

Declaration of Conformity

For the following products:

Urine Bag

(Product Name)

Urine Bag

(Model Designation)

100ml, 200ml, 350ml, 500ml, 750ml, 900ml, 1000ml, 1500ml, 2000ml, 2600ml, 3000ml, 4000ml, 5000ml

(UMDNS Code)

14298

(Classification)

Is, rule1

is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC)

Applicable standards are: EN ISO 13485:2016, EN ISO 14971:2012, EN 1041:2008+A1:2013, EN ISO 15223-1:2016, EN 556-1:2001/AC:2006, EN 62366:2008, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, EN ISO 10993-7:2008/AC:2009, EN ISO 10993-10:2013, EN ISO 10993-12:2012, EN ISO 11135:2014, ISO 11607-1:2009, EN ISO 11607-2:2006, ISO 14644-1:2015, ISO 14644-2:2015, EN ISO 11737-1:2006/AC2009, EN ISO 11737-2:2009, EN ISO 8669-2:1996

Conformity Assessment Route:

Annex V of Medical Device Directive

Notified Body:

DNV GL Presafe AS (NB No. 2460)

Veritasveien 3, 1363 Høvik, Norway

The following European Authorized Representative is stated to the declaration:

Company Name: **MedNet EC-REP GmbH**

Company Address: **Borkstrasse 10, 48163 Münster, Germany**

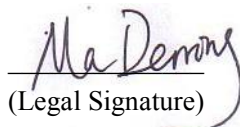
The following manufacturer is exclusively responsible for making this declaration:

Company Name: **Changshu Taining Medical Equipment Co., Ltd.**

Company Address: **Nan shou, Yangyuan Town, 215562 Changshu city, Jiangsu Province, China**

Certificate No.: 9823-2017-CE-RGC-NA-PS Rev. 2.0

Valid Until: 27 May 2024


(Legal Signature)

General Manager
(Position/title)

常熟市泰宁医疗器械有限责任公司
20th, May 2021
CHANGSHU TAINING MEDICAL EQUIPMENT CO., LTD.
(Date)