EC Declaration of Conformity

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 with the brand Euromed

Type:100ML, 200ML, 500ML,1000ML, 2000ML

Intended purpose of the product: The Urine Bag is intended to use with an indwelling catheter in persons who are incontinent of urine, can not urinate in the normal way, or need to have the bladder flow continually.

GMDN: 14298

Risk Classification: Class Is, according to rule 1, Annex VIII, Regulation (EU) 2017/745

Manufacturer SRN Number: APP000048659

Basic UDI-DI: 697252741urinebagN4

We herewith declare that the above mentioned products meet with the European Medical Device Regulations (EU) MDR 2017/745. Ningbo Great Mountain Medical Instruments Co., Ltd is exclusively responsible for the declaration of conformity.

Conformity Assessment Procedure: Annex II +III of Regulation (EU) 2017/745

Applicable Standards: EN ISO 14971:2019
EN ISO 15223-1:2016
EN 1041:2008+A1:2013
ISO 10993-1:2018
EN ISO 10993-5:2009
EN ISO 10993-10:2013

Signature of issue person：

Position：General Manager Name: Yang Bin

Date：19th Jan, 2023 Place：Ningbo

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

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

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
104356	SH241520A01	medical_devices@tuvsud.com		2024-07-09	1 of 3

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 104356 0004 Rev. 00

Reference: SH241520A01

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: CN-MF-000033311

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC

(MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 104356 0004 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-07-09

TÜV SÜD Product Service GmbH
Medical and Health Services

Mr. Xujian Liu
Mr. Xujian Liu (Jul 9, 2024 23:13 GMT+7)

Liu Xujian
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Clara Höhneke
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 **Urine Bag** **697252741urinebagN4**	☒ Class I devices in sterile condition	☒ N/A	Certificate #1 **No.G2S 104356 0003 Rev.01** NB# **0123**
Device 2 **Oxygen Mask** **697252741oxygenmaskPU**	☒ Class IIa	☒ N/A	Certificate #1 **No. G2 104356 0002 Rev.01** NB# **0123**
Device 3 **Nebulizer Mask** **697252741nebulizermaskBC**	☒ Class IIa	☒ N/A	Certificate #1 **No. G2 104356 0002 Rev.01** NB# **0123**
Device 4 **Nasal Oxygen cannula** **697252741nasalcannulaHY**	☒ Class IIa	☒ N/A	Certificate #1 **No. G2 104356 0002 Rev.01** NB# **0123**
Device 5 **Yankauer Handle with Connecting Tube** **697252741Yankauertube8S**	☒ Class IIa	☒ N/A	Certificate #1 **No. G2 104356 0002 Rev.01** NB# **0123**
Device 6 **RESPIRATORY FILTERS** **697252741filtersHF**	☒ Class IIa	☒ N/A	Certificate #1 **No. G2 104356 0002 Rev.01** NB# **0123**
Device 7 **RESPIRATORY CIRCUITS AND KITS** **697252741circuitFW**	☒ Class IIa	☒ N/A	Certificate #1 **No. G2 104356 0002 Rev.01** NB# **0123**

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-07-09	SH241520A01	Initial issue

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

TÜV SÜD 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

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

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

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