



EC Certificate – Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
Certificate No. MDD-069

Issued to: Saving d.o.o.
Finžgarjeva 4, 1000 Ljubljana, Slovenia

Place of production: L-tek d.o.o.
Obrtna cesta 18, 8310 Šentjernej, Slovenia

Product category: Electrocardiography telemetric monitoring transmitter – reusable
UMDSN: 36367

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 00661/2016, 2016-06-30
OSV 00637/2016, 2016-06-30
OSV 00901/2016, 2016-09-30
OSV 00935/2016, 2016-10-28
OSV 00998/2016, 2016-10-28

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: 2016-11-10

Issue : 1/2016-11-10

Valid until: 2019-11-30



Director of SIQ

Igor Likar