



AT-DECLARATION of CONFORMITY

MANUFACTURER : Medikal 2000 Tıbbi Cihazlar ve İleri Teknoloji Sanayi ve Ticaret A.Ş.

ADRESS: KOS Bölgesi, T. Ziyaeddin Akbulut Cd. No:19 42300, Selçuklu/Konya/TÜRKİYE

REFERENT : Necip ÇİMEN

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PRODUCT NAMES : Hospital Bed, Strechers, Treatment Table, Gynecology Examination Table, Trolleys, Cabinets, Overbed Tables, Mattress, Other Products

EUDAMED SRN : TR-MF-000019533

CLASSIFICATION : Class I, Rule 1 according to MDR Regulation (EU) 2017/745

COUNCIL DIRECTIVE: Compliance has been assessed according to the procedure set out in Regulation (EU) 2017/745 of the European Parliament and of the Council, Annexes I, II, III, IV, VIII.

USED HARMONISED STANDARDS:

- TS EN 15223-1 – Medical Devices- Symbols to be used with Medical Device Labels, Labelling and Information to Supplied, Part 1: General Requirements
- TS EN 14073-2 Office furniture - Storage furniture - Part 2: Safety requirements
- TS EN 12520 Furniture - Strength, durability and safety - Requirements for domestic seating
- TS-EN 60601-2-52 Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds

We hereby declare that the equipment specified above conforms to the applicable sections of the Council Regulation concerning medical devices (EU) 2017/745. Any modifications made to this product without our express permission and approval shall render this declaration null and void.

This certificate of conformity is certified according to EN ISO 9001, EN ISO 13485, EN ISO 14001 and ISO 45001.

Place: Konya, Türkiye

Date: 06.01.2024

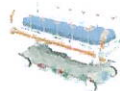
Signature

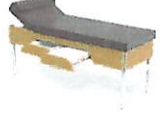
Chairman of the Board

Necip ÇİMEN



PRODUCT CODE	PRODUCT NAME	PRODUCT PICTURE	BASIC UDI-DI	GMDN CODE
MN-01	MECHANIC HOSPITAL - 1 Function		8697601522707	34873
MN-02	MECHANIC HOSPITAL BED - 2 Functions		8697601521809	34873
MN-03	MECHANIC HOSPITAL BED - 3 Functions		8697601522714	34873
PLUS A2	ELECTROMECHANIC HOSPITAL BED - 2 Motors		8697601520628	34870
PLUS A3	ELECTROMECHANIC HOSPITAL BED - 3 Motors		8697601520635	34870
PLUS A7	ELECTROMECHANIC HOSPITAL BED - 3 Motors		8697601520673	34870
PLUS A8	ELECTROMECHANIC HOSPITAL BED - 4 Motors		8697601520680	34870
PLUS A9	ELECTROMECHANIC HOSPITAL BED - 4 Motors with 2 Column Motors		8697601522677	34870
PLUS T	ELECTROMECHANIC HOSPITAL BED - 5 Motors with 2 Column Motors		8697601522790	34870
PLUS 3T	ELECTROMECHANIC HOSPITAL BED 5 Motors with 3 Column Motors		8697601522813	34870

ALARA 3M	ELECTROMECHANIC HOSPITAL BED - 3 Motors		8697601522653	37010
ALARA Y	ELECTROMECHANIC PEDIATRIC BED - 4 Motors		8697601522660	37010
RC-01	HOME CARE BED - 3 Motors		8697601522776	34870
M2-DB	DELIVERY BED - 3 Motors		8697601522806	15732
M2- DXS	DELIVERY BED - 4 Motors		8697601522318	13960
M2-T38	PATIENT STRETCHER		8697601522547	13818
HYS-01	PATIENT WASH STRETCHER		8697601522844	31092
M2-T42	OPERATION ROOM TRANSFER STRETCHER		8697601522554	35892
M2- T300	HYDRAULIC EMERGENCY STRETCHER		8697601521243	13818
M2- T700	HYDRAULIC EMERGENCY STRETCHER		8697601522561	13818
M2- T800	HYDRAULIC EMERGENCY STRETCHER		8697601522103	13818
LFT-01	PATIENT TRANSPORT LIFT- 1 Motor		8697601522851	46148

MM-01	METAL TREATMENT TABLE		8697601522721	36065
MM-02	WOODEN TREATMENT TABLE		8697601522738	36065
M20- EMM	ELECTRICAL TREATMENT TABLE - 2 Motors		8697601522820	31362
DC-02	BLOOD DONOR CAHIR - 2 Motors		8697601522752	10789
DC-03	BLOOD DONOR CAHIR - 3 Motors		8697601522769	10789
PC-01	PODIATRY CHAIR- 3 Motors		8697601522868	36065
JX-02	GYNECOLOGY EXAMINATION TABLE - 3 Motors		8697601522783	36065
JX-03	GYNECOLOGY EXAMINATION TABLE - 4 Motors		8697601522745	36065
PT-01	PATIENT TRANSPORTATION CHAIR		8697601522264	41619
BK-01	BABY COT		8697601522837	38140

Place: Konya, Türkiye
Date: 01.06.2024

Signature
Chairman of the Board
Necip ÇİMEN

Medikal 2000
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