EC Certificate – Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
Certificate No. MDD-083

Issued to:	Heltschl GmbH Niederndorf 27, 4707 Schlüßlberg Austria
Place of production:	Heltschl GmbH Niederndorf 27, 4707 Schlüßlberg Austria
Product category:	Laser - therapeutic
GMDN:	60410 (General therapeutic low-intensity laser, battery powered)
Product category:	Laser delivery systems
UMDNS:	17-807 (Laser delivery systems, Fiberoptic)
Product category:	Laser - therapeutic
GMDN:	60409 (General therapeutic low-intensity laser, line-powered)

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 00252/2018, 2018-03-30
OSV 00468/2018, 2018-05-10
OSV 00649/2018, 2018-06-29
OSV 01055/2018, 2018-10-05
OSV 01432/2019, 2019-12-11
OSV 00492/2019, 2019-05-31
OSV 00095/2020, 2020-03-16
OSV 01247/2020, 2020-10-27

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: 2017-12-20

Issue: 3/2020-11-17

Valid until: 2024-05-27

SIQ Ljubljana
Mašera-Spasićeva ulica 10
1000 Ljubljana

Managing Director of SIQ
Igor Likar