

## Declaration of conformity

Manufacturer Huaian Angel Medical Instruments Co., Ltd.  
Address 19 East Zhuhai Road, Huaian , Jiangsu 223001, P.R.China

Eu-Representative: AXOR

Address: 10 GRANDE RUE 10160  
PLANTY,FRANCE

TEL.NO.0033-3-25405544 FAX NO.0033-3-25406090

Product Sterile Urinary Drainage Bags

Model Code 2000ml / 100ml

Classification (MDD, Annex IX): I\*

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and notified body.

### DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standard

All applicable harmonized Standard (published in the Official Journal of the European Communities)

ISO9001、ISO13485、EN552、EN868-1、EN980、ISO10993-1、ISO14971

Notified Body: TUV Rheinland Product Safety GmbH

Certificate: DD 60025609 0001

Expirate data of the Certificate: 27.01.2014

Data CE mark was affixed:

Place, Date: 19 East Zhuhai Road, Huaian , Jiangsu 223001, P.R.China

July 3, 2009

Signature

Name: Mr. Cao Ming Tuo

Position: General Manager

