



**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 21603027318

Nama Dagang / Merek : **INSPITAL Electrosurgical Unit**
Kelompok / Kelas Resiko : Elektromedik Non Radiasi / C
Kategori Produk : Peralatan Bedah Umum dan Bedah Plastik
Sub Kategori : Peralatan Bedah
Jenis Produk : Electrosurgical cutting and coagulation device and accessories.
Tipe / Ukuran : NS02.00 TOUCH/Terlampir
Kemasan : Unit
Nama Produsen / Pabrikan : OLTRE MEDIKAL ELEKTRONIK A.S., Turkey
Untuk INSPITAL MEDIKAL TEKNOLOGI A.S., Turkey
Nama Pendaftar : PT. MEGAH ALKESINDO, DKI Jakarta
Atas dasar lisensi dari : -

Ketentuan

1. Persetujuan izin edar berlaku sampai dengan 10 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, 29 November 2020



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 21603027318

No.	Deskripsi	Tipe / Kode
1	Finger-Switch Pencil Reusable Cut and Coagulation Reusable Pencil.	NS30.11
2	Finger-Switch Pencil Disposable Cut and Coagulation Reusable Pencil.	NS30.10
3	Silicone Bipolar Cable 3.0 M	NS30.12
4	Silicone European Bipolar Cable 3.0 M	NS30.13
5	Silicone Diathermy Cable 3.0 M	NS30.14
6	Patient Return Cable 3.0 M	NS30.15
7	Ball type Electrode Dia. 2mm, 7 cm, straight, reusable	NS30.40
8	Ball type Electrode Dia. 3mm, 7 cm, straight, reusable	NS30.42
9	Ball type Electrode Dia. 4mm, 7 cm, straight, reusable	NS30.44
10	Ball type Electrode Dia. 5mm, 7 cm, straight, reusable	NS30.46
11	Ball type Electrode Dia. 3mm, 13 cm, straight, reusable	NS30.48
12	Ball type Electrode Dia. 5mm, 13 cm, straight, reusable	NS30.49
13	Ball type Electrode Dia. 2mm, 7 cm, curved, reusable	NS30.41
14	Ball type Electrode Dia. 3mm, 7 cm, curved, reusable	NS30.43
15	Ball type Electrode Dia. 5mm, 7 cm, curved, reusable	NS30.45
16	Ball type Electrode Dia. 7mm, 7 cm, curved, reusable	NS30.47
17	Circle & Loop Type Electrodes Circle Loop Electrode 6mm, reusable	NS30.55
18	Circle & Loop Type Electrodes Circle Loop Electrode 8mm, reusable	NS30.56
19	Circle & Loop Type Electrodes Circle Loop Electrode 4mm, reusable	NS30.57
20	Circle & Loop Type Electrodes D Loop Electrode 20x20 cm, reusable	NS30.50
21	Circle & Loop Type Electrodes D Loop Electrode 20x20 cm, reusable	NS30.51
22	Circle & Loop Type Electrodes Square Loop Electrode 20x20 cm, reusable	NS30.52
23	Conization Electrode Conization Electrode 13x15 mm, reusable	NS30.53
24	Needle Type Electrodes Needle Electrode 13cm, straight, reusable	NS30.32
25	Needle Type Electrodes Needle Electrode 7cm, straight, reusable	NS30.30
26	Needle Type Electrodes Needle Electrode 7cm, curved, reusable	NS30.31
27	Needle Type Electrodes Fine Needle Electrode 7cm, straight, reusable	NS30.33
28	Needle Type Electrodes Needle Electrode 7cm, straight, disposable, non-stick	NS30.34
29	Needle Type Electrodes Needle Electrode 7cm, straight, disposable	NS30.35
30	Needle Type Electrodes Bipolar Electrode, 20 cm, angled, reusable	NS30.63
31	Blade Type Electrodes Bipolar Electrode, 19 cm, angled 45, reusable	NS30.64
32	Blade Type Electrodes Bipolar Electrode, 20 cm, straight, reusable	NS30.65
33	Blade Type Electrodes Blade Electrode 15cm, straight, reusable	NS30.22
34	Blade Type Electrodes Blade Electrode 7cm, straight, reusable	NS30.20
35	Blade Type Electrodes Blade Electrode 7cm, curved, reusable	NS30.21

Lampiran 1 dari 2 Halaman



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No.	Deskripsi	Tipe / Kode
36	Blade Type Electrodes Blade Electrode 7cm, straight, disposable, non-stick	NS30.23
37	Blade Type Electrodes Blade Electrode 16cm, straight, disposable, non-stick	NS30.24
38	Europen Bipolar Forceps Dia. 2mm, 20 cm, Bayonet, reusable	NS31.40
39	Europen Bipolar Forceps Dia. 1mm, 20 cm, Bayonet, reusable	NS31.41
40	Europen Bipolar Forceps Dia. 1mm, 20 cm, angled, reusable	NS31.42
41	Europen Bipolar Forceps Dia. 1mm, 20 cm, straight, reusable	NS31.43
42	Europen Bipolar Forceps Dia. 0.7mm, 11.5cm, Jeweler, reusable	NS31.44
43	Europen Bipolar Forceps Dia. 1mm, 20 cm, straight, reusable, non-stick	NS31.45
44	Europen Bipolar Forceps Dia. 2mm, 20 cm, straight, reusable	NS31.46
45	Scissors & Artery Sealer Bipolar Artery Sealer , 16cm, reusable, non-stick	NS31.70
46	Scissors & Artery Sealer Bipolar Artery Sealer , 22cm, reusable, non-stick	NS31.71
47	Scissors & Artery Sealer Bipolar Scissor, 18cm, curved, reusable	NS31.72
48	Scissors & Artery Sealer Bipolar Artery Sealer, 26cm, reusable, non-stick	NS31.73
49	Diathermy Instruments Wilson Hey Forcept 17.8cm, monopolar male 4mm conn., reusable	NS31.80
50	Diathermy Instruments Artery Forcept 17.8cm, monopolar male 4mm conn., reusable	NS31.81
51	Patient Return Plates Monopolar Patient Plate, disposable	NS30.05
52	Patient Return Plates Bipolar Patient Plate, disposable	NS30.09
53	Patient Return Plates Monopolar Patient Plate, 16x12 cm, reusable	NS30.06
54	Accessories Holster (Electrodes&Pencils)	NS31.01
55	Accessories Tip Cleaner (Electrodes&Pencils)	NS31.02
56	Accessories Bipolar Adaptor	NS31.03
57	Waterproof Foot Pedals Double Water-Proof Foot-Switch	NS30.08
58	Waterproof Foot Pedals Single Water-Proof Foot-Switch	NS30.07

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

Jakarta, 29 November 2020



KEMENTERIAN
KESEHATAN
REPUBLIK
INDONESIA

Ditandatangani Secara Elektronik Oleh :

a.n Direktur Jenderal
Direktur Penilaian Alat Kesehatan dan PKRT

Dr. IGM. Wirabrata, Apt
NIP. 19751206 200312 1 001



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INSPIRAL

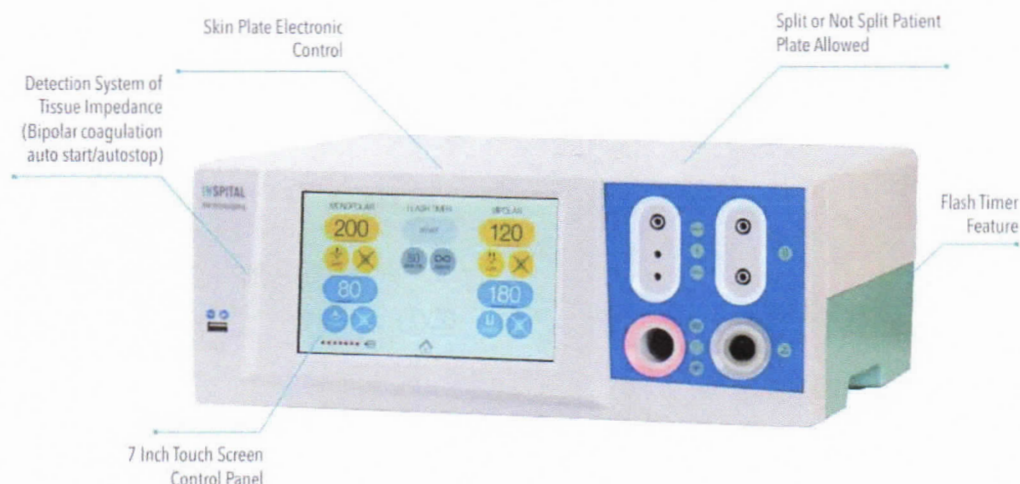
Electrosurgical Device



Operating Together for Life



Inspital NS02.00 is new generation of electrosurgery devices with microprocessor control and 7" touchscreen control panel. It is suitable to use in emergencies and minor or major surgeries



General Features

- Device Modes : Monopolar (Cut-Coag Mode) / Monopolar (Coag Mode) / Bipolar (Cut-Coag Mode) Vessel Sealing L1, L2, L3 shape
- Voice Alert Feature : 40-70 dB Adjusted in the range-Volume control which depends output power
- Device Use Language : Turkish / English
- Duty - Cycle : Intermittent 10 seconds emission / 30 seconds of pause
- Classification : Class IIb (MDD 93/42 EEC)
- Standards : EN 60601-1, EN 60601-1-2, EN 60601-2-2
- Packaging Documentation : CE
- Fuse : 2xT 10AL, 250V
- Class : I CF
- Duty - Cycle : Intermittent 10 seconds emission / 30 seconds of pause
- Inlet Voltage : 100-240 VAC / 50-60 Hz
- Input Voltage : 750 VA
- Insurance Types : 115 VAC(2xT 10A GLASS FUSE)- 230VAC(2xT 5A GLASS FUSE)
- Electrical Protection Class : Class I, CF
- Patients Electrical Circuit : F
- Menu / Screen Features : Touch Screen

Features

- Bipolar Coagulation Function
- Pure and Blend Cutting, Superficial and Deep Coagulation
- Adjustable Power and Sound Levels
- Automatic System Control At Each Start Up
- Compatibility with Foot Switch and Manual Use

Cutting & Coagulation Options

- Can be used in all surgery branches like general surgery, orthopedics, urology, cardiovascular surgery and neurosurgery with 200 and maximum output power options
- Advanced technology with automatic self-test feature at each start up informs the user about device functions
- Blend cutting modes with pure cutting and at 5 different modulation levels
- Wide, Rapid and non-contact coagulation with spray coagulation mode
- Safe hemostasis by superficial and deep contact coagulation modes

Patient Safety System & Memory

- Contact impedance between patient body and return electrode is continuously watched by Skin Plate Electronic Control (SPEC)
- 50 different usage modes can be stored in the memory by preprogramming method, offering possibility for immediate call.

Vessel Sealing Function

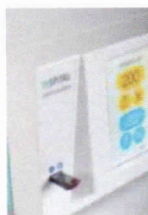
- Effective and safe sealing process in laparoscopy, open surgery veins and muscles bundles thanks to the vessel sealing function integrated onto cautery device.

Argon Coagulation

- If Argon coagulation is needed, Argon Plasma Coagulation Device can be easily added to the electrosurgical unit in use.
- Auto-detection of argon coagulator equipment
- Automatic communication with electrosurgical devices and activation by a single cable connection

TECHNICAL SPECIFICATIONS

- Maximum Output Power CUT : 200 W - 300 Ω
- Maximum Output Power BLEND (CUT/ COAG) : 150 W - 300 Ω
- Maximum Output Power FORCED COAG : 150 W - 200 Ω
- Maximum Output Power SOFT COAG : 100 W - 200 Ω
- Maximum Output Power BIPOLAR PURE CUT : 120 W - 50 Ω
- Max Output Power BIPOLAR COAG : 100 W - 50 Ω
- Max Output Power BIPOLAR SEALING : 200 W - 50 Ω
- Max Output Power BIPOLAR TUR (CUT) : 120 W - 50 Ω
- Selectable Input Voltage : 100 - 240 VAC / 50-60 Hz
- Inlet Power : 750 VA
- Working Frequency : 360 Hz



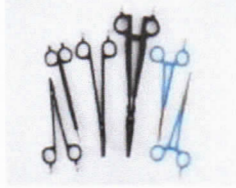
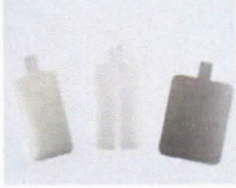
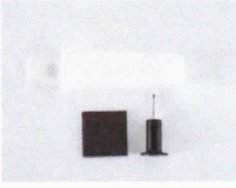
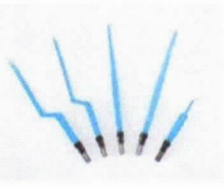
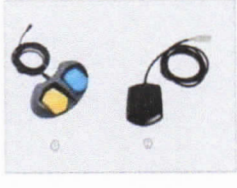
USB support



One Touch
Many Surgeries



ELECTROSURGICAL ACCESSORIES

	Finger-Switch Pencil Reusable NS30.11		Finger-Switch Pencil Disposable NS30.10
	GeSilicone Bipolar Cable 3.0 M NS30.12 Instrument Connector : Ethicon Generator Connector: 4mm Banana Plug		Silicone Europen Bipolar Cable 3.0 M NS30.13 Instrument Connector : Europen Flat Plug Generator Connector: 4mm Banana Plug
	Silicone Diathermy Cable 3.0 M : NS30.14 Instrument Connector : 4mm Male Fitting (Europen Diathermy) Generator Connector : 4mm Banana Plug		Patient Return Cable 3.0 M NS30.15
	Ball Type Electrodes Dia. 2mm, 7 cm, straight, reusable NS30.40 Dia. 3mm, 7 cm, straight, reusable NS30.42 Dia. 4mm, 7 cm, straight, reusable NS30.44 Dia. 5mm, 7 cm, straight, reusable NS30.46 Dia. 3mm, 13 cm, straight, reusable NS30.48 Dia. 5mm, 13 cm, straight, reusable NS30.49 Dia. 2mm, 7 cm, curved, reusable NS30.41 Dia. 3mm, 7 cm, curved, reusable NS30.43 Dia. 4mm, 7 cm, curved, reusable NS30.45 Dia. 5mm, 7 cm, curved, reusable NS30.47		Blade Type Electrodes Bipolar Electrode, 20 cm, angled, reusable NS30.63 Bipolar Electrode, 19 cm, angled 45, reusable NS30.64 Bipolar Electrode, 20 cm, straight, reusable NS30.65
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	Europen Bipolar Forceps Dia. 2mm, 20 cm, Bayonet, reusable NS31.40 Dia. 1mm, 20 cm, Bayonet, reusable NS31.41 Dia. 1mm, 20 cm, angled, reusable NS31.42 Dia. 1mm, 20 cm, straight, reusable NS31.43 Dia. 0.7mm, 11.5cm, Jeweler, reusable NS31.44 Dia. 1mm, 20 cm, straight, reusable, non-stick NS31.45 Dia. 2mm, 20 cm, straight, reusable NS31.46		Waterproof Foot Pedals Double Water-Proof Foot-Switch NS30.08 Single Water-Proof Foot-Switch NS30.07

INSPITAL

Manufacture :

OLTRE MEDIKAL VE ELEKTRONIK CIHAZLAR SAN VE TIC A.S.
Karaoglan Mah. Kümeevler Cad No:745 , Gölbaşı, Ankara, Turkey

untuk

INSPITAL MEDIKAL TEKNOLOJİ A.S.,
Karaoglan Mah. Kümeevler Cad No:745 , Gölbaşı, Ankara, Turkey

REG. NO : KEMENKES RI AKL.....

PT MEGAH ALKESINDO

Jl. Rawa Bambu Raya No. 15 F-H

Pasar Minggu Jakarta Selatan 12520 Indonesia

Phone : +62 21 788 77990 (Hunting) Fax : +62 21 788 47144

Email : info@megahalkesindo.com Website : www.megahalkesindo.com



Marking Plate

INSPITAL Electrosurgical Unit

Type : NS02.00TOUCH

INSPITAL

INSPITAL MEDİKAL TEKNOLOJİ A.Ş.
Karaoğlu Mah. Kümeevler Cad. No:745 Gölbaşı-Ankara TURKEY
03126190222 F.03126190225 www.inspital.com

model: NS02.00 TOUCH
duty cycle ON 10 s - OFF 30 s

class I CF
IP 40

MONOPOLAR

CUT 200 W - 300 Ω - 360 kHz
COAG 150 W - 200 Ω - 360 kHz

BIPOLAR

CUT 200 W - 50 Ω - 360 kHz
COAG 200 W - 50 Ω - 360 kHz

WARNING: DO NOT OPEN. FOR
TECHNICAL SERVICE CONTACT
QUALIFIED STAFF ONLY.

DİKKAT: CİHAZA SADECE YETKİLİ
SERVİS MÜDAHALE EDEBİLİR.

Ensure that the correct voltage is
selected before connecting to the
mains power supply

ŞEBEKEYE BAĞLAMADAN ÖNCE DOĞRU
VOLTAJIN SEÇİLDİĞİNE EMİN OLUN.

100 - 240 V~ 3A
50/60 HZ
750 VA
FUSE 2X T10AL 250V



ULTR Medikal ve Elektronik Cihazları San. ve Tic. A.Ş.
Karaoğlu Mah. Kümeevler Cad. No: 745
Gölbaşı-Ankara TÜRKİYE 03126190222
F.03126190225 www.ultr.com.tr



SN

582 0000001 2018



CE
1984



F



Manufacture :

OLTRE MEDİKAL VE ELEKTRONİK CİHAZLAR SAN VE TİC A.Ş.
Karaoğlu Mah. Kümeevler Cad No:745 ,
Gölbaşı, Ankara, Turkey

untuk

INSPITAL MEDİKAL TEKNOLOJİ A.Ş.,
Karaoğlu Mah. Kümeevler Cad No:745 ,
Gölbaşı, Ankara, Turkey

Reg No KEMENKES RI AKL

Distributor:

PT. Megah Alkesindo
Jl Rawa Bambu Raya No. 15 F-H
Pasar Minggu, Jakarta Selatan
INDONESIA 12520

