

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 Meters (w/wo Urine Sampling Blunt Cannular)

REF	Product Description	REF	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: 14-288

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 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).

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: No. G2MS 071789 0044 Rev.01

Expiry 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