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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 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."

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 60601-2-26:2002
IEC 60601-2-40:1998

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

Certificate Number(s): CE611073

Start of CE-Marking: April 2008 (item 1)
June 2009 (item 2)
March 2007 (items 3, 4)
May 2009 (items 5, 6)

Place and Date: Neurosoft Ltd, Ivanovo, Russia
July 21, 2014

Signature:

Aleksey Borisovich Shubin
President of Neurosoft Ltd