

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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