

常熟市神灵医用器材有限公司 Changshu SENLIN Medical Appliance CO., Ltd

Declaration of Conformity

Manufacturer Name: Changshu Senlin Medical Appliance Co., Ltd.

Address: No.18 Zengfu Road, Baimao Industrial Park, Guli Town

215532 Changshu, Jiangsu

PEOPLE'S REPUBLIC OF CHINA

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

Address: Eiffestraße 80, D- 20537, Hamburg Germany

Product Name: Urine Bag

UMDNS Code: 10944

Classification (MDD, Annex IX): I, Rule 1

Conformity Assessment Route: Annex VII

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 of 14 June 1993 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 SENLIN Medical Appliance Co., Ltd.

SENLIN

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215532 Changshu, Jiángsú PEOPLE'S REPUBLIC OF CHINA CHAIGGEU SEILIN MEDICAL APPLIANCE COLLTE 2014-3-18

Signature Daharon 2014.2.8

Position: Management Representative