

Declaration of Conformity

ID: EEG-9-1.24

Products:	EEG Studio software
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 Tel./fax: +359 888 71 22 91 E-mail: office@medisat.org Web site: www.medisat.org

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: Eurofins Expert Services Ltd
(previous name VTT Expert Services Ltd)
Medical Devices, Notified Body No. 0537
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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

Validity date: 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: 23.11.2020

St. Petersburg

Alexander A. Grushvitskiy

CEO

MITSAR Co. Ltd.

