VTT EXPERT SERVICES LTD

DECISION
on changes to the approved quality system as specified in Annex II, Section 3 of Council Directive 93/42/EEC concerning medical devices, or to the product range covered.

Decision no.:	**VTT-C-2322-01-1121-308-07-P1**
Manufacturer:	**Mitsar Co. Ltd** **Novorossiyskaya str. 21-2, 194021, St. Petersburg,** **Russia**
Date of manufacturer's notification:	30.8.2009
Procedure and product category:	Design, manufacture and final inspection of EEG- and Biofeedback Equipment, class IIa.
Description of the changes:	A new product, EEG-equipment Mitsar-EEG-10/70-201 has been added under the certificate. The Certificate covers the following products: - EEG-equipment: Mitsar-EEG-202-1 - EEG-equipment: Mitsar-EEG-202-3 - EEG-equipment: Mitsar-EEG-03/35-201 - EEG-equipment: Mitsar-EEG-05/70-201 - EEG-equipment: Mitsar-EEG-10/70-201 - Biofeedback trainer: Mitsar-BFB
The decision:	The manufacturer's quality system related to the aforementioned changes has been assessed and it still meets the requirements in Annex II of Medical Device Directive 93/42/EEC. The decision is based on the report no. NB-1121-MR1 and audit report NB-1121-A3. The company has signed the undertaking to follow the obligations of Annex II of the Directive.
Certificate related to the decision:	VTT-C-2322-01-1121-308-07
Validity:	This decision is valid until 31st December 2010 unless the validity of the related certificate is changed.
Date:	Tampere, 22nd of March 2010

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Kaarle Kylmälä

Seppo Lavonen

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

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