

Issuing Department:
Technical Section
Revision: 0
Date of Revision:

Huainan Angel Medical Instruments Co., Ltd.
CE Technology Documents
Title: Declaration of Conformity
Effective Date: May 15, 2004

No.: CE-10
Edition: A
Page: 1 of 1

Declaration of conformity

Manufacturer Huainan Angel Medical Instruments Co., Ltd.
Address South Hantai Road, Economic Development District, Huainan,
Jiangsu 223005, P.R.China

Eu-Representative: The Medical Export Group of The Netherlands BV
Address: P.O. BOX 598
4200 An Gorinchem The Netherlands

Product Sterile Drainage Bags

Model Code

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/EBC of 14 June 1993 concerning medical devices (MDD 93/42/EBC).

Standard

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

EN ISO 9001, EN46002, EN30993, EN552, EN556, EN980,

EN1174-1, EN868-1, EN1441, EN1041

Notified Body: TÜV Rheinland Product Safety GmbH

Certificate: HD 600008461 0001

Expirate data of the Certificate: 14 June 2009

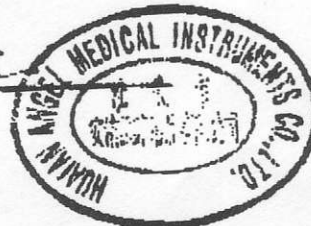
Data CE mark was affixed:

Place, Date: South Hantai Road, Economic Development District, Huainan, Jiangsu
223005 China 1 April 2004

Signature

Name: Mr. Cao Ming Tuo

Position: General Manager



Compiling Person:

Verifying Person:

Approving Person: