Declaration of Conformity

We, manufacturer

Monidor Oy
Elektroniikkatie 3
90590 Oulu
Finland

certify under our sole responsibility that the

IV Screen® infusion remote monitoring software (Product Number 004, Version 1.8.x) has been classified as
Class IIa, (rule 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)

GMDN code: 64513

Basic UDI-DI: 643006695V0046S

UDI-DI: 06430066950041

EC certificate number:

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 60601-1:2006+A1:2013+A12:2014+A2:2021/AC:2023. Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
- EN 62366-1: 2015/AC:2018+A1:2020. Medical devices - Application of usability engineering to medical devices
- EN 60601-1-11:2015+A1:2021 General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- 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.

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

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

Oulu, 29-Oct-2024
Place and Date of Issue

On behalf of Monidor Oy

PUOLITAIVAL KALERVO 12327518V

Digitaalinen allekirjoittaja:
PUOLITAIVAL KALERVO 12327518V
Päiväys: 2024.10.29 16:53:04 +02'00'

Signature

Seppo Puolitaival
Name

Quality Manager
Title