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Identification number: 0086

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

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

Valid until: November 18, 2018

Place and Date: Neurosoft Ltd, Ivanovo, Russia
February 28, 2018

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. Magnetic stimulator "Evidence 9200ms"
17. Angulated figure-of-eight coil "AFEC-03-100"
18. Figure-of-eight coil "FEC-03-100"
19. Small ring coil "RC-03-100"
20. Big ring coil "RC-03-125"