

27<sup>th</sup> May, 2015

To whom it may concern:

BSI has issued an EC certificate CE 538571 (expiry: 2 Sep 2018) to:

Medicom MTD Ltd  
99 Petrovskaya Str  
Taganrog, Rostov Region  
347900  
Russian Federation

In accordance with Annex V Section 3.2 of the Medical Device Directive 93/42/EEC. The scope of this certificate is currently: "The manufacture of equipment for EEG/EMG/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's 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"

- Neuromyoanalyzer NMA-4-01 "Neuromyan" Models:
  - Neuromyoanalyzer NMA-4-01 "Neuromyan" modification 01 (2 channels) ;
  - Neuromyoanalyzer NMA-4-01 "Neuromyan" modification 02 (4 channels);
  - Neuromyoanalyzer NMA-4-01 "Neuromyan" modification 03 (5 channels);
- Sleep Signals Recorder Models:
  - Sleep Signals Recorder "ApnOx-04";
  - Sleep Signals Recorder "ApnOx-10";

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

Yours faithfully,



Sharmila Gardner

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