

**Manufacturer:**

Neurosoft Ltd  
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**Notified body:**

BSI Group Deutschland GmbH  
Eastgate, Hanauer Landstrasse 115  
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Identification number: 0535

**European Representative:**

SAS Neuromed  
Chemin du temple  
84330 Le Barroux, France

**Medical device(s):**

1. Digital neurophysiological system for EP and ERG "Neuro-ERG"
2. 2-channel digital neurophysiological system for EMG and EP with a built-in miniature dedicated keyboard "Evidence 3002evo"
3. Digital neurophysiological system for EMG and SSEP "Neuro-EMG-Micro"
4. Digital neurophysiological system for EMG and SSEP "Evidence 1002"
5. Digital neurophysiological system for EMG and SSEP "BITMED EMGMicro"
6. 2-channel digital neurophysiological system for EMG "Neuro-EMG-MS"

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 (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 V, Section 3 of Council Directive 93/42/EEC concerning medical devices.

**Certificate Number(s):**

CE577347

**Start of CE-Marking:**

December 2004 (item 1),  
November 2004 (item 3),  
January 2007 (item 6),  
March 2007 (item 2),  
May 2009 (items 4, 5)

**Place and Date:**

Neurosoft Ltd, Ivanovo, Russia  
November 28, 2013

**Signature:**

Aleksey Borisovich Shubin  
President of Neurosoft Ltd