

Declaration of Conformity

Manufacturer Conod Medical Co., Limited.
 Address No.11 Hongfeng Road, Baimao Industrial Park, Guli Town 215532 Changshu City, Jiangsu Province,P.R. China

European Representative Shanghai International Holding Corp. GmbH (Europe)
 Eiffestrasse 80, 20537 Hamburg Germany

Product Urine Meters

Product No.	Product Description	Product No.	Product Description
74.5681.200	Urine measuring system	74.5685.001	Exchange bag 3,0l
74.5684.001	Exchange bag 2,0l	74.5685.002	Exchange bag 3,0l w outlet
74.5684.002	Exchange bag 2,0l w outlet	/	/

UMDNS code 15-310

Classification (MDD, Rule 1 of Annex IX): I sterile, with measurement function

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

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

Certificate: G2MS 071789 0044 Rev.01

Expiry date of the certificate: 2024-05-26

Start of CE Marking: 2019-02-28

Place, Date: Conod Medical Co., Limited. No.11 Hongfeng Road, Baimao Industrial Park, Guli Town 215532 Changshu City, Jiangsu Province, P.R. China 2020-01-17

Signature  _____

Name: Song pinran

Position: Management Representative

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 Address No.11 Hongfeng Road, Baimao Industrial Park, Guli Town, 215532 Changshu City, Jiangsu Province. P.R. China
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 Product Urine Bag

Product No.	Product Description	Product No.	Product Description
74.5330.500	UD3 double hanger; 100 cm tube	74.5340.500	TUR bag; w bulb
74.5330.520	UD3 double hanger; 120 cm tube	74.5340.501	TUR bag; w/o bulb
74.5330.600	UD3 small hanger; 100 cm tube	74.5485.005	2.0l Drainage bag
74.5330.620	UD3 small hanger; 120 cm tube	74.5232.005	leg bag 0.75l; straight inlet; EO-Sterile; blister
74.5330.700	UD3 large hanger; 100 cm tube	74.5233.005	leg bag 0.75l; canted inlet; EO-Sterile; blister
74.5330.720	UD3 large hanger; 120 cm tube	/	/

UMDNS code 14-298

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

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, Ridlerstraße 65,80339 Munchen, Germany
 NB Identification number: 0123

Certificate: G2S 071789 0047 Rev.00

Expiration date of the certificate: 2024-05-26

Start of CE Marking:2018-10-02

Place, Date: Conod Medical Co., Limited. No.11 Hongfeng Road, Baimao Industrial Park, Guli Town,215532,Changshu City, Jiangsu Province. P.R. China 2020-01-17

Signature _____

Name: Song pinran

Position: Management Representative