EC Certificate – Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Certificate No. MDD-081

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:	Multiparameter physiologic analysis workstation
GMDN:	64338
Product category:	Wireless multichannel electrocardiograph
GMDN:	16231
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 00362/2019, 2019-04-30
OSV 00699/2019, 2019-06-28
OSV 00911/2019, 2019-08-27
OSV 00912/2019, 2019-08-27
OSV 01016/2019, 2019-09-20

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: 2017-10-02

Issue: 02/2019-09-23

Valid until: 2024-05-27

SIQ Ljubljana
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