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: Urine Meter
EMDN Code: A060303 Urine collection system and bags, single-use

Intended Use: The Urine Meter is intended to measure the volume of and collect urine from a patient.

Classification (MDR, Rule 1 of Annex VIII): Class I in sterile condition, w/ measuring function
Conformity Assessment Procedure: Annex IX of Regulation(EU) MDR 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.01
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
2025-01-14

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

Annex: Model and Specification:

S/N	Article number	Product Description	Basic UDI-DI
1	690311	Urine measurement system, closed, Latex free	69558240CS0500110UM00016F
2	690312	Urine measurement system, closed, Latex free	69558240CS0500110UM00016F
3	690313	Urine measurement system, closed, Latex free	69558240CS0500110UM00016F
4	690313-L	Urine measurement system, closed, Latex free	69558240CS0500110UM00016F
5	690313-N	Urine measurement system, closed, Latex free	69558240CS0500110UM00016F
6	690321	Urine measurement system, closed, Latex free	69558240CS0500110UM00016F
7	690322	Urine measurement system, closed, Latex free	69558240CS0500110UM00016F
8	690323	Urine measurement system, closed, Latex free	69558240CS0500110UM00016F
9	690343	Urine measurement system, closed, Latex free	69558240CS0500110UM00016F
10	690343-N	Urine measurement system, closed, Latex free	69558240CS0500110UM00016F
11	690500-N	Urine Meter, Urine Measurement System closed with exchange bag, with drainage valve, latex free	69558240CS0500110UM00026H
12	690500-BAG	Urine meter Exchange bag, with drainage valve, latex free	69558240CS0500110UM00036K
13	690501-N	Urine Meter, Urine Measurement System closed with exchange bag, without drainage valve, latex free	69558240CS0500110UM00026H
14	690501-BAG	Urine meter Exchange bag, without drainage valve, latex free	69558240CS0500110UM00036K