

**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**

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**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**





**TÜV Rheinland**  
**LGA Products GmbH**  
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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**

