

REGISTERED COMMERCIAL TITLE AND ADDRESS OF THE MANUFACTURER:

TUR-MED HASTANE MALZEMELERİ SAN VE TİC. LTD. ŞTİ.

-SEYHAN, 722/1 St. NO: 30-32 BUCA- İZMİR- TÜRKİYE

-İTOB OSB, 10035.St. NO: 1 MENDERES-İZMİR-TÜRKİYE

VIII. RISK CLASS OF THE DEVICE ACCORDING TO THE RULES SET FORTH IN THE ATTACHMENT; CLASS 1

WE ARE THE MANUFACTURER OF THE DEVICES LISTED BELOW AND THAT THE DEVICES ARE COMPLIANT WITH THE MEDICAL DEVICE REGULATION (EU) 2017/745 (MDR) AND MEET ALL RELEVANT REQUIREMENTS WITHIN THE MDR.

METHOD OF ASSESSMENT OF CONFORMITY: ANNEX-IV DECLARATION OF CONFORMITY (ANNEX II & APPENDIX III)

CHAPTER III OF THE PRODUCTS MEDICAL DEVICE REGULATION APPENDIX VIII 4.1- RULE 1 / CLASS:1 ALL NON-INVASIVE DEVICES ARE CLASSIFIED AS CLASS I.

COMMON SPECIFICATIONS: EN ISO 13485:2016, EN ISO 14971: 2019, EN ISO 15223-1:2016, EN ISO 9001:2015, EN ISO 14001:2015, EN ISO 45001:2018.

INTENDED USE: THESE PRODUCTS ARE MEDICAL SUPPORT EQUIPMENT USED TO ASSIST HEALTHCARE PERSONNEL IN THE EXAMINATION, DIAGNOSIS, TREATMENT, TRANSPORTATION, AND CARE OF PATIENTS. THEY ARE DESIGNED TO INCREASE PATIENT COMFORT AND ENSURE THE EFFECTIVENESS AND SAFETY OF HEALTHCARE SERVICES IN HOSPITALS, CLINICS, DOCTOR'S OFFICES, AND EMERGENCY RESPONSE AREAS.

THIS DECLARATION OF CONFORMITY IS CREATED SOLELY UNDER THE MANUFACTURER'S RESPONSIBILITY.

PLACE AND DATE OF ISSUING THE DECLARATION,
İZMİR, 10.09.2025

Mehmet Onur Yenil
General Manager

(Signature)
Hast. Malz. San. ve Tic. Ltd. Şti.
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PRODUCT LIST

UDI-DI Number	Basic UDI-DI Number	GMDN	EMDN	REF	Product Name
8698943380017	869894338GEN01TF	38458	V080603	TM-A-1001	EXAMINATION TABLE (FOLDING)
8698943380062	869894338GEN01TF	38458	V080603	TM-A-1002	EXAMINATION TABLE (FIXED)
8698943380079	869894338GEN01TF	38458	V080603	TM-A-1003	EXAMINATION TABLE (WOODEN)
8698943380048	869894338GEN01TF	38458	V080603	TM-A-1004	EXAMINATION TABLE (WOODEN)
8698943380055	869894338ORT0123	38458	V080603	TM-A-1005	EXAMINATION TABLE (WOODEN)

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Sayfa 1 / 3

CE DECLARATION OF CONFORMITY

Document Nr.: DC.001
Release Date: 27.05.2021
Revision Nr.: 1
Revision Date: 01.08.2021

8698943383773	8698943383MSJUF	32266	V080603	TM-A-1006	MASSAGE TABLE
8698943383780	8698943383MSJUF	32266	V080603	TM-A-1007	MASSAGE TABLE (BAG TYPE)
8698943380093	869894338ORT0123	10789	V080202	TM-A-1009	BLOOD DONOR CHAIR
8698943380109	869894338GEN01TF	10789	V080202	TM-A-1010	BLOOD DONOR CHAIR
8698943380116	869894338GEN01TF	36065	V080603	TM-A-1011	GYNEACOLOGICAL EXAMINATION TABLE
8698943380130	869894338GEN01TF	13960	V080603	TM-A-1013	GYNEACOLOGICAL EXAMINATION TABLE
8698943381595	869894338MAS01VE	36065	V08020199	TM-A-1020	GYNEACOLOGICAL EXAMINATION CHAIR (TWO MOTOR)
8698943381601	869894338MAS01VE	36065	V08020199	TM-A-1021	GYNEACOLOGICAL EXAMINATION CHAIR (THREE MOTOR)
8698943381625	869894338MAS01VE	10789	V08020199	TM-A-1022	BLOOD DONOR CHAIR (TWO MOTOR)
8698943381632	869894338MAS01VE	10789	V08020199	TM-A-1023	BLOOD DONOR CHAIR (THREE MOTOR)
8698943386965	869894338MAS01VE	31362	V080603	TM-A-1024	EXAMINATION TABLE WITH TWO MOTORS
8698943381250	869894338MAS01VE	31362	V080603	TM-A-1025	EXAMINATION TABLE (SINGLE MOTOR)
8698943381243	869894338MAS01VE	31362	V080603	TM-A-1026	EXAMINATION TABLE (TWO MOTOR)
8698943381618	869894338MAS01VE	36065	V080603	TM-A-1027	GYNEACOLOGY AND DELIVERY TABLE
8698943387405	869894338ORT0123	36801	V0899	TM-B-2003	MAYO TABLE
8698943380383	869894338SED01VZ	13818	V08050101	TM-C-3001	STRETCHER (FOLDING)
8698943380390	869894338SED01VZ	35892	V08050101	TM-C-3002	STRETCHER (WITH UPPER PLATFORM)
8698943381274	869894338SED01VZ	13818	V08050101	TM-C-3003	STRETCHER
8698943380444	869894338SED01VZ	35843	V08050101	TM-C-3007	STRETCHER
8698943380475	869894338SED01VZ	35843	V08050103	TM-C-3010	AMBULANCE STRETCHER
8698943381281	869894338SED01VZ	35892	V08050101	TM-C-3017	STRETCHER (HYDRAULIC)
8698943383766	869894338SED01VZ	35892	V08050103	TM-C-3033	EMERGENCY STRETCHER
8698943380505	869894338KA01SW	34873	V080603	TM-D-4001	PATIENT BED
8698943380512	869894338KA01SW	34873	V080603	TM-D-4002	PATIENT BED (SINGLE SETTING)
8698943380529	869894338KA01SW	34873	V080603	TM-D-4003	PATIENT BED (TWO SETTING)
8698943380628	869894338KA01SW	34873	V080603	TM-D-4013	PATIENT BED (SINGLE SETTING)
8698943380666	869894338KA01SW	34873	V080603	TM-D-4017	PATIENT BED (TWO SETTING)
8698943385111	869894338KA01SW	34873	V080603	TM-D-4018	PATIENT BED (TWO SETTING, MANUAL)
8698943380697	869894338KA01SW	34873	V080603	TM-D-4020	PATIENT BED (TWO SETTING WITH BEDPAN)
8698943385104	869894338KA01SW	34873	V080603	TM-D-4021	PATIENT BED (TWO SETTING, MANUAL)
8698943384992	869894338KA01SW	34873	V080603	TM-D-4022	PATIENT BED (TWO SETTING, MANUAL)
8698943384985	869894338MAS01VE	34870	V08060101	TM-D-4023	PATIENT BED (DUAL MOTOR)
8698943384978	869894338MAS01VE	34870	V08060101	TM-D-4024	PATIENT BED (DUAL MOTOR)
8698943384961	869894338MAS01VE	34870	V08060101	TM-D-4025	PATIENT BED (DUAL MOTOR)
8698943384954	869894338MAS01VE	34870	V08060101	TM-D-4026	PATIENT BED (DUAL MOTOR)
8698943389829	869894338KA01SW	34873	V080603	TM-D-4027	PATIENT BED (THREE SETTING)
8698943380833	869894338MAS01VE	34870	V08060101	TM-D 4034	PATIENT BED (DUAL MOTOR)
8698943380857	869894338ORT0123	14105	Z12130202	TM-D-4036	ORTHOPEDIC TRACTION FRAME
8698943381687	869894338MAS01VE	34870	V08060102	TM-D 4053	INTENSIVE CARE UNIT BED (FOUR MOTOR)



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Sayfa 2 / 3

8698943381663	869894338KA01SW	34870	V08060101	TM-D-4055	PATIENT BED (THREE MOTOR)
8698943381335	869894338MAS01VE	34870	V08060101	TM-D-4056	PATIENT BED (FOUR MOTOR)
8698943381366	869894338MAS01VE	34870	V08060101	TM-D-4058	PATIENT BED (THREE MOTOR)
8698943381373	869894338KA01SW	34870	V08060101	TM-D-4059	PATIENT BED (FOUR MOTOR)
8698943381342	869894338MAS01VE	34870	V08060101	TM-D-4060	PATIENT BED (DUAL MOTOR)
8698943381359	869894338MAS01VE	34870	V08060101	TM-D-4062	PATIENT BED (DUAL MOTOR)
8698943381380	869894338MAS01VE	13960	V08060101	TM-D-4065	DELIVERY BED (FOUR MOTOR)
8698943381397	869894338MAS01VE	13960	V08060101	TM-D-4066	DELIVERY BED (THREE MOTOR)
8698943380642	869894338KA01SW	34873	V080602	TM-D-4067	PATIENT BED (SINGLE SETTING)
8698943387733	869894338KA01SW	35183	V080399	TM-D-4069	CNC MATTRESS
8698943381311	869894338KA01SW	34870	V080602	TM-D-4070	PATIENT BED (THREE SETTING)
8698943380680	869894338KA01SW	34873	V080602	TM-D-4071	PATIENT BED (THREE SETTING)
8698943387740	869894338KA01SW	34871	V080602	TM-D-4073	PATIENT BED (SINGLE SETTING)
8698943387757	869894338KA01SW	34871	V080602	TM-D-4074	PATIENT BED (TWO SETTING)
8698943388396	869894338MAS01VE	30032	V08060101	TM-D-4077	PATIENT BED (DUAL MOTOR)
8698943384121	869894338KA01SW	35183	V08030102	TM-D-4078	ANTI DECUBITUS MATTRESS
8698943384138	869894338KA01SW	35183	V08030102	TM-D-4079	ANTI DECUBITUS MATTRESS
8698943388402	869894338MAS01VE	30032	V08060102	TM-D 4080	INTENSIVE CARE UNIT BED (FIVE MOTOR)
8698943381120	869894338GEN01TF	36488	Z11069005	TM-F-6003	NEGATOSCOPE (SINGLE)
8698943381137	869894338ORT0123	36488	Z11069005	TM-F-6004	NEGATOSCOPE (DOUBLE)
8698943381144	869894338ORT0123	36488	Z11069005	TM-F-6005	NEGATOSCOPE (TRIPLE)
8698943387955	869894338ORT0123	16800	V0899	TM-F-6007	EYE SCALE
8698943381175	869894338IVSTNDCC	36069	V0880	TM-F-6008	IV STAND
8698943381212	869894338IVSTNDCC	36069	V0880	TM-F-6012	IV STAND
8698943387962	869894338ORT0123	12276	Z129004	TM-F-6013	EXAMINATION LAMP
8698943385159	869894338IVSTNDCC	36069	V0880	TM-F-6026	IV STAND
8698943389027	869894338KA01SW	37010	V080602	TM-K-2203	PEDIATRIC BED (SINGLE SETTING)
8698943389065	869894338ORT0123	38140	V0809	TM-K-2207	INFANT COT
8698943389072	869894338KA01SW	37008	V08060199	TM-K-2208	INFANT BED
8698943381458	869894338ORT0123	38140	V0809	TM-K-2210	INFANT COT
8698943389089	869894338ORT0123	37010	V080602	TM-K-2211	PEDIATRIC MATTRESS
8698943381441	869894338MAS01VE	38140	V08060107	TM-K-2213	PEDIATRIC PATIENT BED (SINGLE MOTOR)
8698943381403	869894338SED01VZ	35892	V08050101	TM-K-2215	PEDIATRIC STRETCHER
8698943381489	869894338GEN01TF	38458	V080603	TM-K-2216	PEDIATRIC EXAMINATION TABLE
8698943381472	869894338GEN01TF	38458	V080603	TM-K-2217	PEDIATRIC EXAMINATION TABLE (WOODEN)
8698943381434	869894338MAS01VE	38140	V08060107	TM-K-2219	PEDIATRIC PATIENT BED (TWO MOTOR)



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Sayfa **3 / 3**

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