APPROVAL

EC Directive 93/42/EEC; Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: M23 69240068 0001

Report No.: 28208466 001

Manufacturer:
MAITREYA Hungary Ltd.
Kálvária tér 2.
1089 Budapest
Hungary

Scope:
Design/development and manufacturing of Universal Electrophysiological Biofeedback System

Product: SCIO

Date of expiry: 2015-02-22

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Budapest, 2010-02-23

Bence Thurnay

MEEI Kft. – member of TÜV Rheinland Group – H-1132 Budapest, Váci út 48/A-B

Notified under No. 1007 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜVRheinland®
MEEI

Certificate

Hungarian Institute for Testing and Certification of Electrical Equipment Ltd (MEEI Kft.)

hereby certifies that

MAITREYA Hungary Ltd.
Kálvária tér 2.
1089 Budapest
Hungary

Place of the audit: H-1089, BUDAPEST Kálvária tér 2.

established and applies a quality system for the following scope:

Design/development, manufacturing, distribution and servicing of Universal Electrophysiological Biofeedback System

Compliance with the requirements of

EN ISO 9001:2008

standard has been proven.
This certification is subject to regular surveillance audits.

Registration no.:	**MQ 692400700001**
Audit report no.:	**28208466 001**
Validity of certificate:	**from 2010.02.23 to 2013.02.22**

Budapest, 2010.02.23

Hungarian Institute For Testing And Certification Of Electrical Equipment

Zoltán Ambrus MD
certifier

MEEI Kft. – TÜV Rheinland group – H-1132 Budapest, Váci út 48/a-b
Tel.: (+36/1) 2888-456 Fax: (+36/1) 2888-499 e-mail:meei@hu.tuv.com http://www.tuv.com/meei/

Certificate

The Certification Body of
MEEI Kft. –Member of TÜV Rheinland Group

hereby certifies that the company

MAITREYA Hungary Ltd.
Kálvária tér 2.
1089 Budapest
Hungary

Has established and applies a quality management system for medical devices for the following scope:

Design/development, manufacturing, distribution and servicing of Universal Electrophysiological Biofeedback System

Proof has been furnished that the requirements specified in

EN ISO 13485:2003+AC: 2007

are fulfilled. The quality management system is subject to periodic surveillance.

Certification Registration No.:	**M28 69240069 0001**
An audit was performed. Report No.:	**28208466 001**
This certificate is valid until:	**2015-02-22**

Budapest, 2010-02-23

Certification Body

Zoltán Ambrus MD

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