

# JIANGSU ZHENGKANG MEDICAL APPARATUS CO.,LTD



江苏正康医疗器械有限公司

Address: Sanhekou, Zhenglu town, Changzhou city, Jiangsu, china

TEL: +86-519-88672658 FAX: +86-519-88671088

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## *Declaration of Conformity*

Manufacturer: Jiangsu Zhengkang Medical Apparatus Co., Ltd  
Sanhekou, Zhenglu town, Changzhou city, Jiangsu, china

Representative: Shanghai International Trading Corp. GmbH (Hamburg)  
Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: URINE BAG

UMDNS Code: 12157

Classification (MDD, Annex IX): 1, rule 7

Conformity Assessment Route: Annex V

Medical device class: IIA

We herewith declare 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.

## 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: See attached list of (harmonised – EN) standards for which documented evidence of compliance can be provided.

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E-mail: zk@jszhengkang.com 邮编 (Zip Code): 213115

Notified Body: TÜV Product Service GmbH, Ridlerstr. 65, 80339  
München, Germany

Identification number: CEO123

(EC) Certificate(s): No .G2 073425 0008 Rev.02

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2019-11-13

Place, Date of Issue:

Signature: \_\_\_\_\_

Name: Xu Tao

Position: Manager



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