BSI

Kitemark House Maylands Avenue
Hemel Hempstead Herts HP2 4SQ

Tel +44 (0)8450 765600
Fax +44 (0)8450 765601
www.bsigroup.com

26 April 2011

To whom it may concern:

BSI has issued an EC certificate CE 538571 (expiry: 02/09/2013) to Medicom MTD Ltd 99 Petrovskaya Str Taganrog, Rostov Region 347900 Russian Fed., in accordance with Annex V Section 3.2 of the Medical Devices Directive 93/42/EEC. The scope of this certificate is currently:
"The manufacture of equipment for EEG/EP studies, long term Video EEG Monitoring, Cerebral Function Monitoring, PSG/Sleep Diagnostics, neurophysiological, psychophysiological and psychological studies, and equipment for biofeedback training and rehabilitation."

This certificate is maintained by BSI performing regular audits of the manufacturer's quality management system.

Furthermore, we can confirm that Medicom MTD Ltd, as the manufacturer, has declared compliance with the Medical Devices Directive for the following devices and BSI is satisfied that the products fall within the generic scope of the above certificate:

- Electroencephalograph-recorder computerized portable «ENCEPHALAN-EEGR-19/26»
  Models:
  - version «ENCEPHALAN-EEGR-19/26» T;
  - version «ENCEPHALAN-EEGR-19/26» AT;
  - version «ENCEPHALAN-EEGR-19/26» AT-Video;
  - version «ENCEPHALAN-EEGR-19/26» AT-PSG;
  - version «ENCEPHALAN-EEGR-19/26» AT-PSG-Video;
  - version «ENCEPHALAN-EEGR-19/26» AT-PSG-Video-POLY;
  - modification «Mini» version «ENCEPHALAN-EEGR-19/26» AT-Mini;
  - modification «Mini» version «ENCEPHALAN-EEGR-19/26» AT-Mini-Video;
  - modification «Mini» version «ENCEPHALAN-EEGR-19/26» AT-SOMNO;
  - modification «Mini» version «ENCEPHALAN-EEGR-19/26» AT-SOMNO-Video;

- Cerebral Function Monitor "Encephalan-CFM"

- Rehabilitation Psychophysiological System «Rehacor»
  Models:
  - Rehabilitation Psychophysiological System «Rehacor» BFB;
  - Rehabilitation Psychophysiological System «Rehacor» Egoscop;
  - Rehabilitation Psychophysiological System «Rehacor» BFB-Egoscop;

- Psychophysiological telemetric system "Rehacor-T"
  Models:
  - Psychophysiological telemetric system "Rehacor-T" version "Mini";
  - Psychophysiological telemetric system "Rehacor-T" version "Micro";

- Objective psychological analysis and testing system "Egoscop"

BSI

Kitemark House Maylands Avenue
Hemel Hempstead Herts HP2 4SQ

Tel +44 (0)8450 765600
Fax +44 (0)8450 765601
www.bsigroup.com

In accordance with the Medical Devices Directive 93/42/EEC a manufacturer who fulfils the obligations imposed by Annex II and Annex V, is permitted to apply CE marking to a device that falls within the scope of the above mentioned certificates.

Prior to placing the product on the market with CE marking the manufacturer is required to make a written declaration of conformity with the above requirements for a particular product. Such products with CE marking are then permitted to be placed on the market in the European Union.

Kind regards,

Ms. Aneela Lala
Product Specialist
Active Devices Certification
BSI Healthcare