

Declaration of Conformity

Manufacturer: **Changshu Kangbao Medical Appliance Factory**
Furong Village, Baimao, Guli Town, 215500 Changshu
City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA
SRN: **CN-MF-000024507**

European
Representative: **MedPath GmbH**
Mies-van-der-Rohe-Strasse 8, 80807 Munich,
Germany
SRN: **DE-AR-000000087**

Product Name: Urine bag
Models: 750ml, 1000ml, 2000ml, 2000+200ml, 2000+500ml,
2600+400ml, 2600+500ml

Basic UDI-DI: 697434391KBNMNJ

Classification (MDR, Annex VIII): **class Is , rule 1**

Conformity Assessment Route: **Annex XI Part A.**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following Regulation(EU) 2017/745 and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: Regulation(EU) 2017/745 of The European Parliament of The council of 5 April. 2017

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

NB Identification number: 0123

(EC) Certificate(s): G21 089714 0007 Rev.00

Expire date of the Certificate: 2028-12-14

Start of CE Marking: 2023-12-15

Place, Date of Issue: **Changshu, 2023-12-20**

Signature:

Name: **Zhou Hongbao**

Position: **General Manager**

EC Declaration of Conformity
KB/CE01-01(A/0)