

ZENGFU	Document Name	Document No.	ACE-NSC-01
	Declaration of Conformity	Version	B
		Effective Date	2020-11-03

Manufacturer: Changshu Zengfu Medical Device Co., Ltd.
Address: No.8 Zengfu Road, Baimao Industrial Park, Guli Town, 215532,
Changshu City, Jiangsu Province, P.R.China.

European Representative: Shanghai International Holding Corp.GmbH(Europe)
Eiffestrasse 80, 20537, Hamburg Germany

Product Name: Urine Bag (Non-sterile)
Model Number: Refer to attachment
UMDNS code: 14298
Classification: (MDD, Annex IX) I, Rule 1
Conformity Assessment Route: Annex VII

We herewith declare in our sole responsibility that the above-mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. The declaration of conformity is issued under our sole responsibility.

DIRECTIVES

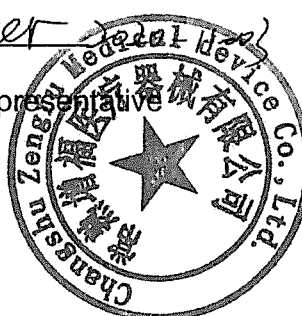
General applicable directives:

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

Standard Applied: Harmonized standards published in the official journal of the European communities applicable to this product.

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

Signature 
Name: Wu Chaoer
Position: Management representative



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Attachment:

Product names

REF Code

Qufora Bed Bag, 750 ml, 10 cm tube, non-drainable	13303802
Qufora Bed Bag, 1500 ml, 110 cm tube, non-drainable	13703412
Qufora Bed Bag, 1500 ml, 10 cm tube, non-drainable	13703802
Qufora Bed Bag, 1500 ml, 35 cm tube, non-drainable	13703902
Qufora Bed Bag, 1500 ml, 90 cm tube, T-tap outlet	13753101
Qufora Bed Bag, 2000 ml, 90 cm tube, non-drainable, step connector	13800101
Qufora Bed Bag, 2000 ml, 90 cm tube, non-drainable, 30 pcs edition	13803104
Qufora Bed Bag, 2000 ml, 90 cm tube, non-drainable	13803112
Qufora Bed Bag, 2000 ml, 130 cm tube, T-tap outlet	13850301
Qufora Bed Bag, 2000 ml, 90 cm tube, T-tap outlet	13853101
Qufora Bed Bag, 2000 ml, 90 cm tube, small t-tap, 30 pcs + 1 hanger	1660003
Qufora Bed Bag, 2000 ml, 110 cm tube, T-tap outlet	13853401
Qufora Bed Bag, 2000 ml, 110 cm large diameter tube, T-tap outlet	13853402
Qufora Bed Bag, 2000 ml, 110 cm large diameter tube, T-tap outlet, SPC	13853403
Qufora Bed Bag, 2000 ml, 130 cm tube, lever tap outlet, hanger, SPC	14851202
Qufora Accessory bag for urimeter U2, 2000 ml, no outlet	16703722
Qufora Accessory bag for urimeter U2, 2000 ml, T-tap outlet	16753722
Qufora Leg Bag, 350 ml, 30 cm tube, 180° lever tap, single chamber	11061901
Qufora Leg Bag, 500 ml, 50 cm tube, T-tap valve, multi chamber	11121501
Qufora Leg Bag, 500 ml, 50 cm tube, 10 bags + straps	11121502
Qufora Leg Bag, 500 ml, 3 cm tube, 10 bags + straps	11121702
Qufora Leg Bag, 500 ml, 10 cm tube, 10 bags + straps	11121802
Qufora Leg Bag, 500 ml, 50 cm tube, 180° lever tap, multi chamber	11161502
Qufora Leg Bag, 600 ml, 50 cm tube, lever tap valve, single chamber	11221502
Qufora Leg Bag, 600 ml, 30 cm tube, lever tap valve, single chamber	11221902
Qufora Leg Bag, 600 ml, 10 cm slanting tube, lever tap, single chamber	11223802
Qufora Leg Bag, 600 ml, 50 cm tube, T-tap valve, single chamber	11251502
Qufora Leg Bag, 600 ml, 30 cm tube, T-tap valve, single chamber	11251902
Qufora Leg Bag, 600 ml, 10 cm slanting tube, T-tap valve, single chamber	11259802
Qufora Leg Bag, 750 ml, 50 cm tube, 180° lever tap, multi chamber	11361502
Qufora Leg Bag, 750 ml, 10 cm tube, no outlet, basic features	11401803
Qufora Leg Bag, 800 ml, 50 cm tube, lever tap valve	11421502
Qufora Leg Bag, 800 ml, 50 cm tube, T-tap valve, single chamber	11451502
Qufora Leg Bag, 750 ml, 50 cm tube, T-tap valve, basic features	11451503
Qufora Leg Bag, 750 ml, 10 cm tube, T-tap valve, basic features	11451803
Qufora Leg Bag, 1500 ml, 90 cm tube, no outlet	11701101
Qufora Leg Bag, 1500 ml, 90 cm tube, T-tap	11751101