

Declaration of Conformity

Manufacturer: Conod Medical Co., Limited

Address: No.11 Hongfeng Road, Baimao Industrial Park, Guli Town, 215532 Changshu City
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA
SRN: CN-MF-000012600

Authorised Representative: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestraße 80, 20537 Hamburg, GERMANY

Device Name: Urine Bag (with and without gloves Pack/with and without Straps)

UMDNS code: 14298

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

Conformity assessment route: Annex V.3

We herewith declare that the above mentioned products meet the provisions of the following EC council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer Conod Medical Co., Limited.

DIRECTIVES/REGULATION

General applicable directives:

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

Regulation (EU) 2023/607 of The European Parliament and of the Council of 15 March 2023
Article 120 of Regulation (EU)2017/745

Notified Body: TÜV SÜD Product Service GmbH

Address: Ridlerstraße 65, 80339 Munich, Germany

NB Identification number: 0123

Certificate: G2S 071789 0047 Rev.00

Expiration date of the certificate: 2024-05-26

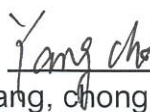

Confirmation Letter: CL 071789 0052 Rev.00

This letter is effective until 31th December 2028 according to “ Confirmation Letter CL 071789 0052 Rev. 00” from Notified Party.

Place, Date: Conod Medical Co., Limited. No.11 Hongfeng Road, Baimao Industrial Park, Guli Town, 215532 Changshu City, Jiangsu Province. PEOPLE'S REPUBLIC OF CHINA

2024--05-27

Signature

Name: Yang, chong

Position: Deputy Director of Quality and Regulatory Affairs

Attachment

REF	Product Description
74.5330.500	UD3 double hanger; 100 cm tube
74.5330.520	UD3 double hanger; 120 cm tube
74.5330.600	UD3 small hanger; 100 cm tube
74.5330.620	UD3 small hanger; 120 cm tube
74.5330.700	UD3 large hanger; 100 cm tube
74.5330.720	UD3 large hanger; 120 cm tube
74.5340.500	TUR bag; w bulb
74.5340.501	TUR bag; w/o bulb
74.5485.005	2.0l Drainage bag
74.5232.005	leg bag 0.75l; straight inlet; EO-Sterile; blister
74.5233.005	leg bag 0.75l; canted inlet; EO-Sterile; blister