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
SRN: CN-MF-000012600

Authorised Representative: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg Germany
SRN: CN-AR-000000001

Device Name: Urine Bag(Leg bag)

EMDN Code: A060303
Basic UDI-DI: 69558240CS0200100UB0001WH、69558240CS0200100UB0003WM
REF: 690120、690190、690220、690120-H、691770、690740、691760、690745、691755、690760、690735

Intended Use: Uring bags are intended for used for draining and collecting accumulated urine from patient.

Classification (MDR, Rule I of Annex Ⅸ): Class Ⅰ device in sterile condition
Conformity assessment procedure: Annex Ⅸ of MDR 2017/745

We herewith declare that the above mentioned products meet the provisions of 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 Munchen, Germany
NB Identification number: 0123
Certificate: 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 2024-12-21

Signature _____
Name: Joey zhao
Position: Management Representative