By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 538571**

Issued To: **Medicom MTD Ltd**
68 Frunze Str.
Taganrog, Rostov Region
347900
Russian Federation

Digitally signed by Ermicev Alexandr
Date: 2021.05.12 17:22:21 EEST
Reason: MoldSign Signature
Location: Moldova

In respect of:

The manufacture of equipment for EEG/EMG/EP studies, long term Video EEG Monitoring, Cerebral Function Monitoring, PSG/Sleep Diagnostics, neurophysiological studies, and equipment for biofeedback training and rehabilitation.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2008-09-03** Date: **2021-02-16** Expiry Date: **2023-09-02**

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Supplementary Information to CE 538571

Issued To:

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68 Frunze Str.
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Device code	Device name	Intended purpose per IFU
Class IIa		
MD1301	Electroencephalograph-recorder computerized portable «ENCEPHALAN-EEGR-19/26»	---
MD1301	Cerebral Function Monitor "Encephalan-CFM"	---
MD1301	Sleep Signals Recorder "ApnOx"	---
MD1301	Neuromyoanalyzer NMA-4-01 "Neuromyan"	---
MD1103	Psychophysiological telemetric system "Rehacor-T"	---

First Issued: **2008-09-03** Date: **2021-02-16** Expiry Date: **2023-09-02**

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Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 538571**
Date:	**2021-02-16**
Issued To:	**Medicom MTD Ltd** **68 Frunze Str.** **Taganrog, Rostov Region** **347900** **Russian Federation**

Subcontractor:	**Service(s) supplied**
Polmed.de Steinacker 5 73773 Aichwald Germany	**EU Representative**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 538571**
Date: **2021-02-16**
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Date	Reference Number	Action
03 September 2008	7218012	First Issue
21 February 2011	7604149	Extention to scope changed from The manufacture of EEG equipment and Biofeedback psychophysiological rehabilitation devices to 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.
28 Jun 2013	7985407	Certificate renewal and addition of Polmed.de as EU representative.
05 January 2015	8269950	Extension to scope to include equipment for EMG studies.
26 October 2017	8799763	Change of address from Medicom MTD Ltd, 99 Petrovskaya Str, Taganrog, Rostov Region, 347900, Russian Federation to Medicom MTD Ltd, 68 Frunze Str, Taganrog, Rostov Region, 347900, Russian Federation.
24 August 2018	9643016	Certificate Renewal.
08 February 2019	7780277	Traceable to NB 0086.

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Date	Reference Number	Action
Current	3376004	Removal of Egoscop system from the list of devices. Change in device table format. Removal of psychophysiological and psychological studies from the scope of certification. Correction of EU Representative address.