DECLARATION OF CONFORMITY

Manufacturer:

Neurosoft Ltd
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Notified body:

BSI Group Deutschland GmbH
Eastgate, Hanauer Landstrasse 115
60314 Frankfurt am Main, Germany
Identification number: 0535

European Representative:

SAS Neuromed
Chemin du tomple
84330 Le Barroux, France

Medical device(s):

1. Digital ECG system "Poly-Spectrum-8"
2. Digital ECG system with measurement and interpretation "Poly-Spectrum-8/E"
3. Digital ECG system for heart rate variability analysis (vegetotester) "VNS-Rhythm"
4. Digital ECG system for heart rate and breath rate variability analysis (vegetotester) "VNS-Micro"

We herewith declare that the above-mentioned products meet the provisions of the Council Directives 93/42/EEC (MD) and 2011/65/EU (RoHS). All supporting documentation is retained under the premises of the manufacturer.

Device Classification:

Class IIa (Rule 10), non-invasive, active device

Standards Applied:

IEC 60601-1:1988+A1:1991+A2:1995
IEC 60601-1-1:2000
IEC 60601-1-2:2007
IEC 60601-2-25:1993+A1:1999

Decision according to Annex V, Section 3 of Council Directive 93/42/EEC concerning medical devices.

Certificate Number(s):

CE577343

Start of CE-Marking:

March 2006

Place and Date:

Neurosoft Ltd, Ivanovo, Russia
November 19, 2013

Signature:

Aleksey Borisovich Shubin
President of Neurosoft Ltd