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

Digitally signed by Iurcu Nicolae
Date: 2023.12.12 10:21:16 EET
Reason: MoldSign Signature
Location: Moldova

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

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

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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

TÜVRheinland®

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

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Ningbo MFLAB Medical Instruments
Co., Ltd.
No.508,Yindong Road(N)
Yinzhou Economic Development
Zone
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

TÜV Rheinland
LGA Products GmbH

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90431 Nürnberg

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Mail service@de.tuv.com
Web www.tuv.com/safety

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:	Ningbo MFLAB Medical Instruments Co., Ltd. No.508, Yindong Road(N), Yinzhou Economic Development Zone, Ningbo315145, China

We declare under our sole responsibility that

the medical device:	Disposable Non Vacuum Blood Tubes
of class:	I, rule 2.
UMDNS:	15315
	according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC Annex VII and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device.

Conformity assessment procedure:	93/42/EEC Annex VII
Registration No.:	SX601503630001
Notified Body:	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg

宁波蓝柏医疗器械有限公司
NINGBO MFLAB MEDICAL INSTRUMENTS CO.,LTD

Ningbo 2022-01-17
Place, date

Yazeng Li General Manager
Name and function

李雅增

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:	Ningbo MFLAB Medical Instruments Co., Ltd. No.508, Yindong Road(N), Yinzhou Economic Development Zone, Ningbo315145, China

We declare under our sole responsibility that

the medical device:	Disposable Vacuum Blood Tubes
of class:	I, rule 2.
UMDNS:	15315
	according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC Annex VII and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device.

Conformity assessment procedure:	93/42/EEC Annex VII
Registration No.:	SX601503630001
Notified Body:	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg

宁波蓝柏医疗器械有限公司
NINGBO MFLAB MEDICAL INSTRUMENTS CO.,LTD

Ningbo 2022-01-17
Place, date

Yazeng Li General Manager
Name and function

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