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

Manufacture, final inspection and test of digital neurophysiological systems for electroencephalography (EEG), electromyography (EMG), study of evoked potentials (EP), polysomnography (PSG) and electroretinography (ERG), portable devices for electromyography (EMG) / electrostimulation (STIM)-guided injections "Neuro-Tox", magnetic stimulators and accessories, digital electrocardiography (ECG) systems, neurophysiological and hearing screening systems (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 (Rules 9 and 10), non-invasive, active device (items 1 – 24)
Class IIa (Rule 10), non-invasive, active device (items 25, 26, 27, 30 – 50)
Class IIa (Rule 10), invasive, active device (items 28, 29)

Standards Applied: IEC 60601-1:2005
IEC 60601-1-2:2007

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

Certificate Number(s): CE577334

Start of CE-Marking: October 2010 (items 1, 2), February 2015 (items 3 – 14), July 2015 (items 15 – 19), December 2006 (item 20), December 2004 (items 25 and 40), March 2007 (items 26, 27, 41, 43, 44), August 2008 (items 21, 22), December 2015 (items 23), May 2016 (item 24), March 2006 (items 28 – 31), April 2008 (item 32), November 2004 (items 33 – 35, 42), November 2009 (item 45), January 2007 (item 36), June 2012 (item 37), June 2009 (items 38, 39)

Valid until: November 18, 2018

Place and Date: Neurosoft Ltd, Ivanovo, Russia
June 27, 2016

Signature: Aleksey Borisovich Shubin
President of Neurosoft Ltd



Medical device(s):

1. Magnetic stimulator "Neuro-MS/D"
2. Magnetic stimulator "Evidence 9100ms"
3. Cooled big ring coil "RC-02-150-C"
4. Cooled angulated figure-of-eight coil "AFEC-02-100-C"
5. Cooled figure-of-eight coil "FEC-02-100-C"
6. Small ring coil "RC-02-100"
7. Big ring coil "RC-02-150"
8. Figure-of-eight coil "FEC-02-100"
9. Angulated figure-of-eight coil "AFEC-02-100"
10. Small figure-of-eight coil "SFEC-02-50"
11. Figure-of-eight coil (placebo) "FEC-02-100-P"
12. Angulated figure-of-eight coil (placebo) "AFEC-02-100-P"
13. Cooled angulated figure-of-eight coil (placebo) "AFEC-02-100-C-P"
14. Angulated figure-of-eight coil "AFEC-02-125"
15. Magnetic stimulator "Neuro-MS"
16. Angulated figure-of-eight coil "AFEC-03-100"
17. Figure-of-eight coil "FEC-03-100"
18. Small ring coil "RC-03-100"
19. Big ring coil "RC-03-125"
20. Portable device for EMG/STIM-guided injections "Neuro-Tox"
21. Portable hearing screening device for ABR and OAE "Neuro-Audio-Screen"
22. Portable hearing screening device for OAE "Neuro-Audio-Screen/OAE"
23. Portable hearing screening system for OAE "aScreen"
24. Portable system for OAE, ABR, impedance testing and hearing screening "Audio-SMART"
25. Digital neurophysiological system for EP and OAE "Neuro-Audio"
26. Digital neurophysiological system for OAE "Neuro-Audio/OAE"
27. Digital neurophysiological system for EP "Neuro-Audio/ABR"
28. Digital ECG system "Poly-Spectrum-8"
29. Digital ECG system with measurement and interpretation "Poly-Spectrum-8/E"
30. Digital ECG system for heart rate variability analysis (vegetotester) "VNS-Rhythm"
31. Digital ECG system for heart rate and breath rate variability analysis (vegetotester) "VNS-Micro"
32. Digital neurophysiological system for EEG and EP "Neuron-Spectrum-1"
33. Digital neurophysiological system for EEG and EP "Neuron-Spectrum-2"
34. Digital neurophysiological system for EEG and EP "Neuron-Spectrum-3"
35. Digital neurophysiological system for EEG and EP "Neuron-Spectrum-4"
36. Digital neurophysiological system for EEG and EP "Neuron-Spectrum-4/P"
37. System for ambulatory EEG and PSG monitoring "Neuron-Spectrum-AM"
38. Digital neurophysiological system for EEG and EP "Evidence EEG23 evo"
39. Digital neurophysiological system for EEG and EP "Evidence EEG28 evo "
40. Digital neurophysiological system for EP and ERG "Neuro-ERG"
41. 2-channel digital neurophysiological system for EMG and EP with a built-in miniature dedicated keyboard "Evidence 3002evo"
42. Digital neurophysiological system for EMG and SSEP "Neuro-EMG-Micro"
43. Digital neurophysiological system for EMG and SSEP "Evidence 1002"
44. Digital neurophysiological system for EMG and SSEP "BITMED EMGMicro"
45. 2-channel digital neurophysiological system for EMG "Neuro-EMG-MS"