Declaration of Conformity

We, manufacturer

Monidor Oy
Elektroniikkatie 3
90590 Oulu
Finland

certify under our sole responsibility that the

Monidor Vitals has been classified as
Class IIb, (rule 10 and 11) according to Regulation (EU) 2017/745 of the European Parliament and of the Council, Annex VIII

Conformity assessment procedure: Annex IX (Regulation (EU) 2017/745 of the European Parliament and of the Council)

EMDN code: Z12030692

Basic UDI-DI: 643006695V01773

UDI-DI: 06430066950171

EC certificate number: FI24/00000050 Issue 3

SRN number: FI-MF-000007941

and is in conformity with the applicable provisions of Regulation 2017/745 of the European Parliament and of the Council

and with the following standards:

- EN 82304-1:2017. Health Software - Part 1: General requirements for product safety.
- EN 62366-1:2015/AC:2018+A1:2020. Medical devices - Application of usability engineering to medical devices
- EN 62304:2006+A1:2015 Medical device software - Software life-cycle processes
- EN-ISO 14971;2019+A11;2021. Medical devices - Application of risk management to medical devices
- EN-ISO 13485:2016+A11:2021. Medical devices. Quality management systems. Requirements for regulatory purposes.
- EN-ISO 15223-1:2021. Medical devices - Symbols to be used with information to be supplied by the manufacturer.
- EN 60601-1-8:2007+A1+A11+A2;2021. Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

The Notified body is: **SGS Fimko Ltd**

- Its Notified Body number: **0598** and
- address: Takomotie 8, 00380 Helsinki, Finland

Oulu, 20-Jan-2025

Place and Date of Issue

On behalf of Monidor Oy

PUURUNEN
VELI-MATTI
141527189

Digitaalinen allekirjoittaja:
PUURUNEN VELI-MATTI
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Päiväys: 2025.01.20 15:30:21
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Signature

Veli-Matti Puurunen
Name

Project Manager, CTO
Title