

Manufacturer: Neurosoft Ltd
5, Voronin str., Ivanovo, 153032, Russia
Phone: +7 (4932) 95-99-99
Fax: +7 (4932) 24-04-35
E-mail: info@neurosoft.com

Notified body: BSI
Kitemark Court, Davy Avenue, Knowhill,
Milton Keynes MK5 8PP, United Kingdom
Identification number: 0086

European Representative: SAS Neuromed
Chemin du temple
84330 Le Barroux, France

Design, development and manufacture of digital systems for electroneuromyography (EMG), electroencephalography (EEG), electroretinography (ERG), evoked potentials (EP), otoacoustic emission (OAE), intraoperative neurophysiological monitoring (IOM) and transcranial electrical stimulators (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), non-invasive, active device
(items 1 – 12)
Class IIb (Rule 10), invasive, active device
(items 13, 14)

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

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

Certificate Number(s): CE577332

Start of CE-Marking: April 2008 (item 1)
June 2009 (item 2, 5, 6)
March 2007 (items 3, 4, 12, 13, 14 and 18)
March 2011 (items 7 – 10)
December 2004 (item 11)
April 2010 (item 17)
January 2013 (item 15)
April 2005 (item 16)
October 2014 (items 19, 20)

Valid until: November 18, 2018

Place and Date: Neurosoft Ltd, Ivanovo, Russia
June 27, 2016

Signature:  Aleksey Borisovich Shubin
President of Neurosoft Ltd



Attachment**Medical device(s):**

1. Digital neurophysiological system for EEG, EP and EMG "Neuron-Spectrum-4/EPM"
2. Digital neurophysiological system for EEG, EP and EMG "Neuron-Spectrum-4/EPM/S"
3. Digital neurophysiological system for EEG, EP and EMG "Neuron-Spectrum-5"
4. Digital neurophysiological system for EEG, EP and EMG "Neuron-Spectrum-5/S"
5. Digital neurophysiological system for EEG, EP and EMG "Evidence EEG29 proff."
6. Digital neurophysiological system for EEG, EP and EMG "Evidence EEG40 proff."
7. Digital neurophysiological system for EMG and EP a built-in dedicated keyboard "Neuro-MEP-5"
8. Digital neurophysiological system for EMG and EP a built-in dedicated keyboard "Neuro-MEP-5/2"
9. Digital neurophysiological system for EMG and EP a built-in dedicated keyboard "Evidence 5002evo"
10. Digital neurophysiological system for EMG and EP a built-in dedicated keyboard "Evidence 5005evo"
11. Digital neurophysiological system for EMG, EP, ERG and OAE "Neuro-MEP"
12. Digital neurophysiological system for EMG, EP, ERG and OAE "Evidence 4004evo "
13. Digital neurophysiological system for EMG, EP, ERG and OAE "BITMED MEP4"
14. Digital neurophysiological system for EMG, EP, ERG and OAE "BITMED MEP8"
15. Transcranial electrical stimulator "Neuro-TES"
16. 2-channel digital neurophysiological system for EMG and EP with a built-in miniature dedicated keyboard "Neuro-MEP-Micro"
17. 2-channel digital neurophysiological system for EMG and EP with a built-in miniature dedicated keyboard "Evidence 3102evo"
18. 2-channel digital neurophysiological system for EMG and EP with a built-in miniature dedicated keyboard "BITMED MEPMicro"
19. System for Intraoperative Monitoring "Neuro-IOM"
20. System for Intraoperative Monitoring "Neuro-IOM/F"