



**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 21603027319

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 : NS01.60/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.



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LAMPIRAN

NOMOR IZIN EDAR
ALAT KESEHATAN
KEMENKES RI AKL 21603027319

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 Europen 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 ElectrodesFine 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



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



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

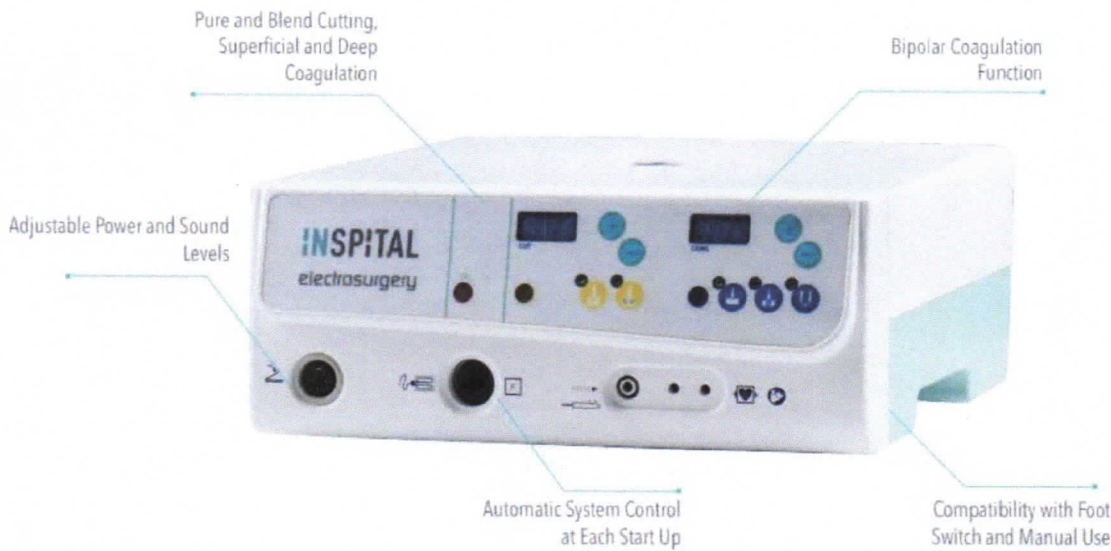
Electrosurgical Device



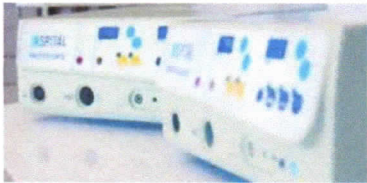
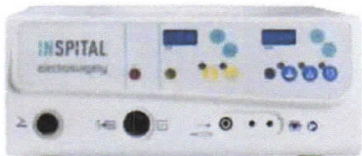
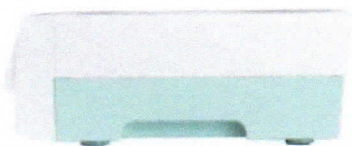
Operating Together for Life



NS01.60 is designed for minor and medium surgery procedures. It has microprocessor controlled wide range of monopolar and bipolar usage with 160 W max output power



- General Features**
 - Max. Output Power : 160 Watt (Cut Mode)
 - Device Modes : Monopolar (Cut-Coag Mode) / Bipolar (Cut-Coag Mode)
 - Voice Alert Feature : 55-75 dB Adjusted in the range-Volume control which depends output power
 - Classification : Class IIb (MDD 93/42 EEC)
 - Standards : EN 60601-1, EN 60601-1-2, EN 60601-2-2
 - Packaging Documentation : CE
 - Device Use Language : Turkish / English
- Electrical Properties**
 - Inlet Voltage : 115-230 VAC / 50-60 Hz
 - Input Voltage : 350 VAC
 - Insurance Types : 115 VAC(T 6,3A GLASS FUSE)-230VAC(T 3,15 A GLASS FUSE)
 - Electrical Protection Class : Class I, CF
 - Patients Electrical Circuit : F

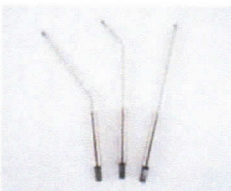
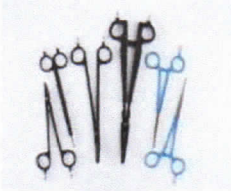
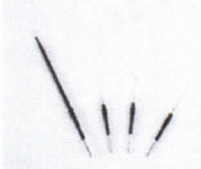
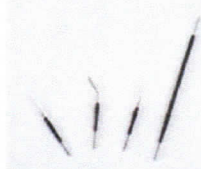
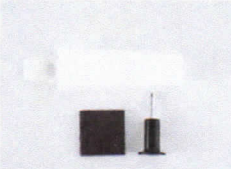
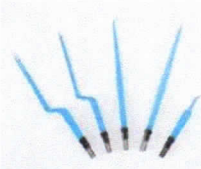


Technical Spesifications

Maximum Output Power Pure CUT	: 160 W - 250 Ω
Maximum Output Power CUT	: 120 W - 200 Ω
Maximum Output Power FORCED COAG	: 100 W - 150 Ω
Maximum Output Power SOFT COAG	: 80 W - 100 Ω
Maximum Output Power BIPOLAR	: 60 W - 100 Ω
Working Frequency	: 600 kHz
Selectable Input Voltage	: 115 - 230 V AC / 50-60 Hz
Dimensions	: 254x288x104 mm



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 Euopen Bipolar Cable 3.0 M NS30.13 Instrument Connector : Euopen Flat Plug Generator Connector: 4mm Banana Plug
	Silicone Diathermy Cable 3.0 M : NS30.14 Instrument Connector : 4mm Male Fitting (Euopen 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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	Blade Type Electrodes Blade Electrode 15cm, straight, reusable NS30.22 Blade Electrode 7cm, straight, reusable NS30.20 Blade Electrode 7cm, curved, reusable NS30.21 Blade Electrode 7cm, straight, disposable, non-stick NS30.23 Blade Electrode 16cm, straight, disposable, non-stick NS30.24		Accessories Holster (Electrodes&Pencils) NS31.01 Tip Cleaner (Electrodes&Pencils) NS31.02 Bipolar Adaptor NS31.03
	Euopen 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

INSPI TAL

Manufacture :

OLTRE MEDIKAL VE ELEKTRONIK CIHAZLAR SAN VE TIC A.S.
Karaoglan Mah. Kümeevler Cad No:745 Gölbaşı / AnkaraTurkey
untuk
INSPI TAL 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 : NS01.60

INSPITAL

INSPI TAL MEDİKAL TEKNOLOJİ A.Ş.

Karaoğlan Mah. Kümeevler Cad. No:745 Gölbaşı-Ankara TURKEY

03126190222 F.03126190225 www.inspital.com

CUT	FREQUENCY	MODEL
160 W → 250 Ω	600 KHz	NS01.60
BLEND	FREQUENCY	CLASS
120 W → 200 Ω	600 KHz	I CF IP 40
FORCED COAG	FREQUENCY	DUTY CYCLE
100 W → 150 Ω	600 KHz	ON: 10 s / OFF: 30 s
SOFT COAG	FREQUENCY	WARNING NO OPERATOR SERVICEABLE PARTS INSIDE, REFER SERVICING TO QUALIFIED PERSONNEL
80 W → 100 Ω	600 KHz	
BIPOLAR	FREQUENCY	
60 W → 100 Ω	600 KHz	ENSURE THAT THE CORRECT VOLTAGE IS SELECTED BEFORE CONNECTING TO THE MAINS POWER SUPPLY

SN

3490000698



2019



OLTRE Medikal ve Elektronik Cihazlar San. ve Tic. A.Ş.
Karaoğlan Mah. Kümeevler Cad. No:745
Gölbaşı-Ankara TURKEY 03126190222 F.03126190225
www.oltre.com.tr



F



1984



CE



115 V ~ - 50/60 Hz 5A
350 VA - FUSE 2 X T6.3AL 250V

230 V ~ - 50/60 Hz 2.5A
350 VA - FUSE 2 X T3.15AL 250V

Manufacture :

OLTRE MEDİKAL VE ELEKTRONİK CİHAZLAR SAN. VE TİC A.Ş.
Karaoglan Mah. Kümeevler Cad No:745
Gölbaşı / AnkaraTurkey
untuk
INSPITAL MEDİKAL TEKNOLOJİ A.Ş.
Karaoglan Mah. Küme Evleri No:745
Gölbaşı / AnkaraTurkey

Distributor :

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

REG KEMENKES RI AKL.....