EC-Certificate

(Production quality assurance system)
according to annex V of Medical Devices Directive 93/42/EEC

It is herewith confirmed by

BSI Group Deutschland GmbH
Eastgate, Hanauer Landstrasse 115
60314 Frankfurt am Main
Germany

in its function as Notified Body (0535), that the manufacturer:

Neurosoft Ltd.
5, Voronin str.,
Ivanovo, 153032, Russia

concerning the medical device

Magnetic stimulator

(products/variants specified in appendix)

fulfils the requirements according to Annex V of the Medical Devices Directive 93/42/EEC. The manufacturer has established a quality assurance system for the production and final inspection of the specified devices.
For the placing on the market of class III products an Annex III certificate is required.

The appendix is part of this certificate and contains 1 page.

Report No.: SMO7864399
Certificate No.: CE 577342

Certificate

Notified by
Zentralstelle der Länder
für Sicherheitstechnik
ZLS-NB-67/12

First Issue Date:
October 05, 2010.

Based on periodical surveillance
this certificate is valid until
November 18, 2018.

Current Issue Date: November 19, 2013

Certification Body

bsi. Certification and Testing · BSI Group Deutschland GmbH ·

Appendix of EC-Certificate

(Production quality assurance system)
according to annex V of Medical Devices Directive 93/42/EEC
Certificate No.: CE 577342

Medical devices of the manufacturer:

Neurosoft Ltd.
5, Voronin str.,
Ivanovo, 153032, Russia

Name of product	Variant	Item	UMDNS	Class
Magnetic stimulator "Neuro-MS"			12-415	IIa
Magnetic stimulator "Evidence 9000ms"			12-415	IIa
Magnetic stimulator "Neuro-MS/D"			12-415	IIa
Magnetic stimulator "Evidence 9100ms"			12-415	IIa

Notified by
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ZLS-NB-67/12

Frankfurt am Main, November 19, 2013

Certification Body