

Certificate

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 devices
Digital Neurophysiological Systems
(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 577347

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

First Issue Date:
November 08, 2009.

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

Current Issue Date: November 28, 2013


Certification Body

Appendix of EC-Certificate

(Production quality assurance system)

according to Annex V of Medical Devices Directive 93/42/EEC

Certificate No.: CE 577347

Medical devices of the manufacturer:



Neurosoft Ltd.

5, Voronin Str.,

Ivanovo, 153032, Russia

Name of product	Variant	Item spec.	UMDNS	Class
Digital neurophysiological system for EP and ERG "Neuro-ERG"	_____	_____	11-474	IIa
2-channel digital neurophysiological system for EMG and EP with a build-in miniature dedicated keyboard "Evidence 3002evo"	_____	_____	11-474	IIa
Digital neurophysiological system for EMG and SSEP "Neuro-EMG-Micro"	_____	_____	11-467	IIa
Digital neurophysiological system for EMG and SSEP "Evidence 1002"	_____	_____	11-467	IIa
Digital neurophysiological system for EMG and SSEP "BITMED EMGMicro"	_____	_____	11-467	IIa
2-channel digital neurophysiological system for EMG "Neuro-EMG-MS"	_____	_____	11-467	IIa



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Frankfurt am Main, November 28, 2013


Wilfried Babelobsky
 Certification Body