

## OM918 Baby Changing Table with Mattress



### **Specifications:**

- Size: 90x80x70 cm or 90x70x70 cm
- Material Type Laminated Particle Board
- Open Storage Space
- Mattress with a thickness of 5 cm, with waterproof cover

# 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  
OM918 Baby Changing Table with Mattress  
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.  
VE DİŞ.TİC.LTD. ŞTİ.  
Oruçreis Mah. Giyimkent 19. Sk. Giyimkent Sit.  
B204 Apt. No95/A Esenler / İSTANBUL  
Atışalanı V.D. N. 642 656603 T. 131440-5  
Mersis No: 064200065030000



# 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, 2020**  
 \*Next Audit Due Date

**July 04, 2018**  
 Date of Initial Registration

**July 03, 2023**  
 Certification Expiry Date

  
 Managing Director/Director



**TRANSPACIFIC CERTIFICATIONS LIMITED**

Website : [www.tclcertifications.com](http://www.tclcertifications.com) E-mail : [info@tclcertifications.com](mailto: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.