



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.

Budapest, 2010-02-23

Bence Thurnay

Notified Bod

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.