

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

Manufacturer: Suzhou Lingyan Medical
Technology Co., Ltd.
No.99, Maopeng Road,
Xujiang Industrial Park
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



Herbert Zhong

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



Overview

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



Company Profile

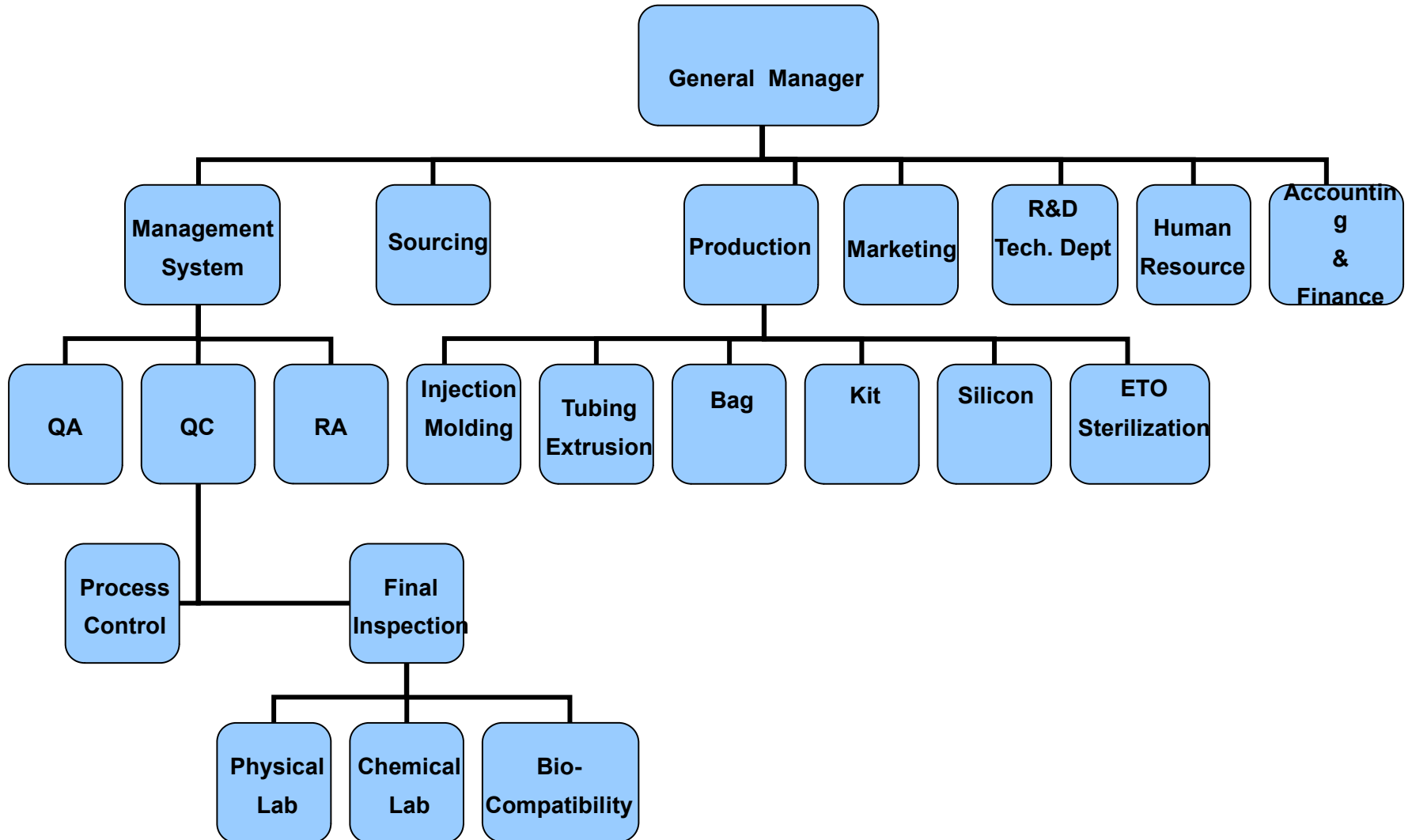
The enterprise established in 1987, and reformed into limited company in 2004.

The company covers an area of 27000 m² ,including 18000 m² for buildings,5000 m² for the 10⁵ Class clean workshop,500 m² for the center test-room,800 m² for the sterilization workshop and 1500 m² 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





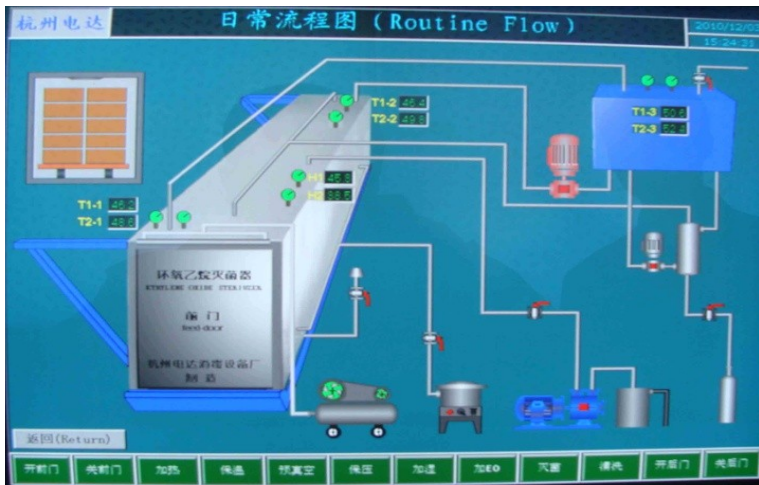
IV Catheters Production



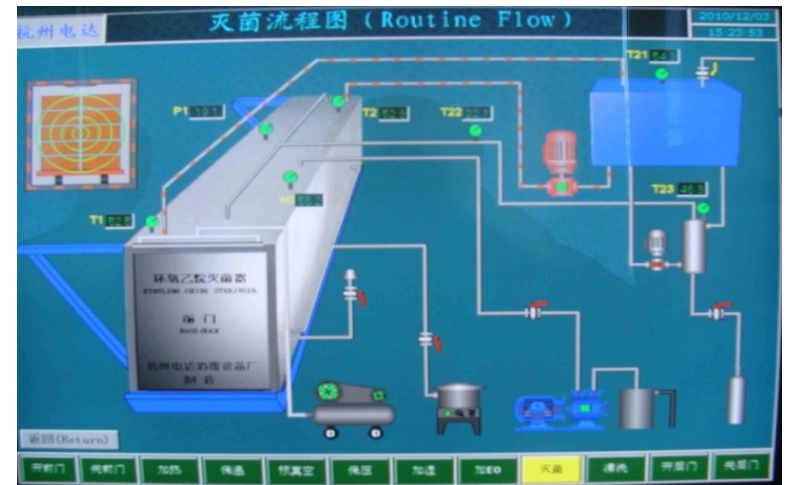
Sterilization Workshop



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

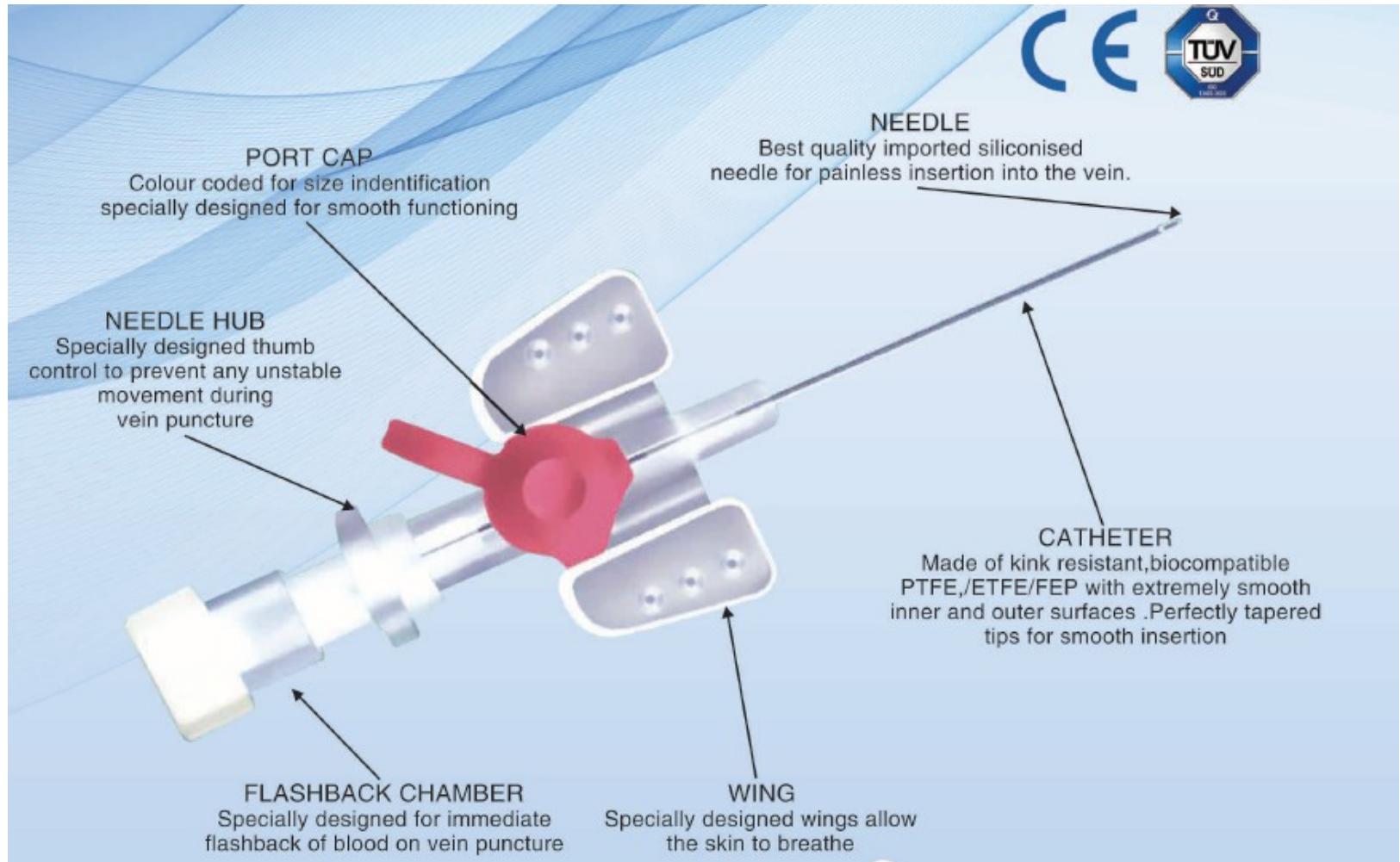


IV.Cannula with
Heparin Injection



"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





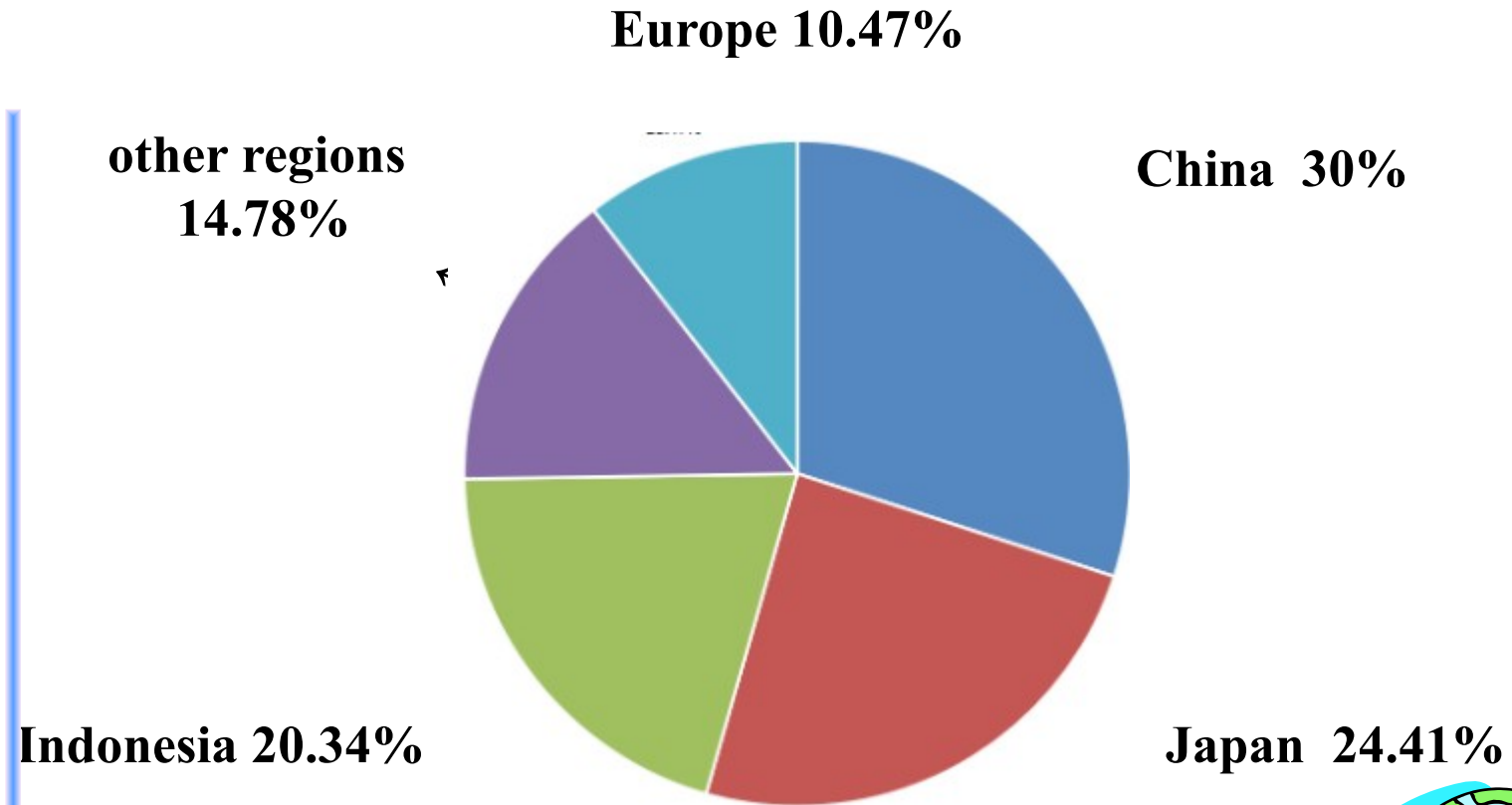
Disposable Oxygen Mask

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

