By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 577332**

Issued To: **Neurosoft LLC**
5, Voronin str.
Ivanovo, 153032
Russian Federation

In respect of:

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.
Проектирование, разработка и производство цифровых нейрофизиологических комплексов, систем мониторинга физиологических параметров, транскраниальных электростимуляторов, магнитных стимуляторов с аксессуарами и активных реабилитационных устройств.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-06-27** Date: **2020-02-13** Expiry Date: **2023-11-18**

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Supplementary Information to CE 577332

Issued To:

Neurosoft LLC
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Number	Device Description	Intended purpose
Class IIb		
MD 1103 MD 1302 MDS 7010	Digital neurophysiological systems for EMG, EP and ERG, nerve conduction studies (NCS), galvanic skin response (GSR) testing, heart rate variability (HRV), cardiovascular reflex tests; Systems for intraoperative monitoring.	Systems are intended for the acquisition, display, analysis, storage and reporting of electrophysiological information from the human nervous and muscular systems, spinal cord and brain.
MD 1103 MD 1302 MDS 7010	Transcranial electrical stimulators.	The stimulators are intended for the diagnostic (together with EMG devices) transcranial impact to motor cortex by electrical pulses.
MD 1103 MD 1302 MDS 7010	Digital neurophysiological systems for recording of EEG, (video EEG), LTM, PSG (including cardiorespiratory monitoring), CFM, long-latency, middle-latency and short-latency EP, EMG, nerve conduction studies (NCS), biofeedback (BFB) training, galvanic skin response (GSR) testing, heart rate variability (HRV) and cardiovascular reflex tests.	Digital systems intended for clinical electroencephalography (EEG), video EEG, long- term monitoring (LTM), polysomnography (PSG), cardiorespiratory monitoring (CRM), cerebral function monitoring (CFM), multimodality long-latency, middle-latency and short-latency evoked potential (EP) testing, EMG (needle and surface EMG) testing, nerve conduction studies (NCS), biological feedback (BFB) testing, galvanic skin response (GSR) testing, heart rate variability (HRV) and cardiovascular reflex tests.

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Number	Device Description	Intended purpose
Class IIa		
MD 1103 MD 1302 MD 1301 MDS 7010	Digital systems for: • EEG, video EEG, LTM, PSG, CFM, EP, BFB; • EMG, NCS, EP, GSR, HRV and cardiovascular reflex tests; • ERG; • ECG; • Audiology (including pure tone audiometry (PTA), auditory brainstem response (ABR), otoacoustic emission (OAE), acoustic impedance testing and hearing screening). Portable device for electromyography (EMG) / electrostimulation (STIM)-guided injections. Vegetotesters.	NA for class IIa devices
MD 1402 MDS 7010	Magnetic stimulators and accessories	NA for class IIa devices
MD 1108 MDS 7010 MDS 7004	Rehabilitation devices	NA for class IIa devices

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 577332**
Date:	**2020-02-13**
Issued To:	**Neurosoft LLC** **5, Voronin str.** **Ivanovo, 153032** **Russian Federation**

Subcontractor:	**Service(s) supplied**
SAS Neuromed 360 avenue du Clapier ZAC du Couquiou Entraigues sur-la-Sorgue 84320 France	**EU Representative**

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bsi.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 577332**

Date: **2020-02-13**

Issued To: **Neurosoft LLC**
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Date	Reference Number	Action
27 June 2016	8488296	First issue. Transfer from another Notified Body.
07 September 2016	8596020	Clarification/Extension of scope to include: systems for electroencephalography (EEG) Wording changes : electroneuromyography (EMG) instead electromyography (EMG) and intraoperative neurophysiological monitoring (IOM) instead intraoperative monitoring (IOM)
08 November 2018	8941756	Renewal. Integration of devices covered by certificate CE 577334. Simplification of the scope of the certificate and description of all Generic Device Groups and of Device Subcategories in the product table included in the certificate. Company name correction from "Neurosoft Ltd." to "Neurosoft LLC".
06 February 2019	8863005	Traceable to NB 0086.
Current	9685034	Extension to scope to include: active rehabilitation devices. Update of the legal address of the EU Representative SAS Neuromed from "Chemin du tomple, Le Barroux, 84330, France" to "360 avenue du Clapier, ZAC du Couquiou, Entraigues sur-la-Sorgue 84320, France".