

Declaration of Conformity

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

SRN:

European Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 Munich,
Germany

SRN: DE-AR-000000087

Product Name: Urine bag

Models: 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: 2018-11-28

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

Signature:

Name: Zhou Hongbao

Position: General Manager

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KB/CE01-01(A/0)

常熟市康宝医疗器械厂
CHANGSHU KANGBAO MEDICAL APPLIANCE FACTORY