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: Exchange bag/replacement bag
EMDN Code: A06030301 Urine collection bags

REF	Basic UDI-DI
690502-BAG	69558240CS0500110UM00036K
690503-BAG	69558240CS0500110UM00036K

Intended Use: The Exchange bag/replacement bag connected to the the chamber of urine meter is intended to collect the urine drained from the chamber.

Classification (MDR, Rule 1 of Annex VIII): Class I device in sterile condition
Conformity Assessment Procedure: Annex IX (Chapter I & III) of MDR (EU) 2017/745

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: G11 071789 0050 Rev.03
Expiry 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, PEOPLE'S REPUBLIC OF CHINA
2026-06-16

Signature Yang Chong
江苏康诺医疗器械股份有限公司
CONOD MEDICAL CO., LIMITED
Name: Yang, Chong
Position: Deputy Director of Quality and Regulatory Affairs