

 Neurosoft	DECLARATION OF CONFORMITY	002
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Identification number: 2797

European Representative: SAS Neuromed
Chemin du temple
84330 Le Barroux, France

Design, development and manufacture of digital neurophysiological systems, digital systems for monitoring of physiological parameters, transcranial electrical stimulators and magnetic stimulators with accessories (See attachment).

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: EN 60601-1:2006/A1:2013
EN 60601-1-2:2015
EN 60601-2-25:2015 (for items 5 – 8)
EN 60601-2-26:2015 (for items 9 – 17)
EN 60601-2-40:2017 (for items 9 – 23)
EN 60645-1:2015 (for items 1 – 4)
EN 60645-3:2007 (for items 1 – 4)
EN 60645-6:2010 (for items 1 – 4)
EN 60645-7:2010 (for items 1 – 4)
EN ISO 8253-1:2010 (for items 1 – 4)
EN ISO 80601-2-61:2011 (for items 9 – 17)

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

Certificate Number(s): CE 577332

Valid until: November 18, 2023

Place and Date: Neurosoft LLC, Ivanovo, Russia
February 6, 2019

Signature:



Aleksey Borisovich Shubin
President of Neurosoft LLC

**Annex to Declaration of Conformity №002 from February 6, 2019****Medical device(s):**

1. Digital system for Auditory EP, OAE and Screening PTA "Neuro-Audio"
2. Digital system for OAE "Neuro-Audio/OAE"
3. Digital system for Auditory EP "Neuro-Audio/ABR"
4. Digital system for Screening PTA "Neuro-Audio/PTA"
5. Digital ECG system "Poly-Spectrum-8"
6. Digital ECG system with measurement and interpretation "Poly-Spectrum-8/E"
7. Digital ECG system for heart rate variability analysis (vegetotester) "VNS-Rhythm"
8. Digital ECG system for heart rate and breath rate variability analysis (vegetotester) "VNS-Micro"
9. Digital neurophysiological system for EEG and EP "Neuron-Spectrum-1"
10. Digital neurophysiological system for EEG and EP "Neuron-Spectrum-2"
11. Digital neurophysiological system for EEG and EP "Neuron-Spectrum-3"
12. Digital neurophysiological system for EEG and EP "Neuron-Spectrum-4"
13. Digital neurophysiological system for EEG and EP "Neuron-Spectrum-4/P"
14. System for ambulatory EEG and PSG monitoring "Neuron-Spectrum-AM"
15. Digital neurophysiological system for EEG and EP "Evidence EEG23"
16. Digital neurophysiological system for EEG and EP "Evidence EEG23 evo"
17. Digital neurophysiological system for EEG and EP "Evidence EEG28 evo "
18. Digital neurophysiological system for EP and ERG "Neuro-ERG"
19. 2-channel digital neurophysiological system for EMG and EP with a built-in miniature dedicated keyboard "Evidence 3002evo"
20. Digital neurophysiological system for EMG and SSEP "Neuro-EMG-Micro"
21. Digital neurophysiological system for EMG and SSEP "Evidence 1002"
22. Digital neurophysiological system for EMG and SSEP "BITMED EMGMicro"
23. 2-channel digital neurophysiological system for EMG "Neuro-EMG-MS"