

**Manufacturer:** Neurosoft Ltd  
5, Voronin str., Ivanovo, 153032, Russia  
Phone: +7 (4932) 24-04-34  
Fax: +7 (4932) 24-04-35  
E-mail: com@neurosoft.ru

**Notified body:** BSI Group Deutschland GmbH  
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)  
June 2009 (items 5, 6)

**Valid until:** November 18, 2018

**Place and Date:** Neurosoft Ltd, Ivanovo, Russia  
February 03, 2014

**Signature:**  Aleksey Borisovich Shubin  
President of Neurosoft Ltd

