

<b>ZENGFU</b>	Document Name	Document No.	ACE-UB-01
	<b>Declaration of Conformity</b>	Version	B
		Effective Date	2020-11-03

**Manufacturer:** Changshu Zengfu Medical Device Co., Ltd.

**Address:** No.8 Zengfu Road, Baimao Industrial Park, Guli Town, Changshu City, Jiangsu Province, 215532. P.R. China

**European Representative:** Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg Germany

**Product Name:** Urine Bag (with and without gloves pack/with and without straps)

**Model code:** Refer to Attachment

**UMDNS Code:** 14298

**Classification:** (MDD, Annex IX): I sterile , Rule I

**Conformity assessment route:** Annex V.3

We herewith declare that the above-mentioned products meet the provisions of the following EC council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

#### DIRECTIVES

**General applicable directives:**

**Medical Device Directive:**

Council Directive 93/42/EEC concerning medical devices (MDD 93/42/EEC).

**Notified Body:** TUV SUD Product Service GmbH, Ridlerstr.65, 80339 Munchen, Germany

**Identification number:** CE0123

**Certificate:** G2S 0023930009

**Expiry date of the certificate:** 2024-01-29

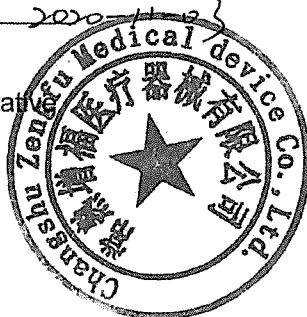
**Start of CE Marking:** Not until now

**Place, date of issue:** Changshu Zengfu Medical Device Co., Ltd. No.8 Zengfu Road, Baimao Industrial Park, Guli Town, Changshu City, Jiangsu Province, 215532. P.R. China 2020-11-03

**Signature** *Wu Chaoer* 2020-11-03

**Name:** Wu Chaoer

**Position:** Management Representative



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Attachment:

<b>Class I, Sterile. Product names</b>	<b>Code</b>
Qufora Leg Bag, 350 ml, 30 cm tube, 180° lever tap, single chamber	12061901
Qufora Leg Bag, 500 ml, 50 cm tube, T-tap outlet, 3 chamber	12121501
Qufora Leg Bag, 500 ml, 25 cm tube, T-tap outlet, 3 chamber	12121601
Qufora Leg Bag, 500 ml, 2 cm tube, T-tap outlet, 3 chamber	12121701
Qufora Leg Bag, 500 ml, 50 cm tube, 180° lever tap, SPC, 3 chamber	12161502
Qufora Leg Bag, 500 ml, 25 cm tube, 180° lever tap, SPC, 3 chamber	12161602
Qufora Leg Bag, 500 ml, 10 cm tube, 180° lever tap, SPC, 3 chamber	12161802
Qufora Leg Bag, 600 ml, 50 cm tube, lever tap outlet, single chamber	12221502
Qufora Leg Bag, 600 ml, 10 cm tube, T-tap outlet, SPC, single chamber	12251802
Qufora Leg Bag, 600 ml, 30 cm tube, T-tap outlet, SPC, single chamber	12251902
Qufora Leg Bag, 750 ml, 50 cm tube, T-tap outlet, 3 chamber	12321501
Qufora Leg Bag, 750 ml, 25 cm tube, T-tap outlet, 3 chamber	12321601
Qufora Leg Bag, 750 ml, 50 cm tube, 180° lever tap, SPC, 3 chamber	12361502
Qufora Leg Bag, 750 ml, 10 cm tube, 180° lever tap, SPC, 3 chamber	12361802
Qufora Leg Bag, 750 ml, 25 cm tube, 180° lever tap, SPC, 3 chamber	12361902
Qufora Leg Bag, 750 ml, 10 cm tube, 180° lever tap, SPC, single chamber	12363802
Qufora Leg Bag, 1000 ml, 90 cm tube, 180° lever tap, SPC, closed system	12561001
Qufora Bed Bag, 2000 ml, 130 cm tube, lever tap outlet, SPC	14851201
Qufora Bed Bag, 2000 ml, 90 cm tube, T-tap outlet, SPC	14853102
Qufora Bed Bag, 2000 ml, 120 cm tube, fold-away lever tap, SPC	14823202
Qufora Bed Bag, 2000 ml, 120 cm tube, fold-away lever tap, double pack, SPC	14823212
Qufora Bed Bag, 2000 ml, 120 cm tube, fold-away T-tap outlet, SPC	14853202
Qufora Closed System Bag, 2000 ml, 130 cm tube, Lever-tap outlet, SPC, CSB	16823201
Qufora Flush Bag, 5000 ml, 125 cm tube, Lever-tap outlet, SPC	16923301
Qufora Flush Bag, 4000 ml, 125 cm tube, Lever-tap outlet, SPC	16923302
Qufora Leg Bag, 350 ml, direct inlet tube, lever outlet, sample port, gloves, straps	12061704
Qufora Leg Bag, 350 ml, long tube, lever outlet, sample port, gloves, straps	12061504
Qufora Leg Bag, 350 ml, short tube, lever outlet, sample port, gloves, straps	12061804
Qufora Leg Bag, 350 ml, direct inlet tube, t-tap outlet, sample port, gloves, straps	12051704
Qufora Leg Bag, 350 ml, long tube, t-tap outlet, sample port, gloves, straps	12051504
Qufora Leg Bag, 350 ml, short tube, t-tap outlet, sample port, gloves, straps	12051804
Qufora Leg Bag, 500 ml, direct inlet tube, lever outlet, sample port, gloves, straps	12161704
Qufora Leg Bag, 500 ml, long tube, lever outlet, sample port, gloves, straps	12161504
Qufora Leg Bag, 500 ml, long tube, lever outlet, sample port, no soft backing, straps	12161514
Qufora Leg Bag, 500 ml, short tube, lever outlet, sample port, gloves, straps	12161804
Qufora Leg Bag, 500 ml, direct inlet tube, t-tap outlet, sample port, gloves, straps	12151704
Qufora Leg Bag, 500 ml, long tube, t-tap outlet, sample port, gloves, straps	12151504
Qufora Leg Bag, 500 ml, short tube, t-tap outlet, sample port, gloves, straps	12151804
Qufora Leg Bag, 750 ml, direct inlet tube, lever outlet, sample port, gloves, straps	12361704
Qufora Leg Bag, 750 ml, long tube, lever outlet, sample port, gloves, straps	12361504
Qufora Leg Bag, 750 ml, short tube, lever outlet, sample port, gloves, straps	12361804
Qufora Leg Bag, 750 ml, direct inlet tube, t-tap outlet, sample port, gloves, straps	12351704
Qufora Leg Bag, 750 ml, long tube, t-tap outlet, sample port, gloves, straps	12351504
Qufora Leg Bag, 750 ml, short tube, t-tap outlet, sample port, gloves, straps	12351804
Qufora Leg Bag, 2000 ml, 90 cm tube, non-drainable	13803104
Qufora Bed Bag, 2000 ml, 120 cm tube, lever tap, sample port, gloves	14851204
Qufora Bed Bag, 2000 ml, 120 cm tube, fold-away t-tap, sample port, gloves	14853204
Qufora Bed Bag, 2000 ml, 120 cm tube, fold-away lever tap, sample port, gloves	14823204