

	Document Name	Declaration of Conformity			Page	Page 1 of 2
	Document No.	CE-UB-02-01-20	Version	V01	Effective Date	2026-03-13

EU Declaration of Conformity

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer: Name: Hangzhou Primecare Medical Co., Ltd.
 Add: Room 408-409, Zancheng Center West, Shangcheng District,
 310008 Hangzhou, PEOPLE'S REPUBLIC OF CHINA
 SRN: CN-MF-000011403
 European Representative: Name: MedPath GmbH
 Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
 SRN: DE-AR-000000087
 Product Name: Urine Bag
 Product REF: Annex 1
 Basic UDI 697236069UB02KP
 Intended purpose This product is used for draining accumulated urine.
 Classification acc. to MDR Ax. VIII: Class Is, Rule 1
 Applied Common Specification/ standard: EN ISO 13485: 2016; EN ISO 14971: 2019; ISO 8669-2:1996
 EN ISO 15223-1:2021/Amd:2025; EN ISO 20417:2021;
 Conformity Assessment Procedure: MDR Annex XI Part A

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany
 Identification number: 0123
 (EU) Certificate(s): No. G21 005225 0005 Rev. 01
 Expire date of the Certificate: 2028-07-17
 Start of CE Marking: 2024.12.01
 Place of Issue: Hangzhou, CHINA
 Date of Issue: 2026-03-13
 Signature: 
 Yan Xueqing

Position: Person responsible for regulatory compliance

	Document Name	Declaration of Conformity			Page	Page 2 of 2
	Document No.	CE-UB-02-01-20	Version	V01	Effective Date	2026-03-13

Annex 1

REF	Product description
04/01/210/GHC	210ml, Leg Bag Sterile
04/01/500/10/GHC	500ml, 3 Chamber Leg Bag Sterile, 10cm Tube,Leg Bag series
04/01/500/30/GHC	500ml, 3 Chamber Leg Bag Sterile, 30cm Tube,Leg Bag series
04/01/500/50/GHC	500ml, 3 Chamber Leg Bag Sterile, 50cm Tube,Leg Bag series
04/01/750/10/GHC	750ml, Leg Bag Sterile, 10cm Tube,T-tap,Leg Bag series
04/01/750/30/GHC	750ml, Leg Bag Sterile, 30cm Tube,T-tap,Leg Bag series
04/01/750/50/GHC	750ml, Leg Bag Sterile, 50cm Tube,T-tap,Leg Bag series
04/01/750A/10/GHC	750ml, Leg Bag Sterile, 10cm Tube,T-tap and Barbed Connector,Leg Bag series
04/01/750A/30/GHC	750ml, Leg Bag Sterile, 30cm Tube,T-tap and Barbed Connector,Leg Bag series
04/01/750A/50/GHC	750ml, Leg Bag Sterile, 50cm Tube,T-tap and Barbed Connector,Leg Bag series
04/01/750A/70/GHC	750ml, Leg Bag Sterile, 70cm Tube,T-tap and Barbed Connector,Leg Bag series
04/01/750F/50/GHC	750ml, Leg Bag Sterile, 50cm Tube,Flip style outlet,Leg Bag series
04/02/1000/90/GHC	1000ml, Urine Bag Sterile, 90cm Tube, Apple-shaped,Luxury series
04/02/2000/90/GHC	2000ml, Economy Urine Bag Sterile, 90cm Tube,Standard series.
04/02/2000/120/GHC	2000ml,Urine Bag Sterile, 120cm Tube, Apple-shaped,Luxury series
04/02/4000/120/GHC	4000ml,Urine bag Sterile, 120cm Tube,Luxury series
04/02/4000/TUR/GHC	4000ml,Urine bag Sterile, 120cm Tube and with Bulb,Luxury series
04/03/1000/30/GHC	1000ml, Day & Night Leg Bag Sterile, 30cm Tube,Leg Bag series
04/03/1000/60/GHC	1000ml, Day & Night Leg Bag Sterile, 60cm Tube,Leg Bag series
04/03/1000/90/GHC	1000ml, Day & Night Leg Bag Sterile, 90cm Tube,Leg Bag series
04/04/2000/90/GHC	2000ml, Economy Urine Bag Sterile, 90cm Tube,Standard series
04/04/2000/100/GHC	2000ml,Urine Bag Sterile, 110cm Tube, A4 Type,Luxury series
04/04/2000/110/GHC	2000ml,Urine Bag Sterile, 110cm Tube, A4 Type,Luxury series
04/04/2000/120/GHC	2000ml,Urine Bag Sterile, 110cm Tube, A4 Type,Luxury series