

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60135413 0001

**Report No.:** 16802607 007

**Manufacturer:** Suzhou Lingyan Medical  
Technology Co., Ltd.  
No.99, Maopeng Road,  
Xujiang Industrial Park  
Wuzhong District, Suzhou  
215164 Jiangsu  
China

**Products:** Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60107681 0001

**Expiry Date:** 2023-12-09

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2019-01-16

**Date:** 2019-01-16

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.:** HD 60135413 0001  
**Report No.:** 16802607 007

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No.99, Maopeng Road,  
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Wuzhong District, Suzhou  
215164 Jiangsu  
China

**Products:**

- Disposable Infusion Pumps
- Disposable I.V. Catheters
- Disposable Hypodermic Needles
- Disposable Oxygen Masks
- Disposable EMG Needles
- Disposable Self-destruction Safety Syringes with Needles
- Disposable Safety Blood Collection Needles

Aspects of manufacture concerned with securing  
and maintaining sterile conditions:

- Disposable Injection Needles for Mixing Medicines

**Date:** 2019-01-16

**Notified Body**





# Certificate

The Certification Body of  
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

**Suzhou Lingyan Medical  
Technology Co., Ltd.  
No.99, Maopeng Road,  
Xujiang Industrial Park  
Wuzhong District, Suzhou  
215164 Jiangsu  
China**

has established and applies a quality management system for medical devices  
for the following scope:

**(see attachment for scope)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-01-16  
Certificate Registration No.: SX 60130007 0001  
An audit was performed. Report No.: 16802607 007  
This Certificate is valid until: 2021-12-09

Certification Body



Date 2019-01-16



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

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

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60130007 0001  
**Report No.:** 16802607 007

**Organization:** Suzhou Lingyan Medical  
Technology Co., Ltd.  
No.99, Maopeng Road,  
Xujiang Industrial Park  
Wuzhong District, Suzhou  
215164 Jiangsu  
China

**Scope:**

Design and Development, Manufacture and Distribution of

- Disposable Infusion Pumps
- Disposable I.V. Catheters
- Disposable Hypodermic Needles
- Disposable Injection Needles for Mixing Medicines
- Disposable Vacuum Blood Collection Tubes
- Disposable Self-destruction Safety Syringes with Needles
- Disposable Oxygen Masks
- Disposable EMG Needles
- Disposable Safety Blood Collection Needles

Provision of Ethylene Oxide Sterilization service for  
Single-use Medical Devices in accordance  
with EN ISO 11135:2014

**Certification Body**



**Date:** 2019-01-16





# Welcome to Lingyan Medical



**Suzhou Lingyan Medical Technology Co.,Ltd**



# Suzhou Lingyan Medical Technology Co.,LTD



**Add:**No.99 Maopeng Rd, Xujiang Industrial Park, Suzhou,China.

**Tel :**0512-66261236 **Fax :**0512-66261236 **Web :** [www.szlingyan.com](http://www.szlingyan.com)



## Overview

- ◆ **Company Profile**
- ◆ **Organizational Structure**
- ◆ **Quality Policy & Certification**
- ◆ **Production Area & Workshop**
- ◆ **Products**
- ◆ **Market Situation**
- ◆ **Partners**



## Company Profile

The enterprise established in 1987, and reformed into limited company in 2004.

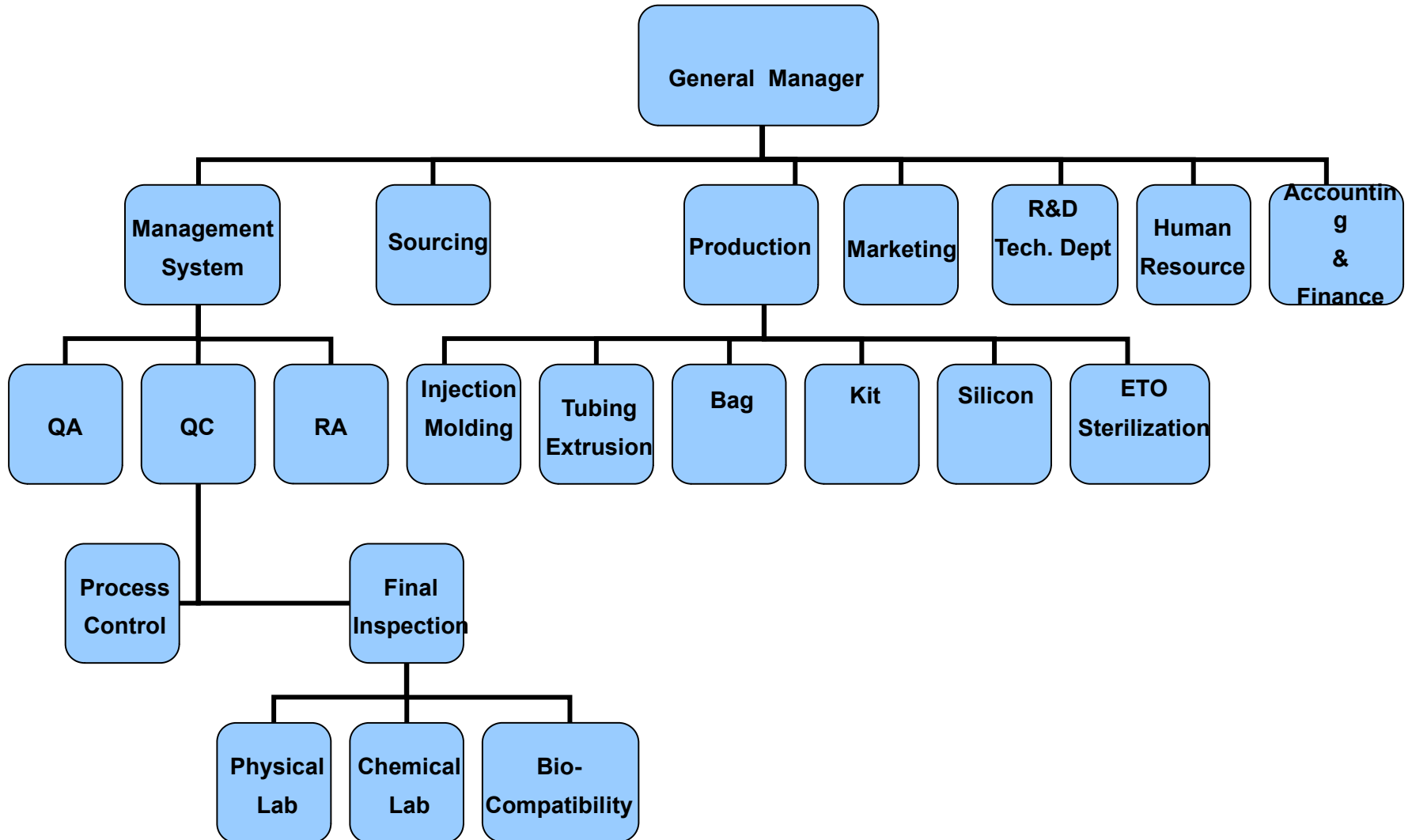
The company covers an area of 27000 m<sup>2</sup> ,including 18000 m<sup>2</sup> for buildings,5000 m<sup>2</sup> for the 10<sup>5</sup> Class clean workshop,500 m<sup>2</sup> for the center test-room,800 m<sup>2</sup> for the sterilization workshop and 1500 m<sup>2</sup> for the office.

The company has three automatic production lines for injection needles assembly and a full set of production equipment and quality testing equipment covering the process for drawing tube, cut, blade-grind, injection ,assembling, blister package and sterilization. There is an annual production capacity of 200 million for disposable needles.





## Organizational Structure





## Quality Policy & Certification

### Quality Policy :

Manufacture safe and effective products

Satisfy customers and regulatory requirements

### Certifications:

ISO13485 & CE & SFDA Registration



## Production area







## Needles Production



**Needle Production:**  
we can produce needle gauge 14 to  
gauge 34



## Disposable blood collect tube production





## Disposable Infusion Pump Production







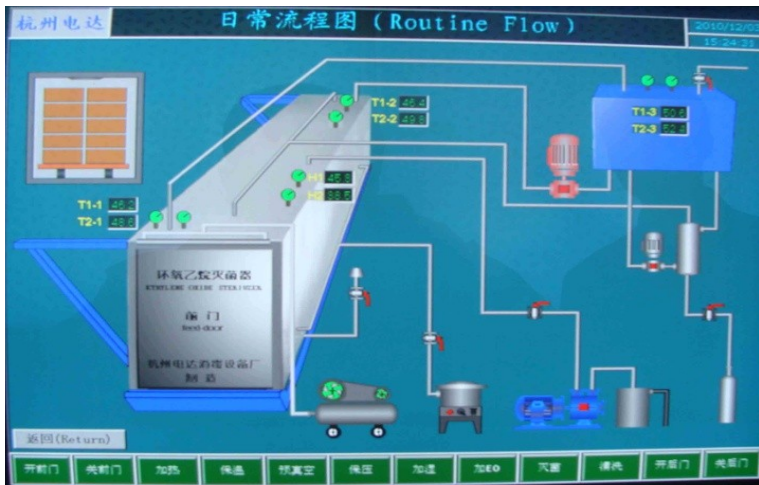
## IV Catheters Production



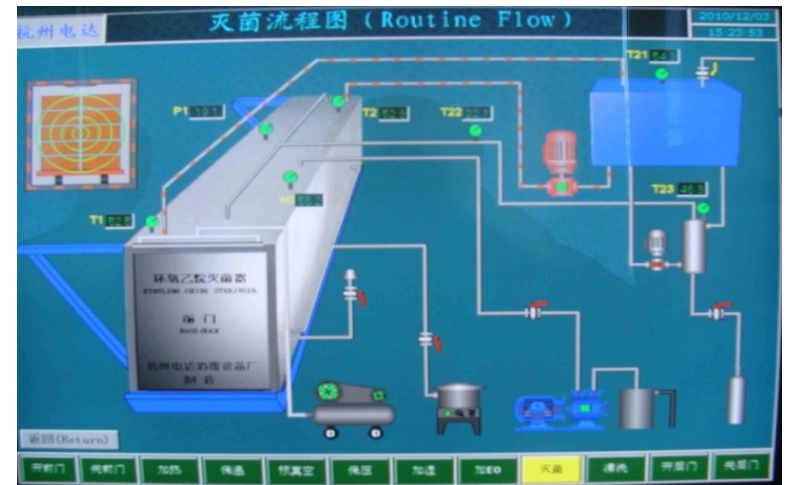
# Sterilization Workshop



## EO Gas Sterilization



## Pre-conditioning Flow



## Sterilization Flow



## Main Products

- **Disposable IV Catheters**
- **Disposable Blood Collect Tubes**
- **Disposable Infusion Pumps**
- **Disposable Anesthesia Puncture Kit**
- **Disposable Hypodermic Needles**
- **Disposable Medicine Mixed Needles**
- **Disposable EMG Needles**
- **Disposable Oxygen Masks**



## Disposable IV Catheters

### I.V. Catheter



I.V. Catheter, pen-like



I.V. Catheter with wings



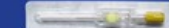
I.V. Catheter with wings  
and injection port



I.V. Catheter with small wing



Safety I.V. Catheter

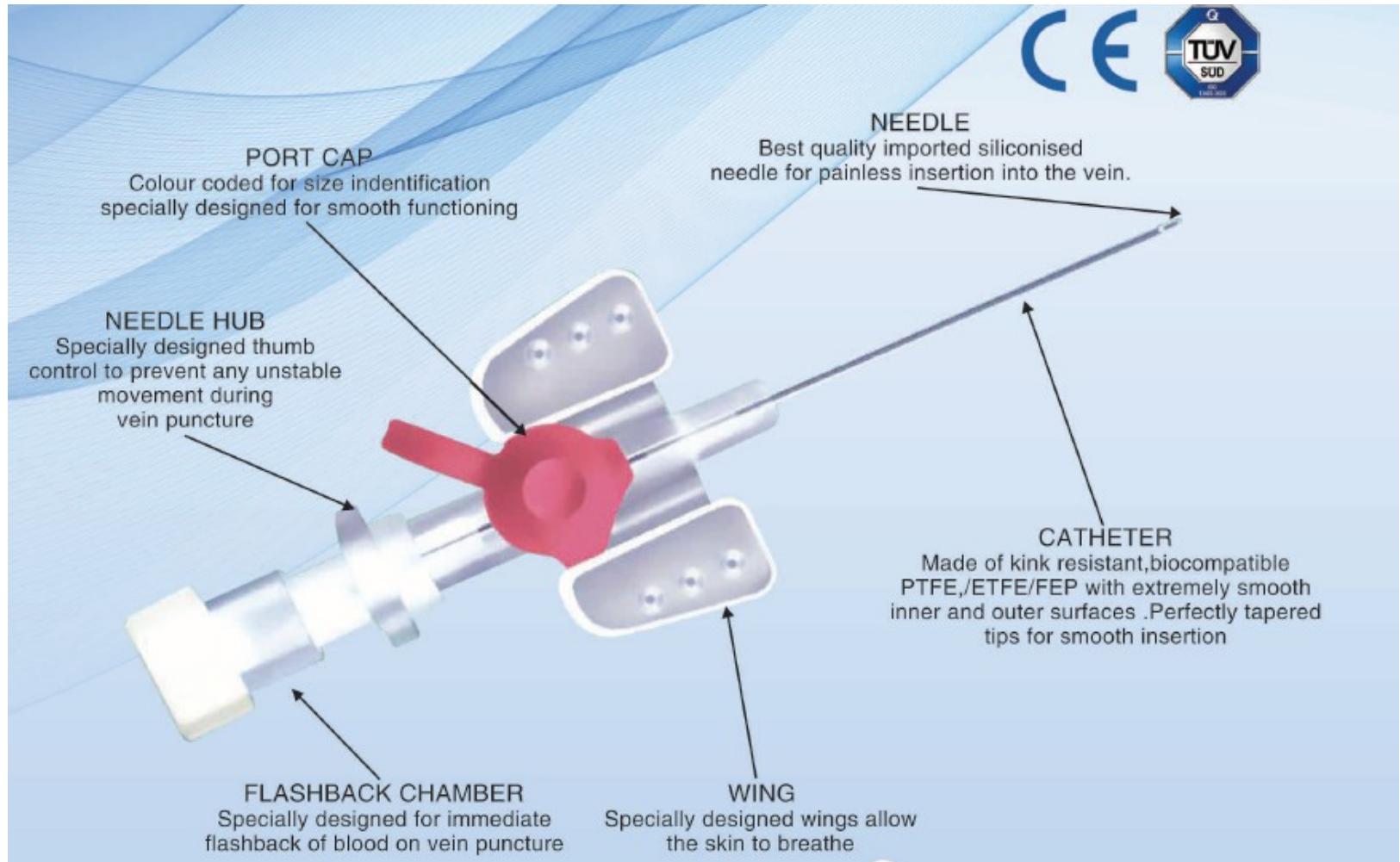


IV.Cannula with  
Heparin Injection



"Y"Type I.V. Catheter

## Disposable IV Catheters





## Disposable IV Catheters



Y Type/Inject port type

18G:green

20G:pink

22G :blue

24G:yellow

26G :purple



# Disposable IV Catheters

## Positive Pressure Type

The needle tip is perfectly shaped to improve the puncture success rate and safety indwelling.

Multi belved design makes puncture more sharp and patients less pain.

Positive pressure joint realizes needle free connection to avoid occupational risk of medical staff. Positive pressure function can avoid blood reflux, prevent plugging.

Second times positive pressure can be achieved by light button single hand clip.

Closed integrated design to avoid blood pollution.

Y three links can achieve multichannel infusion demand.



## Disposable Blood Collect System





## Disposable Vacutainer Needles







## Disposable Infusion Pumps

**Capacity:** 60ml, 100ml, 200ml, 275ml *CBI/PCA/Multirate*





## Disposable Anesthesia Puncture Set

✧ **Model:** AS/E,AS-E/S



**Product Classification:**AS-E epidural anesthesia puncture set  
AS-E/S epidural and spinal anesthesia puncture set  
**Application:**This product is suitable for epidural anesthesia



## Disposable Hypodermic Needles



Application: The hypodermic needles are for injection and clinica use.

0.3、0.33、0.36、0.4、0.45、0.5、0.55、0.6、0.7、0.8、0.9、1.1、1.2 (mm)

Standard: GB15811-2001;CE





# Disposable Medicine Mixing Needles



Secification	0.4x15mm	0.45x15mm	0.5x20mm	0.55x25mm	0.6x25mm	0.7x30mm	0.8x30mm	0.9x30mm	1.2x30mm
	27G	26G	25G	24G	23G	22G	21G	20G	18G
									
	Gray	Brown	Orange	Purple	Blue	Black	Green	Yellow	Pink



## Disposable EMG Needles

【 Model 】 CNE35-25、CNE45-28、CNE45-38、CNE45-50、CNE50-60





## Disposable Oxygen Mask

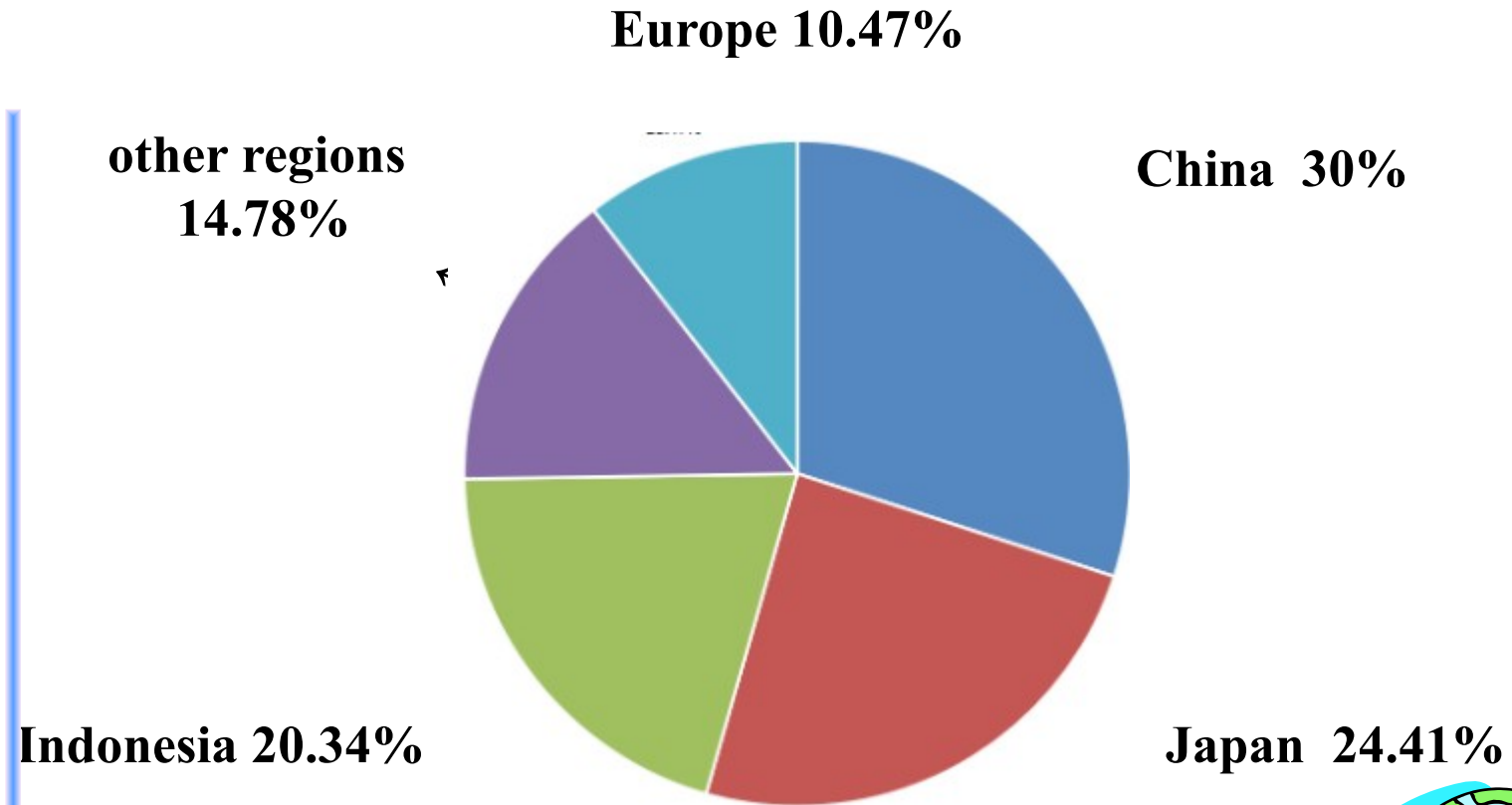
The product is composed of mask, oxygen pipe, nebulization cup , which is used for Clinical atomization therapy. It is a disposable product. It is packed by PE and double dialysis paper ,EO GAS sterlized . It is made of medical grade PVC material. The nose and elastic band of the mask can be adjusted. The nebulization cup well sealed , no leakage and low noise.







## Market Situation





## Partners



COVIDIEN

*positive results for life™*



MCKESSON



We believe that we will be your trustworthy supplier in  
China

