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

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.

Cancelled on March 10, 2022 by BSI Group due to the inability of BSI Group to provide conformity assessment services and services of the accreditation body for medical devices to a sufficient extent

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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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"	---

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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 Beata Rozwadowska Fichtenstr. 12a 90763 Fuerth Germany	**EU Representative**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 538571**

Date: **2021-02-16**

Issued To: **Medicom MTD Ltd**
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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
16 February 2021	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.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.		
19 November 2021	3566294	EU Representative address change

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Inspiring trust for a more resilient world.

19th November 2021

Medicom MTD Ltd
68 Frunze Str.
Taganrog, Rostov Region
347900
Russian Federation

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 538571	93/42/EEC Annex II excluding Section 4	3566294	EU Representative address change from "Polmed.de, Steinacker 5, 73773 Aichwald, Germany" to "Polmed.de, Beata Rozwadowska, Fichtenstr. 12a, 90763 Fuerth, Germany"

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

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