



Notified Body No. 1023
INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a.s.
trida Tomase Bati 299, Louky, 763 02 Zlín, Czech Republic

EU Quality Management System Certificate No. 24 0263 QR/NB

Quality management system of the company

KARDI AI Technologies s.r.o.

28. října 459/11, Olomouc, 779 00, Czech Republic

SRN: CZ-MF-000026438

is certified in accordance with the requirements of

**REGULATION (EU) 2017/745 OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL**

on medical devices, Annex IX, Chapters I and III

for the following device-range:

ECG telemetric monitoring system

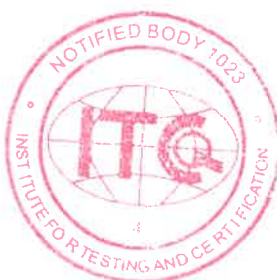
Notified Body No. 1023 declares that it has assessed the quality management system of the above manufacturer in accordance with Annex IX, Chapters I and III of Regulation (EU) 2017/745. The quality management system put in place by the manufacturer for the design, manufacture and final inspection of the products concerned complies with the requirements of Regulation (EU) 2017/745 and is subject to regular surveillance audits. A detailed description of the system elements, requirements and measures adopted by the manufacturer is provided in the final report No. 803602911/2024, which is issued together with the present certificate.

Valid from: 2024-07-29

Valid until: 2029-07-28

Previous EU certificate No.: -

Previous EU certificate issue date: -



Date of issue: 2024-07-29

Mgr. Jiří Heš
Representative of Notified Body No. 1023



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Annex to EU Quality Management System Certificate No. 24 0263 QR/NB

issued to the manufacturer:

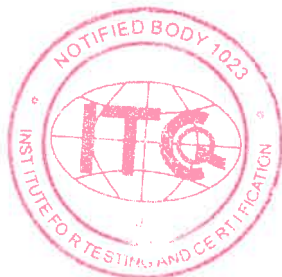
KARDI AI Technologies s.r.o.
28. října 459/11, Olomouc, 779 00, Czech Republic

Manufacturer details:

Manufacturer's company name: KARDI AI Technologies s.r.o.
Single registration number (SRN): CZ-MF-000026438
Registered office address: 28. října 459/11, Olomouc, 779 00
Production site address: Sokolská 789/1, Olomouc, 779 00

Details of the authorised representative (if required):

Name of the EU authorised representative: -
Address of the EU authorised representative: -



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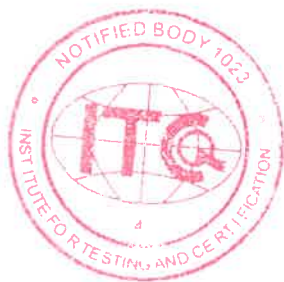
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No. 24 0263 QR/NB
issued to the manufacturer:

KARDI AI Technologies s.r.o.
28. října 459/11, Olomouc, 779 00, Czech Republic

Product(s):

Product name:	Kardi Ai
Trade mark(s):	Kardi Ai
Model(s):	version 2.0
Class:	Ila



Date of issue: 2024-07-29


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