

证明书

CERTIFICATE



中国国际贸易促进委员会



China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书 CERTIFICATE

号码 No. 173302A0/30841

兹证明：所附文件的影印件与原件相符。

THIS IS TO CERTIFY THAT: the annexed photostated copy of DOCUMENT is in conformity with the original.



China Council for the Promotion
of International Trade



授权签字:

Authorized
Signature :


YANG JIN JIN

日期: 2017 年08月04日

(Date: AUG. 04, 2017)

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60121490 0001

Report No.: 15050519 008

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

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60112064 0001

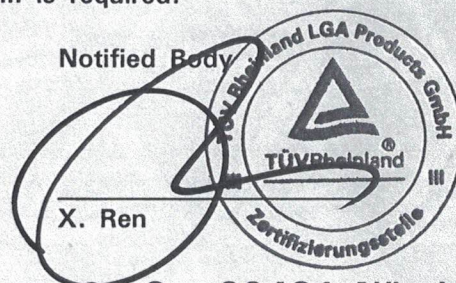
Expiry Date: 2022-07-26

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: 2017-07-27

Date: 2017-07-21

Notified Body



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**

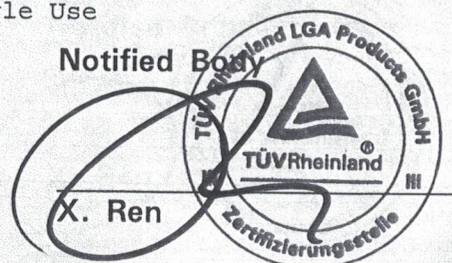
Registration No.: DD 60121490 0001
Report No.: 15050519 008

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

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 Cannula
- 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

Date: 2017-07-21



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60121490 0001
Report No.: 15050519 008

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

Products:

- Disposable Breathing Circuits
- Breathing System Filters
- Heat and Moisture Exchangers
- Burette Infusion Sets

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

Date: 2017-07-21

Notified Body

