

Certificate

EC-Certificate

(full quality assurance system)
according to Annex II (excluding section 4) 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 II (excluding section 4) of the Medical Devices Directive 93/42/EEC. The manufacturer has established a quality assurance system for the design, production and final inspection of the specified devices.

For the placing on the market of class III products an additional Annex II section 4 certificate is required.

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

Report No.: SMO7864399

Certificate No.: CE 611073

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

First Issue Date:
March 04, 2011.

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

Current Issue Date: February 03, 2014


Certification Body



Appendix of EC-Certificate

(full quality assurance system)

according to Annex II (excluding section 4) of Medical Devices Directive 93/42/EEC

Certificate No.: CE 611073

Medical devices of the manufacturer:

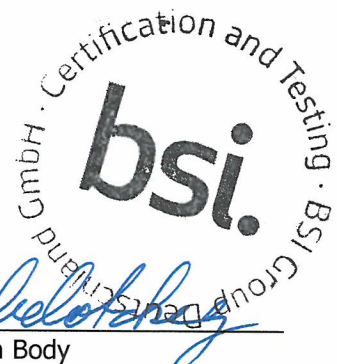


Neurosoft Ltd.

5, Voronin str.,
Ivanovo, 153032, Russia

Name of product	Variant	Item spec.	UMDNS	Class
Digital neurophysiological system for EEG, EP and EMG "Neuron-Spectrum-4/EPM"	_____	_____	11-467	I Ib
Digital neurophysiological system for EEG, EP and EMG "Neuron-Spectrum-4/EPM/S"	_____	_____	11-467	I Ib
Digital neurophysiological system for EEG, EP and EMG "Neuron-Spectrum-5"	_____	_____	11-467	I Ib
Digital neurophysiological system for EEG, EP and EMG "Neuron-Spectrum-5/S"	_____	_____	11-467	I Ib
Digital neurophysiological system for EEG, EP and EMG "Evidence EEG29 prof."	_____	_____	11-467	I Ib
Digital neurophysiological system for EEG, EP and EMG "Evidence EEG40 prof."	_____	_____	11-467	I Ib

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Frankfurt am Main, February 03, 2014.