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 577343

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

Certification Body

BSI Group Deutschland GmbH · Certification and Testing

Appendix of EC-Certificate

(Production quality assurance system)
according to Annex V of Medical Devices Directive 93/42/EEC
Certificate No.: CE 577343

Medical devices of the manufacturer:

Neurosoft Ltd.
5, Voronin Str.,
Ivanovo, 153032, Russia

Name of product	Variant	Item spec.	UMDNS	Class
Digital ECG system "Poly-Spectrum-8"	_____	_____	11-411	IIa
Digital ECG system with measurement and interpretation "Poly-Spectrum-8/E"	_____	_____	11-411	IIa
Digital ECG system for heart rate variability analysis (vegetotester) "VNS-Rhythm"	_____	_____	11-411	IIa
Digital ECG system for heart rate and breath rate variability analysis (vegetotester) "VNS-Micro"	_____	_____	11-411	IIa

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Frankfurt am Main, November 19, 2013

Certification Body