

## Declaration of Conformity

ID: EEG-9-1.19

Products:	<b>EEG Studio software</b>
Classification:	class IIa (MDD, Annex IX)
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Confirmation is hereby given that the EEG Studio software conforms to the essential requirements laid down in the Council Directive regarding the harmonization of statutory requirements of the member states on Medical Devices 93/42/EEC (MDD, Annex II) as amended by Directive 2007/47/EC concerning medical devices.

The Quality Management System meets the requirements of ISO 13485.

The software conforms to following standards:

EN 62304:2006	Medical device software – software life cycle processes
MDD 93/42/EEC	Medical Device Directive
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices

Notified Body: VTT Expert Services Ltd (0537)  
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Conformity Assessment procedure for CE: Council Directive 93/42/EEC (MDD, Annex II)

Certificate number: VTT-C-11476-01-1121-573-15

Date of issue: 31.12.2015

Validity date: 31.12.2020

The declaration of conformity is issued under the sole responsibility of MITSAR Co. Ltd.

Signed for and on behalf of manufacturer:

Date: 28.11.2018

St. Petersburg

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Alexander A. Grushvitskiy  
CEO  
MITSAR Co. Ltd.

