evondos®

FI-MF-000007647

Declaration of Conformity

We, Evondos Oy, declare the conformity of product:

Vitacam V2

Software version: 2.1

Basic UDI-DI: 0642981028VITACAMNY

EMDN: Z12030292

Certificate number:

FI26/00000033

With:

Regulation (EU) 2017/745

The product is classified as a

Class IIa medical device

according to Rule 11 from Annex VIII of the Regulation (EU) 2017/745

The conformity assessment procedure applied to the device is in accordance with Article 52 of Regulation (EU) 2017/745, using Annex IX, Chapters I and III (Conformity Assessment based on a Quality Management System and Assessment of Technical Documentation), with the involvement of Notified Body 0598, SGS Fimko Ltd.

Vitacam is intended for non-invasive spot measurement of respiratory rate, pulse, pulse rate analysis and variability, and oxygen saturation.

This declaration of conformity is issued under the sole responsibility of the manufacturer: Evondos Oy, Salorankatu 5-7, 24240 Salo, Finland
The Notified body is: SGS Fimko Ltd - Its Notified Body number: 0598 and - address: Takomotie 8, 00380 Helsinki, Finland

Standards applied:
EN ISO 13485:2016+A11:2021: Medical devices --Quality management systems --Requirements for regulatory purposes
EN ISO 14971:2019 +A11:2021: Medical devices. Application of risk management to medical devices
EN IEC 62304:2006+A1:2015: Medical device software –software life cycle processes
EN IEC 62366-1:2015+A1:2020: Medical devices –Part 1: Application of usability engineering to medical devices
EN ISO 14155:2020: Clinical investigation of medical devices for human subjects. Good clinical practice:
EN ISO 15223-1:2025+A1:2025: Symbols to be used with medical device labels, labelling and information to be supplied

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Ville Haavisto, Quality & Regulatory Affairs Director