

## EC DECLARATION OF CONFORMITY

Product:	<b>ECG Electrode Belts</b>
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 <b>7290016423ECGB6Uh5F</b>
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 <b>7290016423ECGB6Us65</b>
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 <b>7290016423ECGBALBhF3</b>
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 <b>7290016423ECGBALBsFR</b>
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 <b>7290016423ECGBDDh5V</b>
1106X/s-YY	Dedicated ECG Electrode Belt with Straps



	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 <b>7290016423ECGBDDs6K</b>
11051/h-YY	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 <b>7290016423ECGBUPh9N</b>
11054	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 <b>7290016423ECGBPDS8F</b>
B-LM31001EU-NL	Levmed ECG limb electrodes Basic UDI-DI <b>7290016423ECGLIMBEL3H</b>
B-LM29008	4 mm ECG electrodes adaptors adaptors Basic UDI-DI <b>72900164234mmadaptorsNJ</b>

\*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.

**7290016423ECGLIMBEL3H**

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.

March 25th , 2024

Yuval Zuk, CEO, LevMed Ltd.

Date