



EC Certificate – Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
Certificate No. MDD-037

Issued to: MESI, razvoj medicinskih naprav, d.o.o.
Leskoškova cesta 11A, 1000 Ljubljana, Slovenia
Place of production: MESI, razvoj medicinskih naprav, d.o.o.
Leskoškova cesta 11A, 1000 Ljubljana, Slovenia
Product category: Noninvasive ankle brachial pressure index measurement unit
GMDN: 58928

SIQ has audited the quality system in accordance with MDD Annex II excluding (4) and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex II. This certificate is based on

Audit report No.:

OSV 00400/2020, 2020-05-27
OSV 00885/2020, 2020-07-30
OSV 00468/2021, 2021-04-21

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

This certificate remains valid as long as the Manufacturer's quality system is subject to periodical surveillance as referred to in Directive 93/42/EEC concerning medical devices Annex II (5) and continues to meet the above requirements.

Certification date: 2012-05-09

Issue: 9/2021-05-12

Valid until: 2024-05-26



Managing Director of SIQ

 Igor Likar