EC Certificate – Full Quality Assurance System

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

Certificate No. MDD-091

Issued to:	Extreme d.o.o. Boletova 51, 1000 Ljubljana, Slovenia
Place of production:	Extreme d.o.o. Plemljeva 8, 1000 Ljubljana, Slovenia
Product category:	Medical therapeutical laser system
GMDN:	16947

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 00802/2017, 2017-07-31
OSV 00879/2017, 2017-08-31
OSV 00949/2017, 2017-10-24
OSV 01257/2017, 2017-12-29
OSV 01301/2017, 2017-12-29
OSV 00170/2018, 2018-03-16
OSV 00196/2018, 2018-03-16

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: 2018-03-20

Issue: 1/2018-03-20

Valid until: 2021-03-20

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