

# DECLARATION OF CONFORMITY

**OMMED SAĞLIK ÜRÜNLERİ SAN. VE DIŞ.TİC.LTD. ŞTİ.**

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

**PRODUCT CATAGORY : HOSPITAL EQUIPMENTS  
BRAND : OMMED HEALTH PRODUCTS**

**PRODUCT TYPE / : OM1001 PLASTIC BEDPAN  
MODEL : OM1002 PLASTIC URINE COLLECTOR**

**CLASSIFICATION : Class I Other(Non-sterile and non-measuring  
function)[MDD 93/42/EEC-Rule I  
APPLIED APPENDIX : Appendix 7 (Declaration Of Conformity)**

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 DIŞ.TİC.LTD. ŞTİ.  
ADRESS :OruçreisMah.Giyimkent 19.Sk.Giyimkent Sit.B204 Apt. No95/A  
Esenler İstanbul Türkiye**

**Revision : 02  
EC Declaration Date : 27.02.2020  
City, Date of issue : İstanbul, 27.02.2020  
Signature :  
Name : Osman Ertuğrul ÇAKMAK  
Position : General Manager**

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VE DIŞ.TİC.LTD. ŞTİ.  
Oruçreis Mah. Giyimkent 19. Sk. Giyimkent Sit.  
B204 Apt. No95/A /Esenler / İSTANBUL  
Atışalan YD No: 642/356603/131440-5  
Mersis No: 0642003566030000