



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:

Certificate



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.

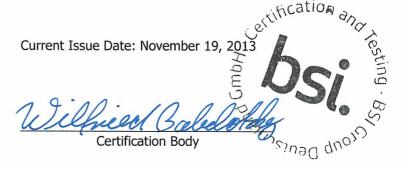
The appendix is part of this certificate and contains 1 page.

Report No.: SMO7864399
Certificate No.: CE 577343

ZLS-NB-67/12

First Issue Date: November 08, 2009.

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







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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Certification Body