

# Certificate

## Of Marketing Authorization of Medical Product

within Germany, the member states of the European Union  
and the other states having a contractual agreement with the European Economic Area

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 ,  
Article 11 of Regulation (EU) 2017/745 (MDR) 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.  
der Verordnung (EU) 2017/745(MDR) Artikel 11 über Medizinprodukte und Medizinproduktgesetz (MPG) § § 5,25,29,30

Manufacturer / Hersteller

**Medicom MTD Ltd**  
68, Frunze str  
Rostov Region  
Taganrog 347900 RUSSIA  
[www.medicom-mtd.com](http://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 II a**

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:

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Valid to : **2023-09-02**  
Gültig bis

Date: **May 26, 2021**

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