

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 Prolinx GmbH
Representative Brehmstr. 56, 40239, Duesseldorf, Germany

Product Name: Urine Bag, Urine Bag With Hanger,
Pediatric Urine Bag, Leg Bag

Models: 2000ml,100ml,160ml,750ml

UMDNS Code: 14298

Basic UDI-DI: 697434391KBNMNJ

SRN: DE-AR000005129

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): 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, 2020-02-10

Signature:

Name: **Zhou Hongbao**

Position: **General Manager**

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KB/CE01-01(A/2)