

# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

**No.** **CE 577334**  
Issued To: **Neurosoft Ltd.**  
**5, Voronin str.**  
**Ivanovo, 153032**  
**Russian Federation**

In respect of:

**See certificate scope page.**

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

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **27 June 2016**

Date: **27 June 2016**

Expiry Date: **18 November 2018**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 577334

## Certificate Scope:

**Manufacture, final inspection and test of digital neurophysiological systems for electroencephalography (EEG), electromyography (EMG), study of evoked potentials (EP), polysomnography (PSG) and electroretinography (ERG), portable devices for electromyography (EMG) / electrostimulation (STIM)-guided injections "Neuro-Tox", magnetic stimulators and accessories, digital electrocardiography (ECG) systems, neurophysiological and hearing screening systems.**

**Производство, выходной контроль и тестирование цифровых нейрофизиологических систем для электроэнцефалографии (ЭЭГ), электромиографии (ЭМГ), исследования вызванных потенциалов (ВП), полисомнографии (ПСГ) и электроретинографии (ЭРГ), портативных приборов для локализации места инъекции методами регистрации ЭМГ и электростимуляции "Нейро-Токс", магнитных стимуляторов и аксессуаров, компьютерных электрокардиографов (ЭКГ) и систем для аудиологического скрининга.**

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## List of Significant Subcontractors

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

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5, Voronin str.  
Ivanovo, 153032  
Russian Federation**

**Subcontractor:**

**Service(s) supplied**

SAS Neuromed  
Chemin du temple  
Le Barroux  
84330  
France

**EU Representative**

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# EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 577334**  
Date: **27 June 2016**  
Issued To: **Neurosoft Ltd.  
5, Voronin str.  
Ivanovo, 153032  
Russian Federation**

<b>Date</b>	<b>Reference Number</b>	<b>Action</b>
27 June 2016	8488296	First issue. Transfer from another Notified Body.

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