



**KEMENTERIAN KESEHATAN REPUBLIK INDONESIA**  
**DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN**

Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950

Telepon : (021) 5201590 Pesawat 2029, 8011

Faksimile : (021) 52964838 Kotak Pos : 203



Berdasarkan Peraturan Menteri Kesehatan R.I Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

NOMOR IZIN EDAR

**A L A T K E S E H A T A N**

**KEMENKES RI AKL 21001122920**

Nama Dagang / Merek : **MEDICOM Electroencephalograph-recorder**

Kelompok / Kelas Resiko : Elektromedik Non Radiasi / B

Kategori Produk : Peralatan Neurologi

Sub Kategori : Peralatan Neurologi Diagnostik

Jenis Produk : Electroencephalograph.

Tipe / Ukuran : Encephalan EEGR-19/26

Kemasan : Unit

Nama Produsen / Pabrikan : MEDICOM MTD. LTD, Russia

Nama Pendaftar : PT. ANDIARTA MATRA UTAMA, DKI Jakarta

Atas dasar lisensi dari : -

**Ketentuan**

1. Persetujuan izin edar berlaku sampai dengan 15 Januari 2024.
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
4. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
5. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.

Jakarta, 21 Mei 2021



Catatan:

- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1

Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.

- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSrE.



**KEMENTERIAN KESEHATAN REPUBLIK INDONESIA**  
**DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN**

Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950

Telepon : (021) 5201590 Pesawat 2029, 8011

Faksimile : (021) 52964838 Kotak Pos : 203



**LAMPIRAN**

**NOMOR IZIN EDAR  
ALAT KESEHATAN  
KEMENKES RI AKL 21001122920**

No.	Deskripsi	Tipe / Kode
1	Ni-MN AA rechargeable batteries	
2	Battery Charger	
3	Electrode Gel	
4	Notebook	
5	PC	
6	Monitor	

Dengan ketentuan bahwa izin edar tersebut hanya berlaku untuk deskripsi dan tipe / kode produk yang tercantum dalam lampiran ini

Jakarta, 21 Mei 2021



Catatan:

- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1

Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.

- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSrE.

# Electroencephalograph-recorder “Encephalan-EEGR-19/26”

● portable ● modular ● transformable ●



CE 2797

● Continuous EEG monitoring

● Autonomous EEG record (Holter-EEG)

● Mobile or stationary variants (more than 50 channels, including 30 EEG)

● Synchronous video-EEG monitoring (for epileptology and somnology)

Diimport dan Dipasarkan  
Oleh PT. Andiarta Matra Utama  
Pusat Niaga Duta Mas Blok C2 No.11-12  
Jl. RS. Fatmawati No.39 Jakarta, Indonesia  
Nama Alat : Electroencephalograph-recorder  
Type : Encephalan EEGR-19/26  
Manufacture : Medicom MTD. Ltd  
Frunze str., 68, Taganrog, Russia, 347900  
KEMENKES RI, AKL.....



Multichannel multiparameter record,  
additional software provide use of electroencephalograph-recorder  
as a multifunctional neuromodular diagnostic system



FM 538691



MD 540857

[www.medicom-mtd.com](http://www.medicom-mtd.com)

**MEDICOM MTD**

Research & Development Limited Company

Taganrog



## Mobile, telemetric or autonomous (Holter-EEG) use of the electroencephalograph

For EEG studies in the hospital room, emergency room, and intensive care or at patient's home, the mobile set includes a patient transceiver-recorder, a phono-photo stimulator, a set of electrodes, a portable PC and it easily fits in a compact computer carrying bag.

Additional mobile kit for synchronized long-term EEG-video monitoring provides effective use of portable electroencephalograph in telemetric mode for differential diagnosis of epilepsy.

The ability to record EEG (over 48 h) on the memory card built into autonomous patient transceiver-recorder ABP-26, provides carrying out of a comfortable long-term outpatient EEG study in environment natural for the patient during active wakefulness or sleep.

Set of electrodes  
"Encephalan-ES"

The unit of  
stimulation control –  
a photostimulator



### The main characteristics of the electroencephalograph-recorder:

The patient transceiver-recorder ABP-26 has 20 channels for standard EEG derivations with simultaneous registration of extra low brain activity and electrode resistances, and 6 additional polygraphic channels for registration of ECG, EMG, EOG, breathing, body position of the patient.

The additional transceiver-recorder ABP-10 increases the number of channels for 10 EEG derivations or for 10 different sensors and electrodes.

**The software for EEG-studies "Encephalan-EEGR" ("elite" suite) provides main functional capabilities of electroencephalograph-recorder**  
*see further in this brochure*

#### Technical characteristics of the patient transceiver-recorder ABP-26 and ABP-10 during EEG registration:

○ AD converter:	24 bit;	○ Low pass filter (LPF):	15; 30; 70 Hz;
○ Sampling rate:	2 kHz per channel;	○ Extra-low noise level:	0,23 $\mu$ V;
○ Allowable input DC offset voltage:	at least $\pm 300$ mV;	○ Common-mode rejection ratio:	
○ Sensitivity:	0,1-200 $\mu$ V /mm (21 stages);	powering from accumulator -	at least 140 dB
○ Input resistance:	at least 200 M $\Omega$ ;	powering from USB-adapter -	at least 120 dB
○ High pass filter (HPF):	0,016–16 Hz;	○ Weight of ABP-26: 400 g    ABP-10: 200 g	

### Contact information

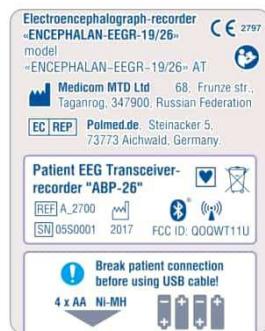
Medicom MTD Ltd.,  
Frunze Str., 68, Taganrog,  
Russia, 347900

Phones: +7 (8634) 62-62-42, -43, -44, -45  
Fax: +7 (8634) 61-54-05 (24 hours)  
e-mail: office@medicom-mtd.com

© Medicom MTD Ltd., 2019 All rights reserved.

Data given is of an informative character and can be changed without preliminary notice. To get correct specification for the equipment and additional ads, address the manufacturer or its authorized representative.

The company's products marked by **CE** are certified in the compliance with the European Directive 93/42/EEC.



Market Plate

v08-09-2020

