

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
**Ningbo MFLAB Medical Instruments
Co., Ltd.**
No.508,Yindong Road(N)
**Yinzhou Economic Development
Zone**
315145 Ningbo
P.R. China

has established and applies a quality management system for medical devices
for the following scope:

Manufacture and Distribution of Medical Devices
(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-07-21
Certificate Registration No.: SX 60150363 0001
An audit was performed. Report No.: 15050519 014
This Certificate is valid until: 2023-07-20

Certification Body



Date 2020-07-21



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60150363 0001
Report No.: 15050519 014

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

Scope:

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
- Bougies
- Resuscitation Masks
- Silicone/SEBS/PVC Manual Resuscitators
- Endotracheal Tubes
- Reinforced Endotracheal Tubes
- Tracheostomy Tubes
- Nelaton Catheters

Certification Body



Date: 2020-07-21

Fuxiu Sheng



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

Scope:

Products:

- 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

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Scope:

Products:

- Disposable Vacuum Blood Collection Systems
- Disposable Vaginal Speculums
- Micro Blood Collection Tubes
- Vacuum Urine Collection Sets
- Disposable Non Vacuum Blood Tubes
- 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

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