EC Certificate – Full Quality Assurance System

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

Certificate No. MDD-194

Issued to:	REPULS Lichtmedizintechnik GmbH, Lemböckgasse 61/Top 1, 1230 Wien Austria
Place of production:	SVI Austria GmbH, Frauentaler Str. 1000, A-8530 Deutschlandsberg; Austria
Place of production:	Sementis Engineering GmbH, Resselstrasse 16, 2120 Wolkersdorf, Austria
Product category:	Electronic therapy device
UMDNS/GMDN:	11-503/45688
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UMDNS/GMDN:	11-503/45688

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 00532/2018, 2018-05-31
OSV 00012A/2019, 2019-02-28
OSV 00229A/2019, 2019-03-22
OSV 00273/2019, 2019-05-27
OSV 01555/2019, 2020-01-09
OSV 00329/2020, 2020-04-06
OSV 00175/2021, 2021-03-03
OSV 00260/2021, 2021-03-12
OSV 00644/2021, 2021-05-24

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: 2021-05-24

Issue: 1/2021-05-24

Valid until: 2024-05-26

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