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Design, development and manufacture of digital neurophysiological systems, digital systems for monitoring of physiological parameters, transcranial electrical stimulators, magnetic stimulators with accessories and active rehabilitation devices (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 IIb (Rule 10), non-invasive, active device

Standards Applied: EN 60601-1:2006/A1:2013
EN 60601-1-2:2015
EN 60601-2-40:2019
EN 60601-2-26:2015 (for items 1 – 6, 16 – 25)
EN ISO 80601-2-61:2011 (for items 2, 4, 16 – 25)

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 13, 2020

Signature:



Aleksey Borisovich Shubin
President of Neurosoft LLC



Annex to Declaration of Conformity №006 from February 13, 2020

Medical device(s):

1. Digital neurophysiological system for EEG, EP and EMG "Neuron-Spectrum-4/EPM"
2. Digital neurophysiological system for EEG, EP and EMG "Neuron-Spectrum-4/EPM/S"
3. Digital neurophysiological system for EEG, EP and EMG "Neuron-Spectrum-5"
4. Digital neurophysiological system for EEG, EP and EMG "Neuron-Spectrum-5/S"
5. Digital neurophysiological system for EEG, EP and EMG "Evidence EEG29 proff."
6. Digital neurophysiological system for EEG, EP and EMG "Evidence EEG40 proff."
7. Digital neurophysiological system for EMG and EP with a built-in dedicated keyboard "Evidence 5005evo"
8. Digital neurophysiological system for EMG and EP with a built-in dedicated keyboard "Skybox"
9. Digital neurophysiological system for EMG, EP and ERG "Neuro-MEP"
10. Digital neurophysiological system for EMG, EP and ERG "Evidence 4004evo "
11. Digital neurophysiological system for EMG, EP and ERG "BITMED MEP4"
12. Digital neurophysiological system for EMG, EP and ERG "BITMED MEP8"
13. 2-channel digital neurophysiological system for EMG and EP with a built-in miniature dedicated keyboard "Neuro-MEP-Micro"
14. 2-channel digital neurophysiological system for EMG and EP with a built-in miniature dedicated keyboard "Evidence 3102evo"
15. 2-channel digital neurophysiological system for EMG and EP with a built-in miniature dedicated keyboard "BITMED MEPMicro"
16. Digital neurophysiological system for EEG, EP, Video EEG, CFM, PSG, biofeedback trainings "Neuron-Spectrum-61"
17. Digital neurophysiological system for EEG, EP, Video EEG, CFM, PSG, biofeedback trainings "Neuron-Spectrum-62"
18. Digital neurophysiological system for EEG, EP, Video EEG, CFM, PSG, biofeedback trainings "Neuron-Spectrum-63"
19. Digital neurophysiological system for EEG, EP, Video EEG, CFM, PSG, biofeedback trainings "Neuron-Spectrum-64"
20. Digital neurophysiological system for EEG, EP, Video EEG, CFM, PSG, biofeedback trainings "Neuron-Spectrum-65"
21. Digital neurophysiological system for EEG, EP, Video EEG, CFM, PSG, biofeedback trainings "Neuromonitor"
22. Digital neurophysiological system for EEG, EP, Video EEG, CFM, PSG, biofeedback trainings "Evidence EEG61"
23. Digital neurophysiological system for EEG, EP, Video EEG, CFM, PSG, biofeedback trainings "Evidence EEG63"
24. Digital neurophysiological system for EEG, EP, Video EEG, CFM, PSG, biofeedback trainings "Evidence EEG64"
25. Digital neurophysiological system for EEG, EP, Video EEG, CFM, PSG, biofeedback trainings "Evidence EEG65"
26. 3-channel EMG/NCS/EP System with a Built-in Keyboard "Litebox"
27. 3-channel EMG/NCS/EP System with a Built-in Keyboard "Evidence 3103evo"