

MANUFACTURER

SORIMEX spółka z ograniczoną odpowiedzialnością (formerly SORIMEX sp. z o.o. sp. k.)
ul. Równinna 25, 87-100 Toruń, Poland

CODE SRN:
PL-MF-000020958

WE DECLARE UNDER OUR SOLE RESPONSIBILITY THAT:

BASIC UDI-DI:

5903002221145F

MEDICAL DEVICE:

reusable ECG electrodes

MODELS:

EKK, EP

CLASS:

I according to rule 1 of Annex VIII of the Regulation (EU) 2017/745 of the European Parliament and of the Council

- comply with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council
- product conformity assessment was carried out in accordance with Annex II and III of the Regulation of the European Parliament and of the Council (EU) 2017/745

APPLIED HARMONIZED STANDARDS, NATIONAL STANDARDS OR OTHER NORMATIVE DOCUMENTS:

- EN ISO 13485:2016
- EN ISO 14971:2019
- EN ISO 20417:2021
- EN ISO 15223-1:2021
- EN ISO 10993-1:2009
- EN 62366:2015

The batch numbers of the products covered by this declaration are included in the Quality Control Certificate confirming that the product was released for sale and should be treated as part of this declaration.



Paweł Sobociński

CEO

LIST OF CONSTRUCTION TYPES ECG ELECTRODES BY THE DECLARATION OF CONFORMITY

EKK-1	EP-15
EKK-2	EP-24
EKK-1N	
EKK-1M	



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CEO