



**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

**ALAT KESEHATAN**

**KEMENKES RI AKL 21001917190**

Nama Dagang / Merek : **NEUROSOFT Intra Operative Monitoring System**  
Kelompok / Kelas Resiko : Elektromedik Non Radiasi / B  
Kategori Produk : Peralatan Neurologi  
Sub Kategori : Peralatan Neurologi Diagnostik  
Jenis Produk : Evoked response electrical stimulator.  
Tipe / Ukuran : Neuro - IOM  
Kemasan : Unit  
Nama Produsen / Pabrikan : NEUROSOFT LTD, Russian Federation  
Nama Pendaftar : PT. NEURO MEDIKA SEJAHTERA, DKI Jakarta  
Atas dasar lisensi dari : -

**Ketentuan**

1. Persetujuan izin edar berlaku sampai dengan 01 Agustus 2022.
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, 01 November 2019**



**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 BSR.E.



LAMPIRAN

NOMOR IZIN EDAR  
ALAT KESEHATAN  
KEMENKES RI AKL 21001917190

No.	Deskripsi	Tipe / Kode
1	Neuro-IOM 32-channel electronic unit	NS064201.012-021
2	Neuro-IOM 32-channel amplifier	NS064201.010-00.02
3	Neuro-IOM 16-channel amplifier	NS064201.010-01.02
4	USB-cable, ???	NS007103.005-01
5	Power supply cable CEE 7/7– IEC C13	Code in ERP System 217898
6	Neuro-IOM electrical stimulator pod (for 1-4 channels)	NS061201.007-12
7	Neuro-IOM electrical stimulator pod (for 5-8 channels)	NS061201.007-22
8	Neuro-IOM low current stimulator pod	NS061201.009-02.50
9	Neuro-TES electronic switch	NS070201.006-020
10	Neuro-TES electronic switch	NS070201.007-02.50
11	Neuro-IOM electronic switch	NS072201.003-02
12	Neuro-IOM acquisition pod(?)	NS064201.009-02
13	Neuro-IOM acquisition pod (B)	NS064201.009-12
14	Neuro-IOM acquisition pod (C)	NS064201.009-22
15	Neuro-IOM acquisition pod (D)	NS064201.009-32
16	Ground electrode with cable (adult) (700 mm) "GE-3"	NS990998.015
17	Ground electrode with cable (adult) (400 mm) GE-2	NS990998.006
18	Cable for disposable electrode connection with "button" clip, touch-proof , 2 m - White	NS990103.037-01.20
19	Cable for disposable electrode connection with "button" clip, touch-proof , 2 m- Green	NS990103.037-02.20
20	Cable for disposable electrode connection with "button" clip, touch-proof , 2 m - Red	NS990103.037-03.20
21	Cable for disposable electrode connection with "button" clip, touch-proof , 2 m - Black	NS990103.037-04.20
22	Cable for disposable electrode connection with "button" clip, touch-proof , 2 m - Yellow	NS990103.037-05.20
23	Cable for disposable electrode connection with "button" clip, touch-proof , 2 m - Blue	NS990103.037-06.20
24	Visual stimulator (LED goggles)	NS064302.001
25	ES detector clip "DK-1-50"	NS074354.001-50
26	Insert earphones ER3?-10	Code in ERP System 229864
27	Video cable SWA3525/10(2RCA?2RCA, 10 m)	Code in ERP System 213199
28	Video capture card	Code in ERP System 201556
29	Medical tape Article 1527-2, Transpore	Code in ERP System 228281
30	TM-630 isolation transformer	DS036.02.02.001.000 TM-630 isolation transformer:
31	TM-630 isolation transformer	NS036201.004
32	Cable IEC C13– IEC ?14	Code in ERP System 217899
33	Power cable IEC C14- Schuko type F socket	Code in ERP System 226076

Lampiran 1 dari 3 Halaman



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34	Patient simulator	NS064201.011-02
35	Cable for stimulating electrode with touch-proof connector	NS070103.002-045
36	Cable to attach transcranial electrical stimulator switch to patient simulator	NS064103.010
37	Cable to connect acquisition pod to patient simulator	NS064103.011
38	Cable to connect electrical stimulator pod to patient simulator	NS064103.012
39	Touch-proof — touch-proof cable	NS990103.038-03.05
40	Video cable	NS015103.013-01
41	Tapered Monopolar Probe "D3605"	Code in ERP System 225787
42	16-contact lightweight CABRIO connector/cable L-SRL-16BDIN	Code in ERP System 230654
43	4-contact lightweight CABRIO connector/cable L-SRL-4DIN	Code in ERP System 230656
44	8-contact lightweight CABRIO connector/cable L-SRL-8DIN	Code in ERP System 230658
45	20-contact lightweight CABRIO connector/cable L-SRL-20DIN	Code in ERP System 230660
46	T-5 trolley	NS059998.010
47	Neuro-MMG electronic unit	DS077.02.01.001.000
48	Neuro-MMG electronic unit	NS077201.001-02
49	Neuro-MMG sensor	NS077356.001
50	IOM probe handle with controls	NS061103.001
51	Monopolar stimulation probe	NS061106.003
52	Ball-tip stimulation probe	NS061106.004
53	Vagus electrode	NS064106.001
54	Dedicated keyboard "DK-01"	NS035201.007-020
55	Dedicated keyboard "DK-02"	NS035201.006-02
56	Dedicated keyboard "DK-02"	NS035201.008-020
57	Bluetooth adapter	Code in ERP System 237971
58	Footswitch	NS028353.004
59	Adjustable electro stimulatingprobe "Skate"	NS056998.001
60	Adjustable electro stimulatingprobe "Skate"	NS056998.001
61	Cup EP electrode with cable (set):	NS990998.023-01
62	Cup EP electrode with cable (set): white, 1 m	NS990106.027-01.10
63	Cup EP electrode with cable (set): green, 1 m	NS990106.027-02.10
64	Cup EP electrode with cable (set): red, 1 m	NS990106.027-03.10
65	Cup EP electrode with cable (set): black, 1 m	NS990106.027-04.10
66	Cup EP electrode with cable (set): yellow, 1 m	NS990106.027-05.10
67	Cup EP electrode with cable "EEP" (set of 8 pieces) :	NS990998.024-01
68	Cup EP electrode with cable "EEP" (set of 8 pieces) : white, 1 m	NS990106.027-01.10
69	Cup EP electrode with cable "EEP" (set of 8 pieces) : green, 1 m	NS990106.027-02.10
70	Cup EP electrode with cable "EEP" (set of 8 pieces) : red, 1 m	NS990106.027-03.10
71	Cup EP electrode with cable "EEP" (set of 8 pieces) :black, 1 m	NS990106.027-04.10
72	Cup EP electrode with cable "EEP" (set of 8 pieces) : yellow, 1 m	NS990106.027-05.10
73	Cup EP electrode with cable "EEP" (set of 8 pieces) : blue, 1 m	NS990106.027-06.10
74	Cup EP electrode with cable "EEP" (set of 8 pieces) : brown, 1 m	NS990106.027-09.10
75	Cup EP electrode with cable "EEP" (set of 8 pieces) : violet, 1 m	NS990106.027-10.10

Lampiran 2 dari 3 Halaman



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No.	Deskripsi	Tipe / Kode
76	Surface electrode "SE-1"	NS990998.001
77	Ring electrode (wide) with cable "RE-2"	NS990998.004
78	Ground electrode with cable GE-1 (pediatric) (250 mm)	NS990998.007
79	Bar electrode (adult) "BE-2"	NS990998.029
80	Bar electrode (pediatric) "BE- 1"	NS990998.028
81	Stimulating bar electrode SBE-2 (adult)	NS990998.009
82	Adapter for needle electrode connection "D60451"	NS990103.044
83	Cable for disposable electrodes connection with Alligator clip - red	NS990103.027-03.02
84	Cable for disposable electrodes connection with Alligator clip - black	NS990106.027-04.02
85	Measuring reel	Code in ERP System 224422/219756
86	Marker pen	Code in ERP System 224039
87	Headphones for EMG playback SVEN SPS-604	Code in ERP System 230485
88	Y-adapter	NS006103.019
89	Auditory stimulator for EP(headphones) "TDH-39"	NS032305.009
90	Patient button "USB-2"	NS028201.009-001
91	SVGA extension cable	Code in ERP System 201808
92	Monitor LCD 18,5"	Code in ERP System 230275
93	Neuro-MEP low current electrical stimulator control unit	NS024201.019
94	Adapter for insert earphones (3.5 stereo -> 2x6.3 mono)	NS032103.004
95	Adapter for bipolar forceps	NS047103.002
96	Dr. Kyrgyzov electrical stimulator electronic unit	NS047201.012-020
97	Patient Simulator electronic unit	NS064201.011-02
98	-IOM 64-channel electronic unit + amplifier	NS064201.012-021+NS06420 1.010-00.02
99	Lodgement	NS064212.005
100	Neuro-TES sync cable for third party equipment	NS070103.001
101	ES detector	NS074201.001-01
102	Neuro-MMG package	NS077901.001
103	Transportation bag	NS216047
104	Battery charger GP	NS217175
105	4-to-1 adapter	NS990103.052
106	8-to-1 adapter	NS990103.057

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

Jakarta, 01 November 2019



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