



Certificate of Registration

This is to certify that

Quality Management System

for Medical Devices

of

OMMED SAĞLIK ÜRÜNLERİ SANAYİ VE DIŞ TİCARET LİMİTED ŞİRKETİ

ORUÇREİS MAHALLESİ GİYİMKENT 19. SOKAK GİYİMKENT SİTESİ
B204 APARTMAN NO:95/A ESENLER / İSTANBUL / TÜRKİYE.

complies with the requirements of

EN ISO 13485:2012

This certificate is valid concerning all activities related to:

**MANUFACTURING, EXPORTING AND WHOLESALING OF
MEDICAL DEVICES, SOFT ORTHOPEDIC, MEDICAL TEXTIL,
RESPIRATORY DEVICES, MEDICAL PLASTIC, PHYSICAL
THERAPY AND REHABILITATION PRODUCTS.**

**TIBBİ CİHAZ, SOFT ORTOPEDİK, MEDİKAL TEKSTİL, SOLUNUM
CİHAZLARI, MEDİKAL PLASTİK, FİZİK TEDAVİ VE REHABİLİTASYON
ÜRÜNLERİNİN İMALATI, İHRACATI VE TOPTAN SATIŞI.**

MD-1033
Certificate No.

July 04, 2018
Date of this Certificate

July 03, 2019
*Next Audit Due Date

July 04, 2018
Date of Initial Registration

July 03, 2021
Certification Expiry Date


Managing Director/Director



TRANSPACIFIC CERTIFICATIONS LIMITED

Website : www.tclcertifications.com E-mail : info@tclcertifications.com

Accreditation by Joint Accreditation System of Australia and New Zealand (Accreditation No.M2640303IN)

4 Phipps Close, DEAKIN, ACT 2600, AUSTRALIA

<http://www.jas-anz.org/our-directory/certified-organisations>

This certificate is only valid if it is available/valid on TCL website at <http://tclcertifications.com/client-register/>.

The certificate of Registration remains the property of Transpacific Certifications Limited and shall be returned immediately upon request.

*In case if Surveillance Audit is not allowed to be conducted on or before the specified date; the Certificate shall be Suspended/Withdrawn.

DECLARATION OF CONFORMITY

OMMED SAĞLIK ÜRÜNLERİ SAN. VE DİŞ.TİC.LTD. ŞTİ.

**OruçreisMah.Giyimkent 19.Sk.Giyimkent Sit.B204 Apt. No95/A
Esenler İstanbul Türkiye**

PRODUCT CATAGORY : Hospital Equipments

**PRODUCT LIST : OM911 Massage Table
OM901 Examination Table
OM1421 Obstetrics Table
OM1424 Blood Donor Chair
OM1418 Stretcher with Wheels**

CLASSIFICATION : Class I

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC with amended directive 2007/47/EEC for Medical Device Directive.

GENERAL APPLICABLE DIRECTIVES

Medical Devices Directive council directive 93/42/EEC with amended directive 2007/47/EEC concerning medical devices.

STANDARDS

EN 980:2008
EN 1041:2008
EN ISO 14971:2009

Graphical symbols for use in the labelling of medical devices
Information supplied by the manufacturer with medical devices
Medical devices - Application of risk management to medical devices

MANUFACTURER :OMMED SAĞLIK ÜRÜNLERİ SAN. VE DİŞ.TİC.LTD. ŞTİ.
**ADRESS :OruçreisMah.Giyimkent 19.Sk.Giyimkent Sit.B204 Apt. No95/A
Esenler İstanbul Türkiye**

EC Declaration Date : 04.05.2018
City, Date of issue : İstanbul, 04.05.2018
Signature :
Name : Osman Ertuğrul ÇAKMAK
Position : General Manager

OMMED SAĞLIK ÜRÜNLERİ SAN.
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