Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 104356 0003 Rev. 01

Manufacturer

Ningbo Great Mountain Medical Instruments Co.,Ltd
No. 309 Xigu Road
Xiangshan County
315700 Ningbo City, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Disposable Airways, Urine Bag, Vaginal Speculum, Sterile Wound Plaster

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G2S 104356 0003 Rev. 01

Report No.: SH20152001

Valid from: 2021-05-03
Valid until: 2024-05-26

Date, 2021-05-03

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Chițanu Ion
Date: 2023.04.11 09:57:00 EEST
Reason: MoldSign Signature
Location: Moldova

CONFORM CU ORIGINALUL

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Ningbo Great Mountain Medical Instruments Co., Ltd.	Document No.: GM-UB	Edition: A0	page: 1/1
CE Technical Documentation	EC Declaration of Conformity	Effective Date: 2019-08-28	

Manufacturer:

Name: Ningbo Great Mountain Medical Instruments Co., Ltd.

Add: No.309 Xigu Road, Xiangshan District, Ningbo, China

Tel: 0574-82815201 Fax: 0574-82815202

European Representative:

Name: Luxus Lebenswelt GmbH

Address: Kochstr.1, 47877, Willich, Germany

DIMDI Code: DE/0000047791

Tel/Fax: 0049-1715605732

Email: Info.m@luxuslw.de

Product Name: Urine bag

Classification and relevant Rule of MDD: Is. MDD 93/42/EEC Annex IX, Rule 15

Type:100ML,500ML,1000ML,2000ML

The UMDNS code: 14298

Product Certification Conformity Assessment Route: Annex V.3 of MDD 93/42/EC

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

Ningbo Great Mountain Medical Instruments Co., Ltd is exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES (MDD 93/42/EEC)

Notified Body: TÜV SÜD Product Service GmbH Ridlerstr.65, 80339 München,Germany

Identification Number: 0123

(EC) Certificate(s): G2 104356 0002

Expire date of the certificate: 2024-05-26

Signature of issue person:

Position: General Manager Name:

Date: 2020-04-26 Place: Ningbo

CONFORM CU ORIGINALUL