



EC Certificate - Full Quality Assurance System

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

No. Issued To: CE 577332 Neurosoft Ltd. 5, Voronin str. Ivanovo, 153032 Russian Federation

In respect of:

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.

Проектирование, разработка и производство цифровых комплексов для электронейромиографии (ЭМГ), электроэнцефалографии (ЭЭГ), электроретинографии (ЭРГ), вызванных потенциалов (ВП), отоакустической эмиссии (ОАЭ), интраоперационного нейрофизиологического мониторинга (ИОМ) и транскраниальных электростимуляторов.

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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: 27 June 2016

Date: 07 September 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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A member of BSI Group of Companies.





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List of Significant Subcontractors

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

Certificate No: Date: Issued To:

07 September 2016 Neurosoft Ltd. 5, Voronin str. Ivanovo, 153032 Russian Federation

CE 577332

Subcontractor:

SAS Neuromed Chemin du tomple Le Barroux 84330 France Service(s) supplied

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: Date: Issued To: CE 577332 07 September 2016 Neurosoft Ltd. 5, Voronin str. Ivanovo, 153032 Russian Federation

Date	Referenc e 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)

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