

## Declaration of Conformity

ID: Mitsar-EEG-202

Products:	<b>Electroencephalographic PC-controlled system MITSAR-EEG-202</b>
Classification:	class IIa (MDD, Annex IX)
Manufacturer:	MITSAR Co. Ltd. Optikov str, 4-2A, 197374 St. Petersburg Russia Federation ph. +7 812 2977274 fax +7 812 2977274 E-mail: info@mitsar-medical.com Web site: www.mitsar-medical.com
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Confirmation is hereby given that the Electroencephalographic PC-controlled system MITSAR-EEG-202 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 system conforms to following standards:

MDD 93/42/EEC	Medical Device Directive
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN 60601-1:2006	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests
EN 60601-2-26:2003	Medical electrical equipment -- Part 2-26: Particular requirements for the safety of electroencephalographs

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

Certificate number: VTT-C-12077-01-1121-619-17  
Date of issue: 08.06.2017

Valid until: 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: 18.06.2019  
St. Petersburg

Alexander A. Grushvitskiy  
CEO «MITSAR Co. Ltd.»

