

Declaration of Conformity

ID: EEG-BT-1730001- 1730050

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

Classification: class IIa (MDD, Annex IX)

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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 60601-1-2:2007	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-2-26:2003	Medical electrical equipment -- Part 2-26: Particular requirements for the safety of electroencephalographs

Notified Body: VTT Expert Services Ltd (0537)
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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: 08.06.2017

St. Petersburg

Alexander A. Grushvitskiy
CEO «MITSAR Co. Ltd»

