Certificate

Quality Management System
EN ISO 13485:2016

Registration No.	SX 2055984-1
Certificate Holder	Ningbo MFLAB Medical Instruments Co., Ltd. No.508, Yindong Road(N), Yinzhou Economic Development Zone, 315145 Ningbo P.R. China
Scope	Design and Development, Manufacture and Distribution of Oxygen Masks for Single Use, Venturi Masks for Single Use, Nebulizer Masks for Single Use, Oxygen Masks with Reservoir Bags for Single Use, Tracheostomy Masks for Single Use, Nebulizers with Mouth-pieces, Nasal Oxygen Cannulas, Oxygen Connection Tubings, Connecting Tubes with Yankauer Handle, Anesthesia Masks, Laryngeal Mask Airways, Bougies, Resuscitation Masks, Silicone/SEBS/PVC Manual Resuscitators, Endotracheal Tubes, Reinforced Endotracheal Tubes, Tracheostomy Tubes, Nelaton Catheters, Stomach Tubes, Suction Catheters, Sterile Three-way Stopcocks for Single Use, Disposable Breathing Circuits, Breathing System Filters, Heat and Moisture Exchangers, Sterile Urine Containers, Rectal Tubes, Oral Pharyngeal Airways, Nasopharyngeal Airways, Feeding Tubes, Burette Infusion Sets, Urinary Collection Bags for Single Use, Cotton Tipped Applicators, Swabs, Peak Meters, Plastic Sample Cups, Disposable Vacuum Blood Tubes, Disposable Vacuum Blood Collection Systems, Disposable Vaginal Speculums, Micro Blood Collection Tubes, Vacuum Urine Collection Sets, Disposable Non Vacuum Blood Tubes,

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.	244513722-200
Effective date	2023-07-21
Expiry date	2026-07-20
Issue date	2023-07-20

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
Precisely Right.

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.	SX 2055984-1
Certificate Holder	Ningbo MFLAB Medical Instruments Co., Ltd. No.508, Yindong Road(N), Yinzhou Economic Development Zone, 315145 Ningbo P.R. China
	Spacers for Aerosol, Spirometers, Disposable Labwares and Instruments for Medical Use (Test Tubes, Tube Stoppers, Centrifuge Tubes, Pipette Tips, Transfer Pipettes, Petri Dishes, Containers (Measuring Cups, Urine Containers, Specimen Containers),Disposable Connecting Extension Tubes, Suction Connecting Tubes, Yankauer Handles, Suction Poole Drains, Umbilical Cord Clamps

Report No.	244513722-200
Effective date	2023-07-21
Expiry date	2026-07-20
Issue date	2023-07-20

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TÜV Rheinland LGA Products GmbH
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EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60149456 0001

Report No.: 15050519 013

Manufacturer:
Ningbo MFLAB Medical Instruments
Co., Ltd.
No.508,Yindong Road(N)
Yinzhou Economic Development
Zone
315145 Ningbo
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60144860 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-05-25

Date: 2020-05-25

Notified Body

Jason Pan

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/2, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60149456 0001
Report No.: 15050519 013

Manufacturer:
Ningbo MFLAB Medical Instruments Co., Ltd.
No.508,Yindong Road(N)
Yinzhou Economic Development Zone
315145 Ningbo
P.R. China

Products:

- Oxygen Masks for Single Use
- Venturi Masks for Single Use
- Nebulizer Masks for Single Use
- Oxygen Masks with Reservoir Bags for Single Use
- Tracheostomy Masks for Single Use
- Nebulizers with Mouth-pieces
- Nasal Oxygen Cannulas
- Oxygen Connection Tubings
- Connecting Tubes with Yankauer Handle
- Anesthesia Masks
- Laryngeal Mask Airways
- Resuscitation Masks
- Silicone/SEBS/PVC Manual Resuscitators
- Endotracheal Tubes
- Reinforced Endotracheal Tubes
- Tracheostomy Tubes
- Nelaton Catheters
- Stomach Tubes
- Suction Catheters
- Sterile Three-way Stopcocks for Single Use
- Bougies

Notified Body

Date: 2020-05-25

Jason Pan

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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Doc. 2/2, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60149456 0001
Report No.: 15050519 013

Manufacturer:
Ningbo MFLAB Medical Instruments Co., Ltd.
No.508,Yindong Road(N)
Yinzhou Economic Development Zone
315145 Ningbo
P.R. China

Products:

- Disposable Breathing Circuits
- Breathing System Filters
- Heat and Moisture Exchangers
- Burette Infusion Sets
- Disposable Connecting Extension Tubes

Aspects of manufacture concerned with securing and maintaining sterile conditions:
- Sterile Urine Containers
- Rectal Tubes
- Oral Pharyngeal Airways
- Nasopharyngeal Airways
- Feeding Tubes
- Urinary Collection Bags for single use
- Cotton Tipped Applicators
- Swabs

Aspects of manufacture concerned with conformity of products with the metrological requirements:
- Peak Meters

Notified Body

Date: 2020-05-25

Jason Pan

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Business Stream Products
Certification Department

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TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Ningbo MFLAB Medical Instruments
Co., Ltd.
No.508,Yindong Road(N)
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315145 NINGBO
P.R. CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date May 26, 2020

Application for : QMS Produktion, Anhang V MDD
Certificate No. : DD 60149456 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. DD 60149456 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body

Jason Pan

Test sample: no, documentation available

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LGA Products GmbH

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Business Stream Products
Certification Department

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No.508, Yindong Road(N), Yinzhou Economic Development Zone,
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Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date April 17, 2024

Notified Body Confirmation Letter
Reference. : 326005702

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has 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 following manufacturer:

Ningbo MFLAB Medical Instruments Co., Ltd.
No.508, Yindong Road(N), Yinzhou Economic Development Zone,
315145 Ningbo
P.R. China
SRN Number (if available): CN-MF-000032006

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

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either 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, by March 20, 2023 for the relevant devices.

TÜV Rheinland
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The transition timelines 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 (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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)

On behalf of the Notified Body

Fuxiu Sheng
Certification body

Table 1: Devices covered by this letter and for which the NB 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 at the pre-application stage)**	**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**
Nasal Oxygen Cannula MODEL:MB01, MB02 **Basic UDI-DI: 697195673901Q2**	Class IIa	Nasal Oxygen Cannula (Tip size: XS, S, M, L, XL)	Certificate # DD 60149456 0001 NB #0197
Oxygen masks for single use MODEL:MS01 **Basic UDI-DI: 697195673410PA**	Class IIa	Oxygen masks for single use (Mask size: S, M, L, XL)	Certificate # DD 60149456 0001 NB #0197
Oxygen masks with Reservoir Bags for single use MODEL:MS02 **Basic UDI-DI: 697195673420PD**	Class IIa	Oxygen masks with Reservoir Bags for single use (Mask size: S, M, L, XL)	Certificate # DD 60149456 0001 NB #0197
Venturi masks for single use MODEL:MS03 **Basic UDI-DI: 697195673430PG**	Class IIa	Venturi masks for single use (Model: insert, revolved)	Certificate # DD 60149456 0001 NB #0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**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**
Venturi masks for single use **MODEL:MS04** **Basic UDI-DI:** **697195673440PK**	Class IIa	Venturi masks for single use (Model: insert, revolved)	Certificate # DD 60149456 0001 NB #0197
Tracheostomy masks for single use **MODEL:MS05** **Basic UDI-DI:** **697195673450PN**	Class IIa	Tracheostomy masks for single use (Model: adult, children)	Certificate # DD 60149456 0001 NB #0197
Oxygen Connection Tubings **MODEL:5.0, 5.5, 6.0** **Basic UDI-DI:** **697195673502PG**	Class IIa	Oxygen Connection Tubings (Various length)	Certificate # DD 60149456 0001 NB #0197
Nebulizer Masks for Single Use **MODEL:MW01、MW02** **Basic UDI-DI:** **697195673310P5**	Class IIa	Nebulizer Masks for Single Use (Mask size: S, M, L, XL; Nebulizer volume: 6cc, 10cc,15cc)	Certificate # DD 60149456 0001 NB #0197
Nebulizers with Mouth-pieces **MODEL:MW03、MW04、MW05** **Basic UDI-DI:** **697195673320P8**	Class IIa	Nebulizers with Mouth-pieces (Model: general type)	Certificate # DD 60149456 0001 NB #0197
Connecting Tubes with Yankauer handle **MODEL:MX01、MX02** **Basic UDI-DI:** **697195673200NV**	Class IIa	Connecting Tubes with Yankauer handle(Connecting tube: ID1/4", ID 3/16" Yankauer handle: Ball-sharped head with regulating hole Plane-sharped head with regulating hole Ball-sharped head without regulating hole Plane-sharped head without regulating hole)	Certificate # DD 60149456 0001 NB #0197
Laryngeal Mask Airways **MODEL:A**	Class IIa	Laryngeal Mask Airways	Certificate # DD 60149456 0001 NB #0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**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**
Basic UDI-DI: 697195673786QS		(Size: 1, 1.5, 2, 2.5, 3, 4, 5)	
Laryngeal Mask Airways MODEL:B **Basic UDI-DI: 697195673791QK**	Class IIa	Laryngeal Mask Airways (Size: 1, 1.5, 2, 2.5, 3, 4, 5)	Certificate # DD 60149456 0001 NB #0197
Laryngeal Mask Airways MODEL:C **Basic UDI-DI: 697195673785QQ**	Class IIa	Laryngeal Mask Airways (Size: 1, 1.5, 2, 2.5, 3, 4, 5)	Certificate # DD 60149456 0001 NB #0197
Nelaton Catheters MODEL:Female **Basic UDI-DI: 697195673040NX**	Class I devices placed on the market in sterile condition	Nelaton Catheters (Size: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr)	Certificate # DD 60149456 0001 NB #0197
Nelaton Catheters MODEL:Male **Basic UDI-DI: 697195673050P2**	Class I devices placed on the market in sterile condition	Nelaton Catheters (Size: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr)	Certificate # DD 60149456 0001 NB #0197
Suction Catheters MODEL:T-type, Y-type, Cap-cone, Plain type **Basic UDI-DI: 697195673774QK**	Class IIa	Suction Catheters (Size: 5, 6, 8, 10, 12, 14, 16, 18, 20)	Certificate # DD 60149456 0001 NB #0197
Sterile Urine Containers MODEL:30mL, 60mL, 120mL、 **Basic UDI-DI: 697195673030NU**	Class I devices placed on the market in sterile condition	N/A	Certificate # DD 60149456 0001 NB #0197
Anesthesia Masks (Size: neonate, infant, toddler, small adult, medium adult, large adult) **Basic UDI-DI: 697195673178PV**	Class IIa	N/A	Certificate # DD 60149456 0001 NB #0197
Oral Pharyngeal Airways (Size: 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0, 11.0, 12.0) **Basic UDI-DI: 697195673125P8**	Class I devices placed on the market in sterile condition	N/A	Certificate # DD 60149456 0001 NB #0197
Nasopharyngeal Airways	Class I devices placed on the	N/A	Certificate # DD 60149456 0001 NB #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
(Size: 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0) **Basic UDI-DI: 697195673126PA**	market in sterile condition		
Resuscitation Masks (Size: infant, adult) **Basic UDI-DI: 697195673536PZ**	Class IIa	N/A	Certificate # DD 60149456 0001 NB #0197
Silicone/SEBS/PVC Manual Resuscitators (including Mask, Positive EndExpiratory Pressure Valve, Oxygen Tube, Reservoir Bag, Mouth Opener, Oropharyngeal airway, Manometer) (Size: infant, pediatric, adult) **Basic UDI-DI: 697195673180PG**	Class IIa	N/A	Certificate # DD 60149456 0001 NB #0197
Endotracheal Tubes (Size: 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0) **Basic UDI-DI: 697195673600PH**	Class IIa	N/A	Certificate # DD 60149456 0001 NB #0197
Reinforced Endotracheal Tubes (Size: 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0) **Basic UDI-DI: 697195673663Q9**	Class IIa	N/A	Certificate # DD 60149456 0001 NB #0197
Tracheostomy Tubes (Size: 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0) **Basic UDI-DI: 697195673678QN**	Class IIa	N/A	Certificate # DD 60149456 0001 NB #0197
Bougies (Size: 6Fr, 10Fr, 15Fr) **Basic UDI-DI: 697195673176PR**	Class IIa	N/A	Certificate # DD 60149456 0001 NB #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Stomach Tubes (Size: 5Fr、6Fr、8Fr、10Fr、12Fr、14Fr、16Fr、18Fr、20Fr、22Fr) **Basic UDI-DI: 697195673750Q5**	Class IIa	N/A	Certificate # DD 60149456 0001 NB #0197
Rectal Tubes (Size: 22Fr, 24Fr, 26Fr, 28Fr, 30Fr, 32Fr, 34Fr, 36Fr) **Basic UDI-DI: 697195673733Q5**	Class I devices placed on the market in sterile condition	N/A	Certificate # DD 60149456 0001 NB #0197
Sterile Three-way Stopcocks for Single Use (Size: general) **Basic UDI-DI: 697195673127PC**	Class I devices placed on the market in sterile condition	N/A	Certificate # DD 60149456 0001 NB #0197
Disposable Breathing Circuits (Model: LB-GL-1(A), LB-GL-1(B), LB-GL-1(C), LB-GL-1(D), LBGL-1(E), LB-GL-1(F), LB-GL-A-1, LB-GL-A-2, LB-GL-A-3, LB-GL-A-4, LB-GL-A-5, LB-GL-C-1, LB-GL-C-2, LB-GL-E-1) **Basic UDI-DI: 697195673191PM**	Class IIa	N/A	Certificate # DD 60149456 0001 NB #0197
Breathing System Filters (Model: LB-GL-1, LB-GL-2, LB-GL-3, LB-GL-4, LB-GL-5, LB-GL-6, LB-GL-7, LB-GL-8, LB-GL-9) **Basic UDI-DI: 697195673128PE**	Class IIa	N/A	Certificate # DD 60149456 0001 NB #0197
Feeding Tubes (Size: Fr4, Fr5, Fr6, Fr8, Fr10, Fr12, Fr14, Fr16, Fr18, Fr20) **Basic UDI-DI: 697195673129PG**	Class I devices placed on the market in sterile condition	N/A	Certificate # DD 60149456 0001 NB #0197
Heat and Moisture Exchangers	Class IIa	N/A	Certificate # DD 60149456 0001 NB #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
(Model: LB-RGB-P-1, LB-RGB-P-2, LB-RGB-P-3, LB-GL-1, LB-GL-2, LB-GL-3, LB-GL-4, LB-GL-5, LB-1, LB-2, LB-3, LB-4, LB-5) **Basic UDI-DI: 697195673130NZ**			
Burette Infusion Sets **Type: 100mL, 150mL** **Basic UDI-DI: 697195673095PQ**	Class IIa	N/A	Certificate # DD 60149456 0001 NB #0197
Urinary Collection Bags for Single Use **Type: Adult, Pediatric** **Basic UDI-DI: 697195673096PS**	Class I devices placed on the market in sterile condition	N/A	Certificate # DD 60149456 0001 NB #0197
Cotton Tipped Applicators **Type: 3"", 6""** **Basic UDI-DI: 697195673097PU**	Class I devices placed on the market in sterile condition	N/A	Certificate # DD 60149456 0001 NB #0197
Swabs **Type: Male Swab, Female Swab** **Basic UDI-DI: 697195673144PC**	Class I devices placed on the market in sterile condition	N/A	Certificate # DD 60149456 0001 NB #0197
Peak Meters **Type: Adult, Pediatric** **Basic UDI-DI: 697195673098PW**	Class I devices with a measuring function	N/A	Certificate # DD 60149456 0001 NB #0197
Disposable Connecting Extension Tubes **Type:1-way, 2-way, 3-way, 4-way** **Basic UDI-DI: 697195673099PY**	Class IIa	N/A	Certificate # DD 60149456 0001 NB #0197

Table 2: Devices covered by this letter and for which the NB 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 at the pre-application stage)	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
NA	NA	NA	NA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/17	326005702	Initial issue