

# 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 and  
Transcranial Electrical Stimulator  
(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.: CE577332**



First Issue Date:  
March 04, 2011.

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

Current Issue Date: October 29, 2014

*E. Schröder*  
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.: CE577332**

Medical devices of the manufacturer:



# Neurosoft

### Neurosoft Ltd.

5, Voronin str.,  
Ivanovo, 153032, Russia

Name of product	Variant	Item	UMDNS	Class
Digital neurophysiological system for EMG and EP with a built-in dedicated keyboard "Neuro-MEP-5"	_____	_____	11-474	IIb
Digital neurophysiological system for EMG and EP with a built-in dedicated keyboard "Neuro-MEP-5/2"	_____	_____	11-474	IIb
Digital neurophysiological system for EMG and EP with a built-in dedicated keyboard "Evidence 5002evo"	_____	_____	11-474	IIb
Digital neurophysiological system for EMG and EP with a built-in dedicated keyboard "Evidence 5005evo"	_____	_____	11-474	IIb
Digital neurophysiological system for EMG, EP, ERG and OAE "Neuro-MEP"	_____	_____	11-474	IIb
Digital neurophysiological system for EMG, EP, ERG and OAE "Evidence 4004evo"	_____	_____	11-474	IIb
Digital neurophysiological system for EMG, EP, ERG and OAE "BITMED MEP4"	_____	_____	11-474	IIb
Digital neurophysiological system for EMG, EP, ERG and OAE "BITMED MEP8"	_____	_____	11-474	IIb
Transcranial electrical stimulator "Neuro-TES"	_____	_____	16-263	IIb
2-channel digital neurophysiological system for EMG and EP with a build-in miniature dedicated keyboard "Neuro-MEP-Micro"	_____	_____	11-474	IIb
2-channel digital neurophysiological system for EMG and EP with a build-in miniature dedicated keyboard "Evidence 3102evo"	_____	_____	11-474	IIb
2-channel digital neurophysiological system for EMG and EP with a build-in miniature dedicated keyboard "BITMED MEPMicro"	_____	_____	11-474	IIb
System for Intraoperative Monitoring "Neuro-IOM"	_____	_____	11-474	IIb
System for Intraoperative Monitoring "Neuro-IOM/F"	_____	_____	11-474	II



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Frankfurt am Main, October 29, 2014.

*E. Schweden*

Certification Body