

Sertifika

certificate

CERTIFICATE of CONFORMITY

APPLICANT : T HEALTH MEDİKAL İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ

Aydınlar Mah. 03062 Nolu Cad. No: 12, Şehitkamil - Gaziantep

MANUFACTURER : T HEALTH MEDİKAL İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ

Aydınlar Mah. 03062 Nolu Cad. No: 12, Şehitkamil - Gaziantep

Product Name : ANNEX I
Model

Product Classification : Class I

Applied Directive(s) : 93/42/EEC Medical Device Directive

This certificate has been issued according to the voluntary application of the manufacturer. This certificate is valid only for the product(s) in above mentioned. This certificate confirms that the declaration of conformity which is prepared by manufacturer is available. It's manufacturer's sole responsibility to meet all the necessary conformity assessment activities according to 93/42/EEC Medical Devices Directive and related standards or the mentioned product(s) before placing them on the market. It is the manufacturer's responsibility to comply a full technical file according to Annex VII of 93/42/EEC and the manufacturer is the responsible to take all necessary actions before affixing **CE** mark on the product(s)

Date of issue of this certificate : 16.08.2022

Expiry date : 15.08.2023

Certificate Number : 22.06.316-CE




Genel Müdür
General Manager

Inspect Uluslararası Belgelendirme ve Gözetim Hizmetleri Tic. Ltd. Şti. / TURKEY
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Belge periyodu 3 yıldır.

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ANNEX I

PRODUCT NAMES AND MODELS:

ELECTRONIC BEDS: T 8070, T 8060, T 8050, T 8040, T 8030, T 8020, T 8021, T 8022, T 8023, T 8024, T 8025

MANUAL BEDS: T 1190, T 1180, T 1170, T 1160, T 1150, T 1140, T 1130, T 1120, T 1110, T 1100

MATTRESSES: TMS 01, TMS 02, TMS 03, TMS 04, TMS 05, TMV 01, TMV 02, TMV 03, TMV 04

BEDSIDE CABINETS: BSC 2710, BSC 2720, BSC 2722, BSC 2725, BSC 2730, BSC 2740, BSC 2750, BSC 2760, BSC 2770, BSC 2780, BSC 2790

OVER BED TABLES: OBT 2710, OBT 2720, OBT 2730, OBT 2740, OBT 2750, OBT 2760, OBT 2770, OBT 2780, OBT 2790

PEDIATRIC BEDS&BASSINETS: T 3300, T 3310, T 3320 T 3327, T 3330, T 3340, T 3350, T 3360, T 3370, T 3380, T 339

GYNECOLOGY&DELIVERY BEDS: T 2800, T 2810, T 2820, T 2830, T 2840, T 2850, T 2860, T 2870, T 2880, T 2890

PATIENT TRANSFER CHAIR: T-COUCH, T-COUCH 01, T-COUCH 02, T-COUCH 03, T-COUCH 04, T-COUCH 05, T-COUCH 07, T-COUCH 08, T-COUCH 09, T-SWIFT AL, T-SWIFT SS, T-SWIFT EP

FUNCTIONAL MEDICAL CHAIR: TE 100, TE 200, TE 300, TE 400, TE 500, TE 600, TE 700, TE 800, TE 900

EMERGENCY STRETCHERS: T-XPRESS, T-XPRESS BASIC, T-XPRESS PIONEER, T-XPRESS HYDRO, T-RANSFER

MEDICAL CARTS: T-ROLLEY EMERGENCY, T-ROLLEY ANESTHESIA, T-ROLLEY MEDICATION, T-ROLLEY TREATMENT, T-ROLLEY DRESSING, TH 6510, TH 7510, TS 7510, TS 7511, TS 7520, TS 7530




Genel Müdür
General Manager

Client Name and address

Müşteri ismi ve adresi

T HEALTH MEDİKAL İÇ VE DIŞ TİCARET LTD. ŞTİ.

AYDINLAR MAH. 03062 CAD. NO:12 ŞEHİTKAMİL/GAZİANTEP/TÜRKİYE

Standard

Standard

ISO 9001:2015

Quality Management System

INSPECT assessed and approved that related firm meets the requirements of the designated standard at related scope
INSPECT ilgili kuruluşun yukarıda belirtilen standardın gereklerine uygunluğunu ilgili kapsamda tetkik etmiş olup onaylamaktadır.

Scope

Kapsam

Hastane mobilyası imalatı ve satışı

Production and sale of hospital furniture

EA/Category Code: 23-29

Initial issue date: 16.Aug.2022

Issue date of this certificate: 16.Aug.2022

Validity of this certificate: 15.Aug.2023

Recertification date: 15.Aug.2025

Certificate No: 22.06.316-QM


General Manager

To verify the validity of this certificate please visit: www.inspect.com.tr

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The validity of this certificate is depend on the success of surveillance assessments

Bu belgenin geçerliliği ara denetimlerin başarılı olmasına bağlıdır.

INSPECT Uluslararası Belgelendirme ve Gözetim Hiz. Tic. Ltd. Şti. / TURKEY
www.inspect.com.tr - Belge periyodu 3 yıldır. / Certificate period is 3 years.



Client Name and address

Müşteri ismi ve adresi

T HEALTH MEDİKAL İÇ VE DIŞ TİCARET LTD. ŞTİ.

AYDINLAR MAH. 03062 CAD. NO:12 ŞEHİTKAMİL/GAZİANTEP/TÜRKİYE

Standard

Standard

ISO 13485:2016 Quality Management Systems-Medical Devices

INSPECT assessed and approved that related firm meets the requirements of the designated standard at related scope
INSPECT ilgili kuruluşun yukarıda belirtilen standardın gereklerine uygunluğunu ilgili kapsamda tetkik etmiş olup onaylamaktadır.

Scope

Kapsam

Hastane mobilyası imalatı ve satışı

Production and sale of hospital furniture

EA/Category Code: A

Initial issue date: 16.Aug.2022

Issue date of this certificate: 16.Aug.2022

Validity of this certificate: 15.Aug.2023

Recertification date: 15.Aug.2025

Certificate No: 22.06.316-MD


General Manager

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The validity of this certificate is depend on the success of surveillance assessments

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