

EU 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

SRN: DE-AR-000000001

Device Name: Catheter Valve

EMDN Code: A0703 Stopcocks

Basic UDI-DI: 69558240CW0200100CV00013J

Classification (MDR, Rule I of Annex VIII): Class I device in sterile condition

Conformity Assessment Route: Annex IX of Regulation(EU) MDR 2017/745

Intended purpose: This product is intended to be connected to a urethral and/or suprapubic catheter to allow intermittent bladder drainage.

We herewith declare that the bellow mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Device and applicable harmonized standards. All supporting documentations are retained under the premises of the manufacturer.

Regulation

General applicable regulations:

Medical Device Regulation: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Notified Body: TÜV SÜD Product Service GmbH

Address: Ridlerstraße 65, 80339 Munich, Germany

NB Identification Number: 0123

Certificate Number: G11 071789 0050 Rev.01

Expiration date of the certificate:2027-10-16

Place, date: Conod Medical Co., Limited. No.11 Hongfeng Road, Baimao Industrial Park, Guli Town 215532 Changshu city, Jiangsu Province, P.R. China 2025-09-08

Name: Liu haijin

Position: RA Manager