



**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 21603025165

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-Mechanic, OT80.25
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.



LAMPIRAN

NOMOR IZIN EDAR
ALAT KESEHATAN
KEMENKES RI AKL 21603025165

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



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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
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:

- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1
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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



Antibacterial surface coating technology is easy to clean, highly resistant to corrosion and has the effect of preventing the production and settlement of blood and body fluids on the surface.



Wide range of accessories for all surgical disciplines

Optimum Mattress Performance

Electro-hydraulic system

Conductive castors with central locking system

Optimum X-Ray image quality

Suitable for patients up to 400 kgs

Suitable for various applications and patient positionings



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 prophylaxis



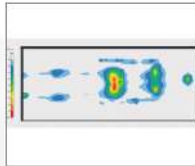
Sliding

- 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.



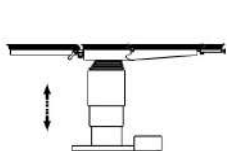
Accessory Positioning

- 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 125 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°	• Visco mattress	: Optional, OT80.25V	• Standards	: TS EN60601-2-46
*Max. & Min. heights are measured without mattress					ve MDD/93/42/EEC

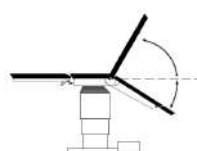
Electro-hydraulic



Height/Up-Down

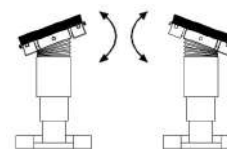


Trendelenburg

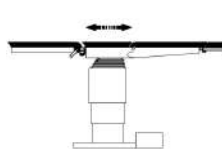


Back Rest

Reverse Trendelenburg



Lateral Tilt

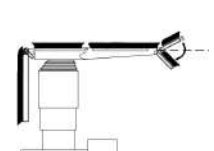


Sliding

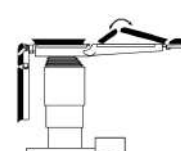
Manual



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 Anaeshtsia



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 Ophtalmologic



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



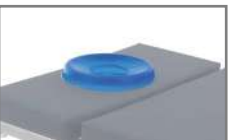
BS10.10 Step, Single



OT60.61 Wilson Frame Set



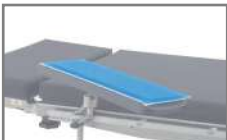
OT60.62 Gel Mattress, Adult



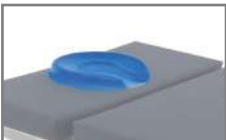
OT60.50 Head Rest, Gel, Adult



OT60.40 Head Rest, PU, Adult



OT60.54 Arm Rest, Gel



OT60.52 Horseshoe Head Rest, Gel, Adult OT60.53 for Pediatric



OT60.4 Horseshoe Head Rest, PU, Adult



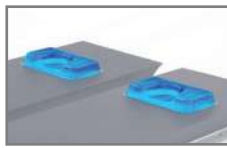
OT60.63 for Pediatric



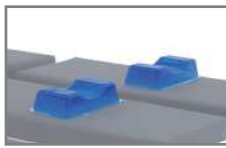
OT60.51 for Pediatric



OT60.42 Chest Roll, PU



OT60.59 Heel Support, Gel



OT60.58 Foot Wrist Support, Gel



OT60.60 Lateral Positioner, Gel





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 : OT80.25

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

SN 19000000



IPX4



TD.OT.03.OT80.25 (Rev01)

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

Reg. No. : KEMENKES RI AKL

