

Declaration of Conformity

ID: EEG-SmartBCI

Products: **Electroencephalographic system
MITSAR–EEG-SmartBCI**

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, Rouse 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 system MITSAR–EEG-SmartBCI 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.»

