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 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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List of Significant Subcontractors

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

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

Subcontractor:	**Service(s) supplied**
SAS Neuromed Chemin du tomple Le Barroux 84330 France	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 577332**

Date: **07 September 2016**

Issued To: **Neurosoft Ltd.**
5, Voronin str.
Ivanovo, 153032
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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)