

EC Certificate - Full Quality Assurance System Directive 93/42/EEC on Medical Devices, Annex II excluding (4) Certificate No. MDD-153

Issued to: SGM d.o.o..

Grge Novaka 22A, 21000 Split, Croatia

Place of production: SGM d.o.o.,

Vlahe Bukovca bb, 21460 Stari Grad, Croatia

Product category: Disposable sterile neurological electrodes

GMDN: 47714

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 00968/2019, 2019-11-22 OSV 01032/2019, 2019-12-11

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: 2019-12-19

Issue: 1/2019-12-19

Valid until: 2024-05-27

Director of SIQ

Igor Likar