

# 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  
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 577345**



**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 19, 2013

*Wilfried Baldoritz*  
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
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

# ZLS

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Zentralstelle der Länder  
für Sicherheitstechnik  
**ZLS-NB-67/12**

Frankfurt am Main, November 19, 2013

  
*Wilfried Babeloth*  
 Certification Body