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Eastgate, Hanauer Landstrasse 115
60314 Frankfurt am Main, Germany
Identification number: 0535

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

Medical device(s):

1. Digital neurophysiological system for EMG and EP a built-in dedicated keyboard "Neuro-MEP-5"
2. Digital neurophysiological system for EMG and EP a built-in dedicated keyboard "Neuro-MEP-5/2"
3. Digital neurophysiological system for EMG and EP a built-in dedicated keyboard "Evidence 5002evo"
4. Digital neurophysiological system for EMG and EP a built-in dedicated keyboard "Evidence 5005evo"
5. Digital neurophysiological system for EMG, EP, ERG and OAE "Neuro-MEP"
6. Digital neurophysiological system for EMG, EP, ERG and OAE "Evidence 4004evo "
7. Digital neurophysiological system for EMG, EP, ERG and OAE "BITMED MEP4"
8. Digital neurophysiological system for EMG, EP, ERG and OAE "BITMED MEP8"
9. Transcranial electrical stimulator "Neuro-TES"
10. 2-channel digital neurophysiological system for EMG and EP with a built-in miniature dedicated keyboard "Neuro-MEP-Micro"
11. 2-channel digital neurophysiological system for EMG and EP with a built-in miniature dedicated keyboard "Evidence 3102evo"
12. 2-channel digital neurophysiological system for EMG and EP with a built-in miniature dedicated keyboard "BITMED MEPMicro"
13. System for Intraoperative Monitoring "Neuro-IOM"
14. System for Intraoperative Monitoring "Neuro-IOM/F"

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: IEC 60601-1:1988+A1:1991+A2:1995
IEC 60601-1-1:2000
IEC 60601-1-2:2007
IEC 60601-2-40:1998

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

Certificate Number(s):

CE577332

Start of CE-Marking:March 2011 (items 1, 2, 3, 4)
December 2004 (item 5)
March 2007 (items 6, 7, 8, 11, 12)
January 2013 (item 9)
January 2007 (item 10)
October 2014 (items 13,14)**Place and Date:**Neurosoft Ltd, Ivanovo, Russia
October 31, 2014**Signature:**Aleksey Borisovich Shubin
President of Neurosoft Ltd