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

PRODUCT LIST : OM719; OM719A; OM721; OM 721A Infusion Stand

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 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 ADRESS

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