Declaration of Conformity

Manufacturer	**Changshu Kangbao Medical Appliance Factory Furong Village, Baimao, Guli Town, 215500 Changshu City, Jiangsu Province, PEOPLE' S REPUBLIC OF CHINA**
European Representative	**PROLINX GMBH BREHMSTR.56, 40239 DUESSELDORF, GERMANY**
Product Name:	Urine bag
Models:	100ml,1000ml, 2000ml, 2000+200ml, 2000+500ml, 2600+400ml, 2600+500ml.
UMDNS Code:	14298
GMDN Code:	40505

Classification (MDD, Annex IX): **I sterile, rule 1**

Conformity Assessment Route: **Annex V.**

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). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany
NB Identification number:	0123
(EC) Certificate(s):	No.G2S 089714 0003 REV.02
Expire date of the Certificate:	2024-05-26
Start of CE Marking:	2019-06-06

Place, Date of Issue: **Changshu, 2019-06-06**

Signature:

Name: **Zhou Hongbao**

Position: **General Manager**

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