



**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 21603027320**

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 : NS04.00/Terlampir  
Kemasan : Unit  
Nama Produsen / Pabrikan : OLTRE MEDIKAL VE ELEKTRONIK CIHAZLAR SAN. VE. TIC. A.S.,  
Turkey  
Untuk INSPITAL MEDIKAL TEKNOLOJI 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 21603027320

| 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     |





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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

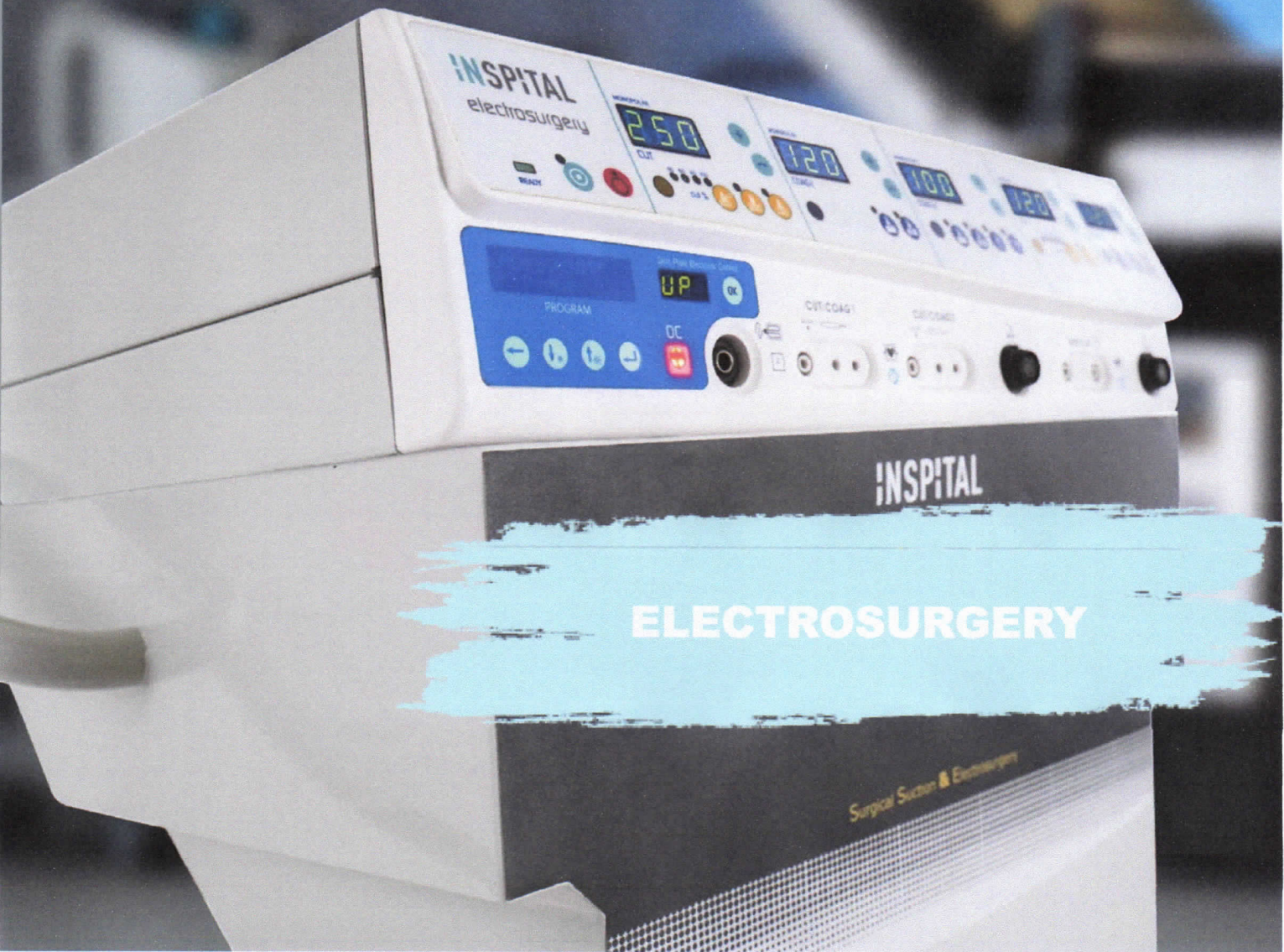


Catatan:

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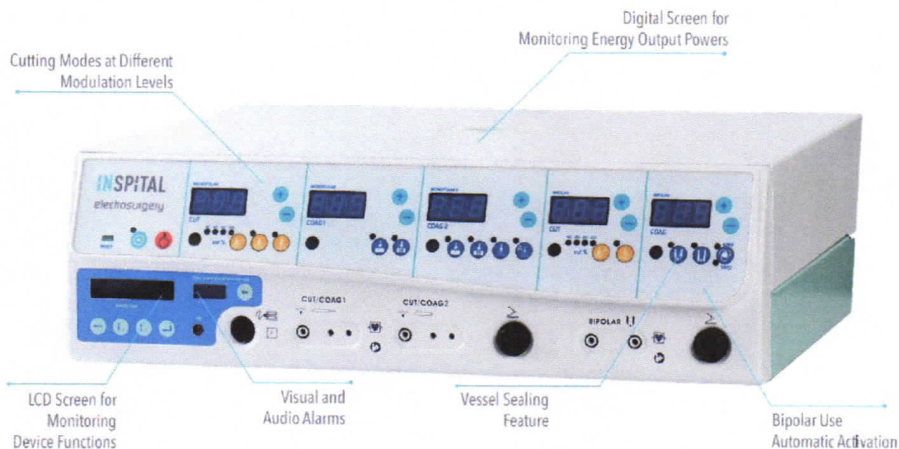


# INSPIRAL





Inspital NS04.00 electrosurgical devices can be used in all type of surgeries like general surgery, orthopedics, urology, cardiovascular surgery and neurosurgery with high performance and micro operation technology.



#### Menu / Screen Features

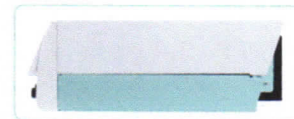
- Output power control
- Control of time for giving current
- High-temperature control
- Internal control of the device parameters
- Device automatically performs all Control

#### 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

#### Control Characteristics

- Bipolar and monopolar matter cutting and different volume output in coagulation
- Foot switch alarm(when you push cutting and coagulation simultaneously, the device stops alarm and foot switch gives alarm)



#### 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
- Classification : Class IIb (MDD 93/42 EEC)
- Standards : EN 60601-1, EN 60601-1-2, EN 60601-2-2
- Packaging Documentation : CE

#### Electrical Properties

- Inlet Voltage : 115-230 VAC / 50-60 Hz
- Input Voltage : 1000 VAC
- Insurance Types : 115 VAC(2xT 10A GLASS FUSE)-230VAC(2xT 5A GLASS FUSE)
- Electrical Protection Class : Class I, CF
- Menu / Screen Features : LCD Screen
- Data / menu display : Display (Seven Segment) screen
- Display screen : 5 level screen brightness
- Current date and clock feature as day,month,year

#### TECHNICAL SPECIFICATIONS

| Monopolar                               |                       | Bipolar                                 |                      |
|-----------------------------------------|-----------------------|-----------------------------------------|----------------------|
| • Maximum Output Power Pure CUT         | 400 W - 300 $\Omega$  | • Maximum Output Power Pure CUT         | 120 W - 50 $\Omega$  |
| • Maximum Output Power Cut-Coag CUT80%  | 300 W - 300 $\Omega$  | • Maximum Output Power Cut-Coag CUT80%  | 100 W - 50 $\Omega$  |
| • Maximum Output Power Cut-Coag CUT60%  | 250 W - 300 $\Omega$  | • Maximum Output Power Cut-Coag CUT60%  | 100 W - 50 $\Omega$  |
| • Maximum Output Power Cut-Coag CUT40%  | 200 W - 300 $\Omega$  | • Maximum Output Power Cut-Coag CUT40%  | 60 W - 50 $\Omega$   |
| • Maximum Output Power Cut ENHANCED     | 250 W - 300 $\Omega$  | • Maximum Output Power Cut-coag BLEND   | 100 W - 150 $\Omega$ |
| • Maximum Output Power Cut-coag BLEND   | 250 W - 300 $\Omega$  | • Maximum Output Power Coag COAG        | 120 W - 50 $\Omega$  |
| • Maximum Output Power Coag SPEEDY      | 120 W - 500 $\Omega$  | • Vessel Sealing Feature                | 200 W - 50 $\Omega$  |
| • Maximum Output Power Coag DEEP        | 120 W - 200 $\Omega$  | • Working Frequency Monopolar / Bipolar | 425 kHz / 525 kHz    |
| • Maximum Output Power Coag SPRAY       | 100 W - 2000 $\Omega$ | • Dimensions (WxLxH)                    | 470 x 380 x 150      |
| • Maximum Output Power Coag SPRAY ARGON | 100 W - 2000 $\Omega$ |                                         |                      |



Marking Plate

INSPITAL Electrosurgical Unit

Type : NS04.00

min

max

SPEAKER  
VOLUME

ARGON UNIT  
CONNECTION

For only Technical Service

INSPI TAL

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

| FUNCTION            | MAX POWER | LOAD   | FREQUENCY | MODEL                 |
|---------------------|-----------|--------|-----------|-----------------------|
| PURE CUT            | 400 W     | 300 Ω  | 425 kHz   | NS04.00               |
| ENHANCED CUT        | 250 W     | 300 Ω  | 425 kHz   |                       |
| BLEND CUT           | 250 W     | 300 Ω  | 425 kHz   |                       |
| SPEEDY COAG         | 120 W     | 500 Ω  | 425 kHz   |                       |
| DEEP COAG           | 120 W     | 200 Ω  | 425 kHz   |                       |
| SPRAY COAG          | 100 W     | 2000 Ω | 425 kHz   | DUTY CYCLE            |
| BIPOLAR CUT         | 120 W     | 50 Ω   | 525 kHz   |                       |
| BIPOLAR BLEND       | 120 W     | 150 Ω  | 525 kHz   |                       |
| BIPOLAR COAG        | 120 W     | 50 Ω   | 525 kHz   |                       |
| VESSEL SEALING      | 200 W     | 50 Ω   | 525 kHz   | ON: 10 s<br>OFF: 30 s |
| CLASS               |           |        |           | I CF<br>IP 40         |
| SN 580 0000001 2018 |           |        |           |                       |

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

WARNING : NO OPERATOR SERVICEABLE PARTS INSIDE  
REFER SERVICING TO QUALIFIED PERSONNEL

ENSURE HAT THE  
CORRECT VOLTAGE  
IS SELECTED  
BEFORE  
CONNEC ING  
TO THE MAINS  
POWER SUPPLY

MAIN POWER

230 V~ - 50/60 Hz  
3.5 A 1000 VA  
FUSE 2 X T5AL 250V

115 V~ - 50/60 Hz  
7 A 1000 VA  
FUSE 2 X T10AL 250V

Manufacture :  
OLTRE MEDİKAL VE ELEKTRONİK CİHAZLAR SAN VE TİC A.Ş.  
Karaoğlan Mah. Kümeevler Cad No:745 , Gölbaşı, Ankara, Turkey  
untuk  
INSPITAL MEDİKAL TEKNOLOJİ A.Ş.,  
Karaoğlan Mah. Kümeevler Cad No:745 , Gölbaşı, Ankara, Turkey

Distributor :  
PT Megah Alkesindo  
Jl Rawa Bambu Raya No. 15 F-H  
Pasar Minggu, Jakarta Selatan  
INDONESIA 12520  
REG KEMENKES RI AKL .....

