

## **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:** 

Portable device for EMG/STIM-guided injections "Neuro-Tox"

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): CE577334

Start of CE-Marking: December 2006

Place and Date:

Neurosoft Ltd, Ivanovo, Russia

November 19, 2013

Signature:

My

Aleksey Borisovich Shubin President of Neurosoft Ltd