EC Certificate – Full Quality Assurance System

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

Certificate No. MDD-098

Issued to:	SGM d.o.o., Grge Novaka 22A, 21000 Split, Croatia
Place of production:	SGM d.o.o., Grge Novaka 22A, 21000 Split, Croatia
Product category:	Evoked response stimulators
GMDN:	/
Product category:	Evoked response stimulators
GMDN:	/

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 00375/2016, 2016-05-16
OSV 00755/2016, 2016-09-26
OSV 00182A/2017, 2017-05-16
OSV 00183/2017, 2017-03-30
OSV 00876A/2017, 2017-10-20
OSV 01042/2017, 2017-10-27
OSV 00544/2017, 2017-12-19
OSV 00285/2018, 2018-06-29
OSV 00286/2018, 2018-06-29

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: 2018-07-13

Issue: 1/2018-07-13

Valid until: 2021-07-13

SIQ Ljubljana
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