

## DECLARATION OF CONFORMITY

005

Manufacturer: Neurosoft LLC

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Notified body: BSI

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Identification number: 2797

European Representative: SAS Neuromed

360 avenue du Clapier ZAC du Couquiou

84320 Entraigues sur-la-Sorgue

France

Design, development and manufacture of digital neurophysiological systems, digital systems for monitoring of physiological parameters, transcranial electrical stimulators, magnetic stimulators with accessories and active rehabilitation devices (See attachment).

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), invasive, active device

Standards Applied: EN 60601-1:2006/A1:2013

EN 60601-1-2:2015 EN 60601-2-40:2019

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

Certificate Number(s): CE 577332

Valid until: November 18, 2023

Place and Date: Neurosoft LLC, Ivanovo, Russia

February 13, 2020

Signature:



And

Aleksey Borisovich Shubin President of Neurosoft LLC

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## **DECLARATION OF CONFORMITY**

005

Annex to Declaration of Conformity №005 from February 13, 2020

## Medical device(s):

- System for Intraoperative Monitoring "Neuro-IOM"
  Transcranial electrical stimulator "Neuro-TES"

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