

Certificate

Of Marketing Authorization of Medical Product

Nr. **00063244**

Issued on the basis of the Declaration of conformity and registration taking into account Article 14 of Directive 93/42/EEC on Medical Devices and Medical Devices Act (MPG) § § 5,25,29,30

Ausgestellt auf Grund der Konformitätserklärung und Registrierung unter Berücksichtigung der Richtlinie 93/42/EWG Artikel 14 über Medizinprodukte und Medizinproduktegesetz (MPG) §§ 5,25,29,30

Manufacturer / Hersteller

Medicom MTD Ltd

68, Frunze str
Rostov Region
Taganrog 347900 RUSSIA
www.medicom-mtd.com

Product name / Produkt

Electroencephalograph - recorder computerized portable "ENCEPHALAN-EEGR-19/26"

Models:

1. „ENCEPHALAN – EEGR – 19/26“ T
2. „ENCEPHALAN – EEGR – 19/26“ AT
3. „ENCEPHALAN – EEGR – 19/26“ AT – Video
4. „ENCEPHALAN – EEGR – 19/26“ AT – PSG
5. „ENCEPHALAN – EEGR – 19/26“ AT – PSG – Video
6. „ENCEPHALAN – EEGR – 19/26“ AT – PSG – Video POLY
7. modification "Mini" „ENCEPHALAN – EEGR – 19/26“ AT – Mini
8. modification "Mini" „ENCEPHALAN – EEGR – 19/26“ AT – Mini – Video
9. modification "Mini" „ENCEPHALAN – EEGR – 19/26“ AT – SOMNO
10. modification "Mini" „ENCEPHALAN – EEGR – 19/26“ AT – SOMNO - Video

Registration number / Registriernummer

DE/CA37/POL042Ä3

Notified body/ Benannte Stelle

2797

Certificate number(s)/ Bescheinigung(en)

CE 538571

Classification / Klassifizierung

Class IIa

Nomenclature code / Nomenklaturcode

12-389

Nomenclature term/Nomenklaturbezeichnung

**Recorders, Long-Term, EEG/
REKORDER, LANGZEIT-, EEG**

Registration date : **2019-02-25**

Registrierdatum

First Registration : **2008-09-11**

Erstregistrierung

Represented in the EC by Polmed.de
Steinäcker 5, 73773 Aichwald, Germany
email: info@polmed.de
tel: +49 711 52853279




Valid to :

2020-05-25

Gültig bis

Date:

February 26, 2019


Polmed.de

**Annex 1 : List of devices produced « Medicom MTD Ltd »
registered in German (DIMDI) with CE marking**

Medicom MTD Ltd
65, Pruzs str., Taganrog, Russia, 347500
Phones: +7(8634) 62 62 42
Fax: +7(8634) 61 54 05 (24 hours)
e-mail: quality@medicom.mtd.com
www: <http://www.medicom.mtd.com>



	Name English	Notified body/ Certificate No.	Nomenclature term English / German	UMDNS Code	Class	Form number DIMDI	Registration number DIMDI	Certificate No. (No. document) DIMDI	Date of first registration by DIMDI	Registration date DIMDI	Exp. date
1.	EEG - ELECTRODE SET "ENCEPHALAN ES"	n/a	Electrodes, Electroencephalographic/ Elektrode, EEG	11-440	I	00247388	DE/CA37/1587/98	00063245	2008-09-11	2017-11-16	
2.	CEREBRAL FUNCTION MONITOR "ENCEPHALAN-QFM"	2797/ CE 538571	EEG Monitors, Telemetric / EEG-MONITOR, TELEMETRISCH	15-719	II a	00272826	DE/CA37/POL047A2	00102579	2011-03-23	2019-02-25	
3.	ELECTROENCEPHALOGRAPH - RECORDER COMPUTERIZED PORTABLE "ENCEPHALAN-EEGR-19/26"										
	<i>Models:</i> 1) "ENCEPHALAN EEGR 19/26" T 2) "ENCEPHALAN EEGR 19/26" AT 3) "ENCEPHALAN EEGR 19/26" AT Video 4) "ENCEPHALAN EEGR 19/26" AT P50 5) "ENCEPHALAN EEGR 19/26" AT P50 Video 6) "ENCEPHALAN EEGR 19/26" AT P50 Video POLY 7) modification "Mini" "ENCEPHALAN EEGR 19/26" AT Mini 8) modification "Mini" "ENCEPHALAN EEGR 19/26" AT Mini Video 9) modification "Mini" "ENCEPHALAN EEGR 19/26" AT SCAND Video 10) modification "Mini" "ENCEPHALAN EEGR 19/26" AT SCAND Video	2797/ CE 538571	Recorders, Long Term, EEG/ REKORDER, LANGZEIT-, EEG	12-389	II a	00272824	DE/CA37/POL042A3	00063244	2008-09-11	2019-02-25	2020-05-25
4.	PSYCHOPHYSIOLOGICAL TELEMETRIC SYSTEM "REHAOR-T"	2797/ CE 538571	Biofeedback Systems/ BIOFEEDBACKSYSTEME	10-396	II a	00272825	DE/CA37/POL044A5	00063246	2008-09-11	2019-02-25	
	<i>Models:</i> 1) "Rehaor-T" version "Mini" 2) "Rehaor-T" version "Micro"										
5.	OBJECTIVE PSYCHOLOGICAL ANALYSIS AND TESTING SYSTEM "EGOSCOB"	2797/ CE 538571			II a	00272827	DE/CA37/POL048A2	00102891	2011-04-08	2019-02-25	
6.	NEURONOMANALYZER NMA 4 01 "NEUROMYAN"	2797/ CE 538571	EMG Monitors, Telemetric / EMG MONITOR, TELEMETRISCH	15-720	II a	00272828	DE/CA37/POL049A2	00125918	2015-01-29	2019-02-25	
	<i>Models:</i> 1) NMA 4-01 "Neuromyan" modification 0112 (channel) 2) NMA 4-01 "Neuromyan" modification 0214 (channel) 3) NMA 4-01 "Neuromyan" modification 0315 (channel)										
7.	SLEEP SIGNALS RECORDER "APNOX"	2797/ CE 538571	Polysomnographs / POLYSOMNOGRAMPH	17-458	II a	00272829	DE/CA37/POL050A2	00129279	2015-06-11	2019-02-25	
	<i>Models:</i> 1) "ApnoX-04" 2) "ApnoX-10"										



Made on the basis of an Extract from the database www.dimdi.de (German Institute for Medical Documentation)

EC REP

Represented in the EC by Polmed.de
Steinhacker 5, 73773 Alchwald
Germany e-mail: info@polmed.de

EC Certificate - Production Quality Assurance

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

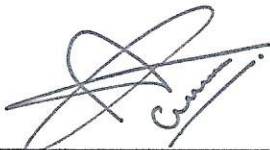
No. CE 538571
Issued To: **Medicom MTD Ltd**
68 Frunze Str.
Taganrog, Rostov Region
347900
Russian Federation

In respect of:

The manufacture of equipment for EEG/EMG/EP studies, long term Video EEG Monitoring, Cerebral Function Monitoring, PSG/Sleep Diagnostics, neurophysiological, psychophysiological and psychological 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):



Albert Roossien, Regulatory Lead

First Issued: **2008-09-03**

Date: **2019-02-08**

Expiry Date: **2023-09-02**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Production Quality Assurance

Supplementary Information to CE 538571

Issued To:

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

Number	Device Name
Class IIa	
NBOG Code	Device or Device subcategory
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"
MD1301	Objective psychological analysis and testing system "Egoscop"
MD1103	Psychophysiological telemetric system "Rehacor-T"

First Issued: **2008-09-03**

Date: **2019-02-08**

Expiry Date: **2023-09-02**

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EC Certificate - Production Quality Assurance

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: **2019-02-08**
 Issued To: **Medicom MTD Ltd**
68 Frunze Str.
Taganrog, Rostov Region
347900
Russian Federation

Subcontractor:	Service(s) supplied
Polmed.de Vertretung und Repräsentanz Dipl.-oec Boguslaw Karcz Steinäcker 5 Aichwald 73773 Germany	EU Representative

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EC Certificate - Production Quality Assurance

Certificate History

Certificate No: CE 538571
Date: 2019-02-08
Issued To: Medicom MTD Ltd
 68 Frunze Str.
 Taganrog, Rostov Region
 347900
 Russian Federation

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.
Current	7780277	Traceable to NB 0086.

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