DECLARATION OF CONFORMITY

Manufacturer:

Neurosoft Ltd
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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 tomple
84330 Le Barroux, France

Medical device(s):

1. Magnetic stimulator "Neuro-MS"
2. Magnetic stimulator "Evidence 9000ms"
3. Magnetic stimulator "Neuro-MS/D"
4. Magnetic stimulator "Evidence 9100ms"

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 (Rules 9 and 10), non-invasive, active device

Standards Applied:

IEC 60601-1:2005
IEC 60601-1-2:2007

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

Certificate Number(s):

CE577342

Start of CE-Marking:

May 2006 (items 1, 2)
October 2010 (items 3, 4)

Place and Date:

Neurosoft Ltd, Ivanovo, Russia
November 19, 2013

Signature:

Aleksey Borisovich Shubin
President of Neurosoft Ltd