



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



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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E. Schwandt

Certification Body

Frankfurt am Main, May 30, 2016