

EU Quality Management System Certificate FI26/00000033

The quality management system of

Evondos Oy

Evondos Oy, Salorankatu 5-7, FI-24240 Salo, Finland SRN: FI-MF-000007647

has been assessed and certified as meeting the requirements of
Regulation (EU) 2017/745 Annex IX (I and III)

for the following:

Software for measuring vital signs

Issue 1

Previous certificate's number and issue: N/A, initial certification.

Change in between this certificate and the previous one: N/A

The devices covered, their risk classifications, codes applied, identification details, intended purposes, standards and common specifications followed, conditions or limitations, as well as applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 18 August 2026 until 17 August 2029 and remains valid subject to satisfactory surveillance audits.

Certified since 18 August 2026.

Certified activities performed by additional sites are listed on the subsequent pages.



Authorised by

Seppo Vahasalo, NB Manager

SGS FIMKO OY

Notified Body 0598 Takomotie 8, FI-00380 Helsinki, Finland

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Regulation (EU) 2017/745 Annex IX (I and III)

Issue 1
Sites
Salorankatu 5-7, FI-24240 Salo, Finland
Software for measuring vital signs
Elektroniikkatie 8, FI-90590 Oulu, Finland
Design, development, testing and manufacturing software for measuring vital signs

Regulation (EU) 2017/745 Annex IX (I and III)

Attachment 1 of Issue 1
Risk classes, codes, identification, and other relevant details of the certified devices: Risk class IIa MDA 0315, MDS 1009, MDS 1010, MDT 2011 EMDN Z12030292: Vital signs monitoring instruments - medical device software Vitamcam V2, Basic UDI-DI 0642981028VITACAMNY, software version 2.1*
The certification decision is based on the following: Report Identification and Date: Audit report: FIMED297122-Evondos Oy-2026-FPMDREG3019 - MD Audit Report Ver I_Rev1_2026-08-03_signed Technical documentation assessment report: FIMED297122_Evondos Oy_FPMDREG3020 – MDR TDA Report Ver J_rev0_2026-07-14sent Applied Standards / Common specifications: EN ISO 13485:2016 + A11/2021, EN ISO 14971:2019 + A11/2021, EN ISO 15223-1:2021 + A1/2025, references to other relevant CS and harmonized standards are in the reports Conditions for or limitation to the validity of the certificate: *The certification is based on the software version indicated here. Non-significant updates to the software need to be implicated in the software version identifier. A PMCF investigation is to be planned and conducted on SpO2 measurements in unhealthy and elderly subjects EU Authorised Representative: N/A, the manufacturer is in the EU.