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

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.

DECLARATION OF CONFORMITY

Name and address of the manufacturer:	Ningbo MFLAB Medical Instruments Co., Ltd. No.508, Yindong Road(N), Yinzhou Economic Development Zone, Ningbo 315145, China
We declare under our sole responsibility that the products:	Beakers, Flasks (Volumetric, Boiling, Filtering, Nitrogen, Conical, Distilling, Iodine), Dishes (Evaporating, Crystalizing), Watch glass, Reagent Bottles, Desiccators, Funnels, Measuring Cylinders.
UMDNS:	according to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998

are General Laboratory Use products and are not intended to contain directly a human sample for diagnostic tests. Laboratory glassware products are not subject to CE marking.

General applicable directives:	ISO9001:2015
Standards:	ENISO14971:2012; EN1041:2008; EN 15223-1:2016
(ISO9001) Certificate(s)	112108006
Expire date of the Certificate:	2024-09-13
Notified Body:	Intertek Certification Limited

Ningbo 2022-09-09

Place, date

Yazeng Li General Manager

Name and function

宁波菲拉医疗器械有限公司
NINGBO MFLAB MEDICAL INSTRUMENTS CO.,LTD

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, Ningbo 315145, China
We declare under our sole responsibility that the medical device:	Cover Glass, Microscope slides
of class:	I
UMDNS:	15687 according to annex IX of directive 93/42/EEC

meets the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.
We are exclusively responsible for the Declaration of Conformity.

General applicable directives:	ISO9001:2015
Standards:	ENISO14971:2012; EN1041:2008; EN 15223-1:2016
(ISO9001) Certificate(s)	112108006
Expire date of the Certificate:	2024-09-13
Notified Body:	Intertek Certification Limited

Ningbo 2022-09-09

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

Yazeng Li General Manager

Place, date

Name and function

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, Ningbo 315145, China
We declare under our sole responsibility that the medical device:	Petri Dishes
of class:	I
UMDNS:	15701 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.:	SX 601503630001
Registration No.:	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg

Ningbo 2022-09-09

Yazeng Li General Manager

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

Place, date

Name and function

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, Ningbo 315145, China
We declare under our sole responsibility that the medical device:	Specimen Containers
of class:	I
UMDNS:	13655 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.:	SX 601503630001
Registration No.:	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg

Ningbo 2022-09-09

Yazeng Li General Manager

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

Place, date

Name and function

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 98/79/EC CONCERNING MEDICAL DEVICE

Name and address of the manufacturer:	Ningbo MFLAB Medical Instruments Co., Ltd. No. 508, Yindong Road (N), Yinzhou Economic Development Zone, 315145 Ningbo, P.R. China
the medical device:	Disposable Vacuum Blood Tubes
Classification-Annex II	Others according to IVDD 98/79/EC
Conformity assessment procedure:	Annex III

WE, Ningbo MFLAB Medical Instruments Co., Ltd. EREWITH DECLARE THAT THE STATED MEDICAL DEVICE MEETS THE TRANSPOSITION INTO NATIONAL LAW. THE PROVISIONS OF COUNCIL DIRECTIVE 98/79/EC CONCERNING MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PRMISES OFTHE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

Registration No.(ISO13485):	SX601503630001
Notified Body:	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg

Ningbo 2022-09-09 — Yazeng Li, General Manager

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

Place, date — 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:	Transfer Pipettes
Specification:	Adjustable Volume Pipette
of class:	I, rule1
UMDNS:	15166 according to Annex IlI of 98/79/EC

meets the provisions of the directive 98/79/EC 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:	98/79/EC Annex III
Registration No.:	SX 60150363 0001
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 2022-03-24 — Yazeng Li General Manager

Place, date — 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 Labwares and Instruments for Medical Use(Test Tube)
of class:	I, rule 1.
UMDNS:	15187
	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.:	SX 601503630001
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 2022-09-09

Place, date

Yazeng Li General Manager

Name and function

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 Labwares and Instruments for Medical Use(Tube Stoppers)
of class:	I, rule 1.
UMDNS:	17821
	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.:	SX 601503630001
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 2022-09-09

Place, date

Yazeng Li General Manager

Name and function

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 Labwares and Instruments for Medical Use(Centrifuge Tubes)
of class:	I, rule 1.
UMDNS:	15682
	according to annex X 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.:	SX 601503630001
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 2022-09-09

Place, date

Yazeng Li General Manager

Name and function

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: Pipettes tips

of class: I
UMDNS: 16822
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.: SX 601503630001

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg

Ningbo 2022-09-09

Place, date

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

Yazeng Li General Manager

Name and function

李雅增