

EU 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

Authorised Representative: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg Germany

SRN: CN-MF-000012600

Product Name: Urine Bag (with and without Straps)

Trade name: Urine bag, leg bag, night bag, urine leg bag, urine leg bag with NRV, Bed bag, Urine leg collector, beg urine collector, leg urine collector etc.

Model and Type:

Standard series (500mL,600mL,750mL,800mL,900mL,1000mL,1500mL,2000mL,2500mL,3000mL);

Luxury series (1000mL,1500mL,2000mL,2500mL,3000mL);

Leg bag series (200mL,250mL,300mL,350mL,400mL,450mL,500mL,600mL,700mL,750mL,800mL, 850mL,900mL,1000mL,1200mL,1500mL);

Basic UDI-DI: 69558240CS0100000UB0001UM, 69558240CS0100000UB0003UR
69558240CS0100000UB0002UP

Classification (MDR, Rule I of Annex VIII): I

Conformity assessment procedure: Article 19+Annex II + Annex III

We herewith declare that the above mentioned products meet the provisions of the following regulation and harmonized standards published on the Official Journal of the European Union, and that this EU declaration of conformity is issued under the sole responsibility of Conod Medical Co., Limited.

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

Place, Date: Conod Medical Co., Limited. No.11 Hongfeng Road, Baimao Industrial Park, Guli Town, 215532, Changshu City, Jiangsu Province. P.R. China 2022-04-28

Signature



Name: Aaron Qin

Position: Management Representative

江苏康诺医疗器械股份有限公司
CONOD MEDICAL CO., LIMITED