ECG Belt with Handles The 10U Universal ECG Electrode Belt with Handles is a reusable accessory intended to be used with ECG devices for short-term 12-lead rest ECG recordings for adults and pediatrics Basic UDI-DI 7290016423ECGBUPh9N</p>
11054	<p>Pediatric ECG Electrodes belt The Pediatric ECG Electrode Belt with Handles is a reusable accessory intended to be used with ECG devices for short-term 12-lead rest ECG recordings for adults and pediatrics Basic UDI-DI 7290016423ECGBPDs8F</p>
B-LM31001EU-NL	<p>Levmed ECG limb electrodes Basic UDI-DI 7290016423ECGLIMBEL3H</p>
B-LM29008	<p>4 mm ECG electrodes adaptors adaptors Basic UDI-DI 72900164234mmadaptorsNJ</p>

*YY = logo applied on product.

*X= connector type

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.

February 5th , 2025

Yuval Zuk, CEO, LevMed Ltd.

Date