

## Declaration of Conformity

ID: BFB-5020118

Products: **Biofeedback trainer MITSAR-BFB**

Classification: class IIa (MDD, Annex IX)

Manufacturer: MITSAR Co. Ltd.  
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Confirmation is hereby given that the Biofeedback trainer MITSAR-BFB 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
ISO 13485:2003	Medical devices — Quality management systems — Requirements for regulatory purposes
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

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Conformity Assessment procedure for CE: Council Directive 93/42/EEC (MDD, Annex II)

Certificate number: VTT-C-6290-01-1121-426-10  
Date of issue: 31<sup>st</sup> December 2010  
Valid until: 31<sup>st</sup> December 2015

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

Signed for and on behalf of manufacturer:

Date: 15 November 2013

St. Petersburg



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Igor I. Lisitsyn  
CEO  
MITSAR Co. Ltd.