

EU Certificate

Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapters I and III

Registration No.: HZ 2416341-1

Manufacturer: Shen.AI OÜ
Lõõtsa tn 8a
11415 Tallinn
Estonia

EUDAMED Single
Registration No.: EE-MF-000050105

Products: Products of class IIa:
Z12030292 – VITAL SIGNS MONITORING INSTRUMENTS –
MEDICAL DEVICE SOFTWARE

Authorized representative(s): Not applicable

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2026-07-30

The Notified Body hereby declares that the requirements of Annex IX, Chapter I of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

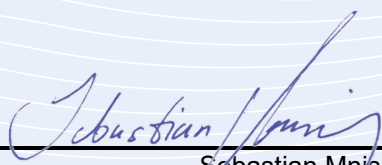
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 84987538-50

Effective date: 2026-07-30

Expiry date: 2031-07-29

Issue date: 2026-07-30


Sebastian Mnjszek
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>

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