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vaš znak / your ref.:

OSV/6425

naš znak / our ref.:

2026-06-30

datum / date:

Mr. Marjan Gušev
INNOVATION TECHNOLOGIES d.o.o.
Drožanje 20, 8290 Sevnica
Slovenia

Dear Mr. Marjan Gušev,

we would like to inform you that the Notified Body Commission for medical devices adopted the following decision at its last meeting:

On the basis of certification audit report (OSV 00572/2025, 2025-05-16), technical documentation audit report (OSV 00541/2025, 2025-05-07) and technical documentation post audit report (OSV 00005/2026, 2026-01-16), certification audit report (OSV 00488/2026, 2026-04-22), second technical documentation audit report (OSV 00516/2026, 2026-04-28) and third technical documentation post audit report (OSV 00782A/2026, 2026-06-30) a decision on granting the EU certificate, Detailed list of product names, models and types, Detailed list of relevant common specifications and standards was adopted:

EU certificate No.: **MDR-0045**

Issued to:	INNOVATION TECHNOLOGIES d.o.o. Drožanje 20, 8290 Sevnica Slovenia
SRN of manufacturer:	SI-MF-000041369
Authorised representative:	Not applicable
SRN of authorised representative:	Not applicable
Device:	ELECTROCARDIOGRAPHS – MEDICAL DEVICE SOFTWARE
EMDN:	Z12050392
Intended purpose:	/
Classification:	Ila

Legislative
act/requirements: Regulation (EU) 2017/745
Annex: IX

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

Specific conditions or provisions or limitations and validity of certificate: /

Identification Number of the Notified Body (1304) can be used in conjunction with EU certificate. Details of affixing CE marking are given in Article 20 of Regulation (EU) 2017/745 on medical devices.

The EU certificate (A4 paper format) is granted in English. EU certificate is enclosed in attachment. Also form for possible additional order of certificate is enclosed.

Detailed list of product names, models and types:

EU certificate No.: **MDR-0045**

Issued to: INNOVATION TECHNOLOGIES d.o.o.
Drožanje 20, 8290 Sevnica
Slovenia

SRN of manufacturer: SI-MF-000041369

Place of production: INNOVATION TECHNOLOGIES d.o.o.
Drožanje 20, 8290 Sevnica, Slovenia

Place of production: INNOVATION DOOEL
Vostanichka 118/1, 1000 Skopje, North Macedonia and
11 Oktomvri 25/717, 1000 Skopje, North Macedonia

Authorised representative: Not applicable

SRN of authorised representative: Not applicable

Device: ELECTROCARDIOGRAPHS – MEDICAL DEVICE SOFTWARE

EMDN: Z12050392

Intended Purpose: ViewECG is intended to continually receive, store, process, and display single-channel electrocardiogram signals for real-time remote cardiac telemetry by healthcare professionals or health conscious individuals. It detects and classifies beats, runs, rates, and rhythm episodes. The cloud-based platform is intended for patients 18 or older with known or suspected low risk heart conditions. These patients need or desire long-term 24/7 heart monitoring. Patients at elevated risk of serious cardiovascular events that would require prompt intervention are excluded from use. A healthcare professional can prescribe ViewECG to enable monitoring and reporting tools for arrhythmia detections and classifications. The healthcare professional then renders a diagnosis based on clinical judgment and experience. Individuals can also use it over the counter to preview a dashboard of automatic arrhythmia detections monitoring their measurements.

Classification: IIa

Basic UDI-DI: 3830085990001Z8

MDR code: MDA 0315

Device name: ViewECG

Model/Type: V 1.2.0

Legislative act/requirements: Regulation (EU) 2017/745

Annex: IX

Date of issuing the list: 2026-06-30

Valid until: 2031-06-29

Detailed list of relevant common specifications and standards:

EU certificate No.: **MDR-0045**
Issued to: INNOVATION TECHNOLOGIES d.o.o.
Drožanje 20, 8290 Sevnica
Slovenia
SRN of manufacturer: SI-MF-000041369
Authorised representative: Not applicable
SRN of authorised representative: Not applicable
List of relevant common specifications and standards: EN ISO 13485:2016 + A11:2021
EN ISO 14971:2019 + A11:2021
EN ISO 15223-1:2021 + A1:2025
EN 60601-1-6:2010 + A1:2015 + A2:2021
EN 60601-2-47:2015
EN 62304:2006 + A1:2015
EN 62366-1:2015
IEC 81001-5-1:2021
IEC/TR 80002-1:2009
ISO/TR 80002-2:2017
Device: ELECTROCARDIOGRAPHS – MEDICAL DEVICE SOFTWARE
EMDN: Z12050392
Intended Purpose: /
Classification: IIa

Legislative act/requirements: Regulation (EU) 2017/745
Annex: IX
Date of issuing the list: 2026-06-30
Valid until: 2031-06-29

For all further information we are available on telephone number 00 386 1 4778 159 and email: mdr@siq.si

Management Systems Assessment
MDR Product Manager
Ana Pribaković Borštnik

