

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer: Mitsar Co. Ltd
Optikov str. 4-2A
RU-197374 St. Petersburg
RUSSIA

Coverage of Certificate: Design, manufacture and final inspection

Product category: EEG- and Biofeedback Equipment
and related software

Valid until: 27th May 2024

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex II Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex II in Directive 93/42/EEC. Products covered by the certificate are specified in the attachment(s).

Valid from: 28th April 2020



Satu Rajala



Anniina Mäkelä



Certificate no.
C-01-1121-734-20

Notified Body no. 0537:
Eurofins Expert Services
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Attachment 1 to the Certificate number: C-01-1121-734-20

Manufacturer:	Mitsar Co. Ltd Optikov str. 4-2A, RU-197374 St. Petersburg Russia															
Activity and product category:	Design, manufacture and final inspection of EEG- and Biofeedback Equipment and related software. GMDN-codes: 11467, 10396															
Products:	<p>The certificate covers the following products:</p> <p>EEG-Equipment (GMDN-code: 11467)</p> <table> <tr> <td>Mitsar</td> <td>EEG-202</td> <td>IIa</td> </tr> <tr> <td>Mitsar</td> <td>EEG-BT</td> <td>IIa</td> </tr> <tr> <td>Mitsar</td> <td>EEG-SmartBCI</td> <td>IIa</td> </tr> </table> <p>EEG- and ERP software (GMDN-code: 11467)</p> <table> <tr> <td>Mitsar</td> <td>EEG studio</td> <td>IIa</td> </tr> </table> <p>Biofeedback trainer (GMDN-code: 10396)</p> <table> <tr> <td>Mitsar</td> <td>BFB</td> <td>IIa</td> </tr> </table>	Mitsar	EEG-202	IIa	Mitsar	EEG-BT	IIa	Mitsar	EEG-SmartBCI	IIa	Mitsar	EEG studio	IIa	Mitsar	BFB	IIa
Mitsar	EEG-202	IIa														
Mitsar	EEG-BT	IIa														
Mitsar	EEG-SmartBCI	IIa														
Mitsar	EEG studio	IIa														
Mitsar	BFB	IIa														
Date:	Valid from: 28 th April 2020															
	  Satu Rajala  Anniina Mäkelä															

Eurofins Expert Services is Notified Body no. 0537 under Council Directive 93/42/EEC.