



# Certificate



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
**ZLG-BS-248.10.04**

First Issue Date:  
November 08, 2009.

With an annual surveillance  
the regular certification cycle would be  
19.11.2013 until 18.11.2018.  
Due to the closure of Notified Body NB0535  
the certificate is valid until 30 June 2016.

## 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

### Neurosoft Ltd.

5, Voronin Str.,  
Ivanovo, 153032, Russia

concerning the medical devices  
neurophysiological and hearing screening systems  
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.: SMO8189436  
**Certificate No.: CE 577345**

Current Issue Date: May 30, 2016



*E. Schweder*

Certification Body

## Appendix of EC-Certificate

(Production quality assurance system)

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

**Certificate No.: CE 577345**

Medical devices of the manufacturer:



# Neurosoft

### Neurosoft Ltd.

5, Voronin Str.,  
Ivanovo, 153032, Russia

Name of product	Variant	Item spec.	UMDNS	Class
Portable hearing screening device for ABR and OAE "Neuro-Audio-Screen"	_____	_____	17-601	IIa
Portable hearing screening device for OAE "Neuro-Audio-Screen/OAE"	_____	_____	17-601	IIa
Portable hearing screening system for OAE "aScreen"	_____	_____	17-601	IIa
Portable system for OAE, ABR, impedance testing and hearing screening "Audio-SMART"	_____	_____	17-601	IIa
Digital neurophysiological system for EP and OAE "Neuro-Audio"	_____	_____	11-474	IIa
Digital neurophysiological system for OAE "Neuro-Audio/OAE"	_____	_____	11-474	IIa
Digital neurophysiological system for EP "Neuro-Audio/ABR"	_____	_____	11-474	IIa



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Frankfurt am Main, May 30, 2016

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