

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

**Registration No.:** DD 60136362 0001

**Report No.:** 15054746 010

**Manufacturer:** Zhejiang Yuantong Medical  
Appliances Co., Ltd.  
East Side of Xinqiao, Shuangxin Highway  
Xinshi Town, Deqing County  
Huzhou  
313201 Zhejiang  
China

**Products:** Medical Devices  
  
(see attachment for products included)  
  
Replaces Approval, Registration No.: DD 60124099 0001

**Expiry Date:** 2022-10-17

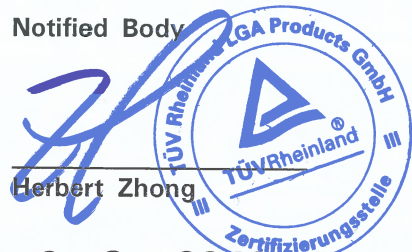
The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned 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:** 2019-09-18

**Date:** 2019-09-18

Notified Body

Herbert Zhong



**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 60136362 0001  
**Report No.:** 15054746 010

**Manufacturer:** Zhejiang Yuantong Medical  
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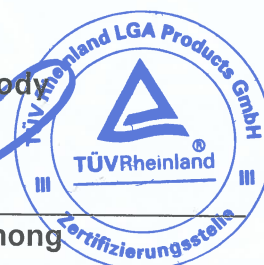
**Products:**

- Medical Nebulizers
- Oxygen Masks
- Disposable Nasal Cannula
- Disposable Suction Catheters
- Endotracheal Tubes
- CPR Masks
- Yankauer Suction Tubes
- Anesthesia Masks
- Relation Catheters

**Date:** 2019-09-18

**Notified Body**

**Herbert Zhong**



# 1. EC Declaration of Conformity

*Manufacturer:*

*whose single Authorized Representative:*

Zhejiang Yuantong Medical Appliances Co., Ltd.

Shanghai International Holding  
Corp.GmbH(Europe)

East side of Xinqiao, Shuangxin Highway, Xinshi  
Town, Deqing County, Huzhou 313201, Zhejiang .  
China

Eiffestrasse 80, 20537 Hamburg Germany

We, the manufacturer, herewith declare that the products

## Oxygen Masks

UMDNS-Code: 12448;

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class **Ila** according to Annex IX of the Directive 93/42/EEC. It bears the mark

**CE 0197**

The product concerned has been designed and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

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

Certificate No: DD601240990001

Issue date: 2017-11-10

Expiry date: 2022-10-17

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

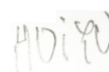
The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Zhejiang Yuantong Medical Appliances Co., Ltd.

Address: East side of Xinqiao, Shuangxin Highway, Xinshi Town, Deqing County,  
Huzhou 313201, Zhejiang . China

Huzhou, 2018-04-14

Place, date



\_\_\_\_\_  
Legally binding signature, Function

# HANGZHOU YUANTONG MEDICAL APPLIANCES CO.,LTD

## Inspection report

NO.:YT/QR 8.2.4-02-02

Product name		Pocket face mask		Batch no.						
Item		Adult								
QTY										
Test standard		YZB/浙2515-2010		Testing time						
NO.	Inspection item	Standard request	Horizontal sampling	Sampling amount	AQL	Standard code		Inspection result		Item conclusion
						Ac	Re	acceptance number	Rejection number	
1	Size	In accordance with the drawings	S-2		2,5					
		The joint is an inner cone of 22mm and an outer cone of 15mm								
2	Appearance	No oil, no scratches, no wrinkles, no breakage, blow full, no deformation	II		2,5					
		0.5mm ≤ Black dot diameter < 1mm, less than three	II		2,5					
		Black dot diameter < 0.5mm, less than four in the 15mm × 15mm area	II		2,5					
		> 1mm black dot	II		2,5					
		> 0.4mm burr	II		2,5					
		diameter > 1mm bubble	II		2,5					
3	Within the cavity cleanliness	no obvious foreign bodies and grease stains	S-3		2,5					
4	completeness	Complete, no leakage parts	S-2		1,5					
5	instruments dead space	< 170ML	S-3		1					
6	sealing property	no leak	II		1					
7	exhale impedance	Adult type < 5cmH <sub>2</sub> O	II		1					
		(traffic: 50L/min)								
	inspiratory impedance	Adult type < 5cmH <sub>2</sub> O	II		1					
		(traffic: 50L/min)								
8	package	No pollution and damage	S-2		2,5					
		label language is correct and clear	S-2		2,5					
9	packing quantity	exact	S-2		2,5					
Conclusion										

Tester:

Auditor :

Approver :