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: Urine Bag
EMDN Code: A060303

Intended purpose: Urine bags are used for draining and collecting, or collection accumulated urine from patients.

Classification (MDR, Rule 1 of Annex VIII): Class I in sterile condition
Conformity Assessment Route: 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 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, PEOPLE'S REPUBLIC OF CHINA
2024-12-25

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 Affair

Attachment

Catalogue Number	Model and size	Basic UDI-DI	UDI-DI Codes
697010-N	Luxury series, 2000ml	69558240CS0200100UB0002WK	(01)*695582400666*
693790	Leg bag series, 1000ml	69558240CS0200100UB0003WM	(01)*695582400667*
693760	Leg bag series, 1000ml	69558240CS0200100UB0003WM	(01)*695582400668*
693730	Leg bag series, 1000ml	69558240CS0200100UB0003WM	(01)*695582400669*
690270-N	Luxury series, 1000ml	69558240CS0200100UB0002WK	(01)*695582400660*
690250	Luxury series, 5000ml	69558240CS0200100UB0002WK	(01)*695582400661*
690240	Luxury series, 4000ml	69558240CS0200100UB0002WK	(01)*695582400662*
690212-N	Luxury series, 2000ml	69558240CS0200100UB0002WK	(01)*695582400663*
690212	Luxury series, 2000ml	69558240CS0200100UB0002WK	(01)*695582400656*
690210-N	Luxury series, 2000ml	69558240CS0200100UB0002WK	(01)*695582400664*
690210	Luxury series, 2000ml	69558240CS0200100UB0002WK	(01)*695582400665*
690092-N	Luxury series, 2000ml	69558240CS0200100UB0002WK	(01)*695582400694*
690092	Luxury series, 2000ml	69558240CS0200100UB0002WK	(01)*695582400695*
690090-N	Luxury series, 2000ml	69558240CS0200100UB0002WK	(01)*695582400696*
690090	Luxury series, 2000ml	69558240CS0200100UB0002WK	(01)*695582400697*