

Declaration of Conformity

Manufacturer: Hangzhou Primecare Medical Co., Ltd.

Address: Room 408-409, Zancheng Center West, Shangcheng District, 310008 Hangzhou,
PEOPLE'S REPUBLIC OF CHINA

European OBELIS S.A

Representative: Bd. General Wahis 53, 1030 Brussels, BELGIUM

Product: Urine Bag (with and without gloves pack/with and without straps)

Model Code: UB500-10, UB500-30, UB500-50, UB600-10, UB600-50, UB750-10, UB750-30,
UB750-50, UB750A-10, UB750A-30, UB750A-50, UB750F-50, UB1000-30, UB1000-60,
UB1000-90, UB2000E, UB2000A, UB2000-90, UB2000-120, UB4000-120, UB4000 TUR

UMDNS Code: 14-298

Classification (MDD, Rule 5 of Annex IX): I sterile

Conformity Assessment Route: Annex V.3

We herewith declare in our sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical device directive: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Notified Body: TUV SUD Product Service GmbH, Ridlerstr.65, 80339 Munchen, Germany

NB Identification number: 0123

EC Certificate: No. G2S 005225 0004 Rev.01

Expiry date of the certificate: 2023-12-03

Start of CE Marking: Not until now.

Place, Date: Room 408-409, Zancheng Center West, Shangcheng District, 310008 Hangzhou,
PEOPLE'S REPUBLIC OF CHINA 2019-10-25

Signature


Yan Xueqing
PRIMECARE MEDICAL CO., LTD

Position: Management Representative

Issued Date: 2019-10-25

Issued By: Management Representative