

Ningbo Great Mountain Medical Instruments Co., Ltd. CE Technical Documentation	Document No.: GM-NOC	Edition: A0	page: 1/1
	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: Phoenix Medtech GmbH

Address: Koenigsberger Strasse 11, 64839, Muenster Hessen, Germany

DIMDI Code: DE/0000049489

Tel/Fax: 0049-60714977513

Email: contact@glgi.de

Product Name: Nasal Oxygen cannula

Classification and relevant Rule of MDD: II a MDD 93/42/EEC Annex IX, Rule 5

Type: L, S, XS, XXS

The UMDNS code: 16422

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): No. G2 104356 0002 Rev. 01

Expire date of the certificate: 2024-05-26

Confirmation letter: CL 104356 0004 Rev.00

Issue date: 2024-07-09

End date of extended validity: 2028-12-31

Signature of issue person:

Position: General Manager

Date: 2024-07-10

Name: Yang Bin

Place: Ningbo



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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
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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

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
Zertifizierstelle für Medizinprodukte /
Certification Body for Medical Products
Ridlerstr. 65
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(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

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)

Clara Hönneke
Clara Hönneke
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 NOT 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