

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

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No.508, Yindong Road(N),
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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

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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

Ningbo 2022-01-17
Place, date

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

Yazeng Li General Manager

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