

**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.



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

**Attachment to  
Certificate**

**Registration No.:** DD 60149456 0001  
**Report No.:** 15050519 013

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**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*  
\_\_\_\_\_  
Jason Pan





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

**Attachment to  
Certificate**

**Registration No.:** DD 60149456 0001  
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**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

*Jason Pan*





**Business Stream Products**  
Certification Department



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

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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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90431 Nürnberg

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