## **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 /** 

MODEL : OM1001 PLASTIC BEDPAN

CLASSIFICATION : Class I Other(Non-sterile and non-measuring

function)[MDD 93/42/EEC-Rule I

**APPLIED APPENDIX**: Appendix 7 (Declaration Of Confirmity)

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 Graphical symbols for use in the labelling of medical devices
EN 1041:2008 Information supplied by the manufacturer with medical devices
EN ISO 14971:2009 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

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City, Date of issue : İstanbul, 27.02.202

Signature :

Name : Osman Ertuğrul ÇAKMAK

Position : General Manager