Declaration of Conformity

ID: Mitsar-EEG-202

Products:	**Electroencephalographic PC-controlled system MITSAR–EEG-202**
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-eeg.ru Web site: www.mitsar-eeg.com
Europe Authorized Representative:	MEDISAT Company Bulgaria, Rousse 7000 ”Han Asparuh”#31 ph../fax: +359 888 71 22 91 E-mail: office@medisat.org Web site: www.medisat.org

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) Medical Devices, Notified Body No. 0537 Hermiankatu 6-8 H, FI-33720 Tampere, Finland P.O.BOX 345, FI-33101 Tampere, Finland Tel. +35840 729 7827 E-mail: medical-device@eurofins.com Web site: www.eurofins.com/medical-device/
Conformity Assessment procedure for CE:	Council Directive 93/42/EEC (MDD, Annex II)
Certificate number:	C-01-1121-734-20
Date of issue:	28.04.2020
Valid until:	27.05.2024

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

Signed for and on behalf of manufacturer:

Date: 05.05.2020
St. Petersburg

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