

## Declaration of Conformity

ID: EEG-BT

Products: **Electroencephalographic system  
Mitsar-EEG-BT**

Classification: class IIa (MDD, Annex IX)

Manufacturer: MITSAR Co. Ltd  
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Confirmation is hereby given that the Electroencephalographic system Mitsar-EEG-BT 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: 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

  
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Alexander A. Grushvitskiy  
CEO «MITSAR Co. Ltd»