EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III

Certificate No. MDR-0045

Issued to:	INNOVATION TECHNOLOGIES d.o.o. Drožanje 20, 8290 Sevnica Slovenia
SRN of the manufacturer:	SI-MF-000041369
EU authorised representative:	Not applicable
SRN of EU authorised representative:	Not applicable

SIQ has audited the quality management system in accordance with MDR Annex IX and found that the above-mentioned Manufacturer's quality management system meets the requirements of the Regulation (EU) 2017/745 concerning medical devices Annex IX. Devices covered by the Manufacturer's quality management system are listed on the page(s) below.
This certificate is based on

Audit reports No.:

OSV 00572/2025, 2025-05-16
OSV 00541/2025, 2025-05-07
OSV 00005/2026, 2026-01-16
OSV 00488/2026, 2026-04-22
OSV 00516/2026, 2026-04-28
OSV 00782A/2026, 2026-06-30

See also decision of NB`s commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality management system is subject to periodical surveillance as referred to in Regulation (EU) 2017/745 concerning medical devices Annex IX and continues to meet the above requirements.

Reference to any previous certificate: /

Certification date:	2026-06-30
Issue:	01/ 2026-06-30
Valid until:	2031-06-29

SIQ Ljubljana
Mašera-Spasićeva ulica 10
1000 Ljubljana
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Managing Director of SIQ
Gregor Schoss

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EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III

Certificate No. MDR-0045

Device:	ELECTROCARDIOGRAPHS – MEDICAL DEVICE SOFTWARE
EMDN:	Z12050392
Intended purpose:	/
Classification:	IIa
Specific conditions for or provisions or limitations to the validity of certificate:	/

Certification date:	2026-06-30
Issue:	01/ 2026-06-30
Valid until:	2031-06-29

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