DECLARATION OF CONFORMITY

Manufacturer:

Neurosoft Ltd
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Notified body:

BSI Group Deutschland GmbH
Eastgate, Hanauer Landstrasse 115
60314 Frankfurt am Main, Germany
Identification number: 0535

European Representative:

SAS Neuromed
Chemin du tomple
84330 Le Barroux, France

Medical device(s):

1. Digital neurophysiological system for EEG and EP "Neuron-Spectrum-1"
2. Digital neurophysiological system for EEG and EP "Neuron-Spectrum-2"
3. Digital neurophysiological system for EEG and EP "Neuron-Spectrum-3"
4. Digital neurophysiological system for EEG and EP "Neuron-Spectrum-4"
5. Digital neurophysiological system for EEG and EP "Neuron-Spectrum-4/P"
6. System for ambulatory EEG and PSG monitoring ''Neuron-Spectrum-AM''
7. Digital neurophysiological system for EEG and EP "Evidence EEG23 evo"
8. Digital neurophysiological system for EEG and EP "Evidence EEG28 evo "

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

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

Certificate Number(s):

CE577352

Start of CE-Marking:

April 2008 (item 1)
November 2004 (items 2, 3, 4)
January 2007 (item 5)
June 2012 (item 6)
June 2009 (item 7, 8)

Place and Date:

Neurosoft Ltd, Ivanovo, Russia
February 03, 2014

Signature:

Aleksey Borisovich Shubin
President of Neurosoft Ltd