



**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 21603025163**

Nama Dagang / Merek : **INSPITAL Operating Table**  
Kelompok / Kelas Resiko : Elektromedik Non Radiasi / B  
Kategori Produk : Peralatan Bedah Umum dan Bedah Plastik  
Sub Kategori : Peralatan Bedah  
Jenis Produk : Operating tables and accessories with modification  
Tipe / Ukuran : Electro-Hydraulic, OT80.20  
Kemasan : Unit  
Nama Produsen / Pabrikan : 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, 09 September 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 21603025163

| No. | Deskripsi                                             | Tipe / Kode |
|-----|-------------------------------------------------------|-------------|
| 1   | Orthopedic Traction Set                               | OT60.90     |
| 2   | Neurosurgery Head Rest with Pin & Horseshoe Head Rest | OT60.80 SET |
| 3   | Cross Bar Adapter                                     | OT60.82     |
| 4   | Arthroscopy Shoulder Support                          | OT60.76     |
| 5   | Leg Positioning Boot                                  | OT60.77     |
| 6   | Arm Support                                           | OT60.01     |
| 7   | Strap                                                 | OT60.02     |
| 8   | Arm Adaptor                                           | OT60.34     |
| 9   | Anaesthesia Screen, Fixed Size                        | OT60.03     |
| 10  | Body Fixing Strap                                     | OT60.07     |
| 11  | IV Stand, 2 hooks                                     | OT60.05     |
| 12  | IV Stand, 4 hooks                                     | OT60.06     |
| 13  | Anaesthesia Screen, Adjustable                        | OT60.04     |
| 14  | Patient Heating System                                | OT60.71     |
| 15  | Geopel Leg Rest                                       | OT60.08     |
| 16  | Irrigation Bowl, Rectangle Form                       | OT60.11     |
| 17  | Irrigation Bowl With Drainage, Rectangle Form         | OT60.12     |
| 18  | Irrigation Bowl With Drainage, Round Form             | OT60.13     |
| 19  | Waste Bin                                             | OT60.14     |
| 20  | Clamp, Easy Fix                                       | OT60.15     |
| 21  | Clamp                                                 | OT60.16     |
| 22  | Clamp, Rotatable                                      | OT60.17     |
| 23  | Clamp, Rotatable                                      | OT60.18     |
| 24  | Shoulder Support                                      | OT60.09     |
| 25  | Lateral Support                                       | OT60.10     |
| 26  | Foot Support Plate                                    | OT60.19     |
| 27  | Proctology Set                                        | OT60.20     |
| 28  | Ophtalmologic Head and Wrist Support                  | OT60.21     |
| 29  | Weinberger Hand Traction Set                          | OT60.22     |
| 30  | Leg Strap                                             | OT60.23     |
| 31  | Meniscus Positioning Roll                             | OT60.24     |
| 32  | Knee Arthroscopy Support                              | OT60.72     |
| 33  | Carbonfiber Extension Board                           | OT60.73     |
| 34  | Sliding Handles                                       | OT60.25     |
| 35  | Arm Surgery Extension                                 | OT60.26     |
| 36  | Hand Control Unit                                     | OT60.27     |
| 37  | Foot Switch                                           | OT60.28     |
| 38  | Support for Hand Control Unit                         | OT60.29     |
| 39  | X-Ray Cassette Support                                | OT60.30     |

Lampiran 1 dari 2 Halaman



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.  
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| No. | Deskripsi                           | Tipe / Kode |
|-----|-------------------------------------|-------------|
| 40  | X-Ray Cassette Tray                 | OT60.31     |
| 41  | Accessory Trolley                   | OT60.32     |
| 42  | Orthopedic Traction Set Trolley     | OT60.33     |
| 43  | Step, Double                        | BS10.20     |
| 44  | Step, Single                        | BS10.10     |
| 45  | Wilson Frame Set                    | OT60.61     |
| 46  | Gel Mattress, Adult                 | OT60.62     |
| 47  | Gel Mattress, Pediatric             | OT60.63     |
| 48  | Head Rest, Gel, Adult               | OT60.50     |
| 49  | Head Rest, Gel, Pediatric           | OT60.51     |
| 50  | Head Rest, PU, Adult                | OT60.40     |
| 51  | Horseshoe Head Rest, Gel, Adult     | OT60.52     |
| 52  | Horseshoe Head Rest, Gel, Pediatric | OT60.53     |
| 53  | Horseshoe Head Rest, PU, Adult      | OT60.41     |
| 54  | Arm Rest, Gel                       | OT60.54     |
| 55  | Prone Head Support, Gel             | OT60.57     |
| 56  | Chest Roll, Gel, Adult              | OT60.55     |
| 57  | Chest Roll, PU                      | OT60.42     |
| 58  | Foot Wrist Support, Gel             | OT60.58     |
| 59  | Foot Wrist Support, PU              | OT60.43     |
| 60  | Heel Support, Gel                   | OT60.59     |
| 61  | Lateral Positioner, Gel             | OT60.60     |
| 62  | Chest Roll, Gel, Pediatric          | OT60.56     |

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

Jakarta, 09 September 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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OPERATING TABLE



Inspital operating tables are designs which can be adjusted to get positionssuitable for carrying out all surgical operations, produced by consi ering the patient and user requirements and maximize the operational efficiency





Feature



Functional Design & Wide Range of Accessory Options

- Modular design taking shape by different surgical operations with high stability
- Solutions ensuring to reach the position required by any kind of surgical operations with its wide range of accessory options



Optimal Clearance In Surgical Area

- Maximum surgical area visibility with its kidney elevator, integrated on the table and adjustable up to 1500(70 mm)



T-Base Specifications

- T-Base enables table optimal approach for the surgical team and equipment
- ABS Material with break and corrosion resistance
- Subbase is made of ABS plastic material. Wall thickness is 5 mm.



Different Mattress Options

- Compact material table top with high X-ray permeability that allows high-quality image reception
- Visco or polyurethane mattress options that ensure the patient's comfort by taking its body shape, thus preventing decubitus prophyllaxis



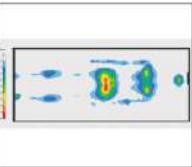
Sliding

- Image reception ability in a wide area without disturbing the sterile environment by its sliding feature within 300 mm on horizontal plane



Easy Approach for C-Arm

- Complete access to all table areas and its X-ray permeable table top allow high image quality
- Suitable base structure for easy access and approach of the C-arm scopy and surgical microscopes



Optimum Mattress Performance

- Inspital operating table mattresses are designed and manufactured according to the Pressure Mapping test results.



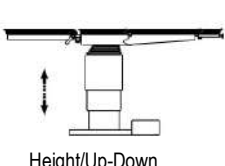
Accessory Positioning

- Stainless steel rail attachment system integrated on both sides of the table, enabling accessory mounting without removing existing accessories

TECHNICAL FEATURES

|                          |                   |                           |                            |                       |                           |
|--------------------------|-------------------|---------------------------|----------------------------|-----------------------|---------------------------|
| • Sliding Movement       | : 300 mm          | • Width x Length          | : 560x2200 mm              | • Voltage             | : 220-240V AC 50/60Hz     |
| • Lateral Tilt Movement  | : + 20° / - 20°   | • Height (min)            | : 595 mm                   | • Working Voltage     | : 24 VDC                  |
| • Back Rest Movement     | : + 80° / - 45°   | • Height (max)            | : 1035 mm                  | • Fuse Type           | : 2 x 1,25A Glass Fuse    |
| • Trendelenburg          | : + 30°           | • Mattress Thickness      | : 70 mm                    | • Battery Duration    | : 30 Full Movement        |
| • Reverse Trendelenburg  | : - 30°           | • Castors Diameter        | : Ø 100 mm                 | • Battery type        | : 2 x 12 V                |
| • Leg Rest Up / Down     | : + 30° / - 80°   | • Max Patient Weight      | : 360 kg / 800 lbs.        | • Battery Charge Time | : 9 Hour                  |
| • Head Rest Movement     | : + 30° / - 90°   | • Kidney Surgery Position | : 150° (optional), OT80.20 | • Classification      | : Class I (MDD 93/42 EEC) |
| • Flex / Reflex Position | : + 225° / - 100° | • Stainless Steel T-base  | : Optional, OT80.20S       | • Standards           | : TS EN60601-2-46         |
|                          |                   | • Visco mattress          | Optional, OT80.20V         |                       | ve MDD/93/42/EEC          |

Electro-hydraulic

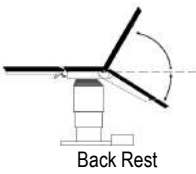


Height/Up-Down

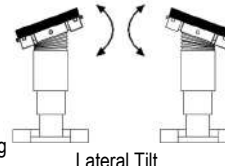


Trendelenburg

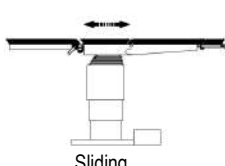
Reverse Trendelenburg



Back Rest



Lateral Tilt



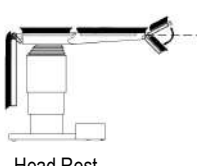
Sliding

\*Central Locking

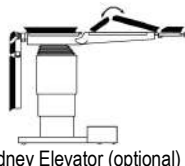
Manual



Leg Rests, Up / Down



Head Rest



Kidney Elevator (optional)



ACCESSORIS OPERATING TABLE



OT60.90 Orthopedic Traction Set



OT60.82 Cross Bar Adapter



OT60.80 SET Neurosurgery Head Rest with Pin &



OT60.76 Arthroscopy



OT60.77 Leg Positioning



OT60.01 Arm Support,



OT60.03 Anaesthesia



OT60.07 Body Fixing Strap



OT60.05 IV Stand, 2 hooks



OT60.06 IV Stand, 4 hooks



OT60.04 Anaesthesia



OT60.71 Patient Heating System



OT60.08 Geopel Leg Rest



OT60.11 Irrigation Bowl,



OT60.12 Irrigat. Bowl With Drainage, Rectangle Form



OT60.14 Waste Bin



OT60.13 Irriga. Bowl With Drainage, Round Form



OT60.17 Clamp, Rotatable & Adjustable Jaw



OT60.18 Clamp, Rotatable



OT60.15 Clamp, Easy Fix



OT60.16 Clamp



OT60.09 Shoulder Support



OT60.10 Lateral Support



OT60.19 Foot Support



OT60.20 Proctology Set



OT60.21 Ophthalmologic



OT60.22 Weinberger Hand



OT60.23 Leg Strap



OT60.24 Meniscus Posi-



OT60.72 Knee Arthroscopy



OT60.73 Carbonfiber



OT60.25 Sliding Handles



OT60.26 Arm Surgery



OT60.29 Support for Hand



OT60.30 X-Ray Cassette Support



OT60.31 X-Ray Cassette Tray



OT60.33 Orthopedic Traction Set Trolley



OT60.32 Accessory Trolley



BS10.20 Step, Double



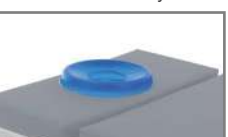
BS10.10 Step, Single



OT60.61 Wilson Frame Set



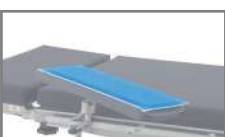
OT60.62 Gel Mattress, Adult



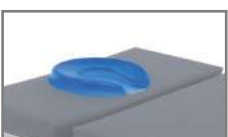
OT60.50 Head Rest, Gel, Adult



OT60.40 Head Rest, PU, Adult



OT60.54 Arm Rest, Gel



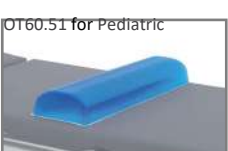
OT60.52 Horseshoe Head Rest, Gel, Adult



OT60.4 Horseshoe Head Rest, PU, Adult



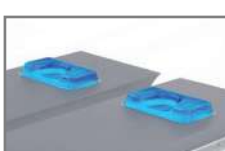
OT60.63 for Pediatric



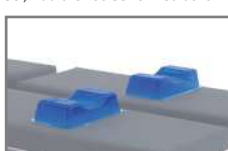
OT60.51 for Pediatric



OT60.42 Chest Roll, PU



OT60.59 Heel Support, Gel



OT60.58 Foot Wrist Support, Gel



OT60.60 Lateral Positioner, Gel

OT60.57 Prone Head Support, Gel

OT60.55 Chest Roll, Gel, Adult





Left Lateral Tilt Position



Struma Surgery Position



Reflex Position



Flex Position



Chest (Breast) Surgery Position



Chest Surgery Position



Gynecologic Surgery Position



Spinal Surgery Position



Meniscus Surgery Position



Ophthalmology Position



Urologic Surgery Position



Orth.Fracture Surgery Position



Leg Positioning Boot



Leg Positioning Boot



Orthopedic Traction Set

Orthopedic traction set is suitable for use with all INSPI TAL operating tables in orthopedic surgeries.

- ◆ Made of 304 quality stainless steel
- ◆ Leg strainer function by mechanical lever
- ◆ Traction boots with up & down movement and rotation capability around its own axis



Neurosurgery Head Rest with Pin & Horseshoe Head Rest

Designed for use in neurosurgery

- ◆ Extremely durable and rigid construction from aluminum alloy
- ◆ 3 pcs fixing system with pins & completely adjust. skull clamps
- ◆ Adjustment mechanism from 4 different points
- ◆ Easily mountable horse shoe head rest accessory

A/C: OT60.80 SET

- ◆ Can be used with skull fixing pins or horseshoe head rest accessories



Marking Plate



İNSPİTAL Medikal Teknoloji A.Ş. Karaoğlan  
Mah. Küme Evleri No:745 06830 Gölbaşı /  
Ankara, TÜRKİYE  
T: 0.312.619 02 22 F: 0.312.619 02 25  
www.inspital.com

Ürünün Adı: Ameliyat Masası  
Product Name: Operating Table  
REF : OT80.20

Giriş Voltajı (Input Voltage): 220-240V AC/ 50-60Hz ~  
Güç (Power): 200W  
Çalışma Voltajı (Operating Voltage): 24VDC ==

SN 19000000



2019

IPX4



TD.OT.03.OT80.20 (Rev01)

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

