Simple OXYGEN MASK
CE Technical Documents

Document No.: CE005

Version No.: B/0

EFFECT DATE:

Name: Ningbo Shengyurui Medical Appliance Co., Ltd.
Add: No.138,BinHaisi Road, Hangzhou Bay New Zone , Cixi City , Zhejiang Province, 315336,P.R.China
Tel: +86-574-63269102/63006301 Fax:+86-574-63269048/63006305

Title	Simple OXYGEN MASK	**Document No.**	CE 005
Version No.	B/0	**Page**	PAGE 1 OF 40

Revision	Description of Change(s)	Author	Effective Date
A/0	First issue	Linna	Jan. 01. 2009
B/0	1) Quality manual A version upgraded to version B 2) The management representative served by Linna Luo 3) Specify manufacturing process	Linna	Sep. 17. 2012

0.0 Contents

Contents

1.0 Declaration of Conformity

MANUFACTURER

Name: Ningbo Shengyurui Medical Appliance Co., Ltd.

Add: No.138,BinHaisi Road, Hangzhou Bay New Zone , Cixi City , Zhejiang Province, 315336,P.R.China

Tel: +86-574-63269102/63006301 Fax:+86-574-63259048/63006305

AUTHORIZED REPRESENTATIVE:

Name:Shanghai International Holding Corp. GmbH (Europe)

Add:Eiffestrasse 80, 20537 Hamburg，Germany

Tel: +49-40-2513175 Fax:+49-40-255726 E-mail：shholding@hotmail.com

MEDICAL DEVICE:

Model Name：Simple Oxygen Mask

TYPE OR SIZE: XL、L、M、S、SJ

UMDNS CODE: 12448

Classification:

IIa (Rule two, Annex Ⅸ, MDD 93/42/EEC)

Conformity Assessment Procedure

Annex V.3

DIRECTIVES

Medical Device Directive: COUNCIL DIRECTIVE DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices.

Standard Applied: All applicable Harmonized EN Standards.

Notified Body: SGS United Kingdom Limited

Address: Unit 202B,Worle Parkway,Weston-super-mare,Somerset,BS22 6WA

Identification Number： CE 0120
(EC) Certificate(s): CN09/21829
Expire date of the Certificate: 2016-10-31
Date CE mark was affixed: 2009-09-19
Place, Date of Issue: 2011-10-31 / CIXI

SIGNATURE : **NAME:** Linna Luo

Add: No.138,BinHaisi Road, Hangzhou Bay New Zone , Cixi City , Zhejiang Province, 315336,P.R.China

2.0 Overview of Product

2.1 INTRODUCTION OF COMPANY：

2.1 INTRODUCTION OF COMPANY：

We are Soundway Medical, who is profesional in producing respiratory mask for many years. Our most competitive products are nebulizer mask, oxygen mask, Simple OXYGEN MASK, nasal cannula, etc.

We will push out new products -- Simple OXYGEN MASK, Silicone mask, filter, CPAP mask, new generation nebulizer mask, new nebulizer chamber in this year and next year We can produce 1.5 million pcs mask / month. With well trained workers, favorable environment, we are faithful to our partners by good quality products. We are facing to customers all over the world and get positive feedback and good fame.

Company Name: Ningbo Shengyurui Medical Appliance Co., Ltd.

Address: No.138,BinHaisi Road, Hangzhou Bay New Zone , Cixi City , Zhejiang Province,P.R.China ZhengJiang Province,China

Tel: +86-574-63269102/63006301 Fax:+86-574-63259048/63006305

Contact Person: DongYing Hu

2.2 MODEL NAME Product structure

SIMPLE OXYGEN MASK :XL、L、M、S、SJ

2.3 PRODUCT STRUCTURE

1-Connector

2-Tubing

3-Interface

4-Mask

5-Aluminum card

6-Ribbon

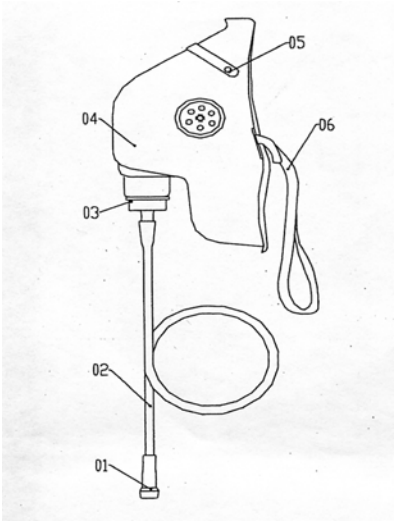


Figure 1 SIMPLE OXYGEN MASK structure drawing

2.4 EC-REPRESENTATIVE AND NOTIFIED BODY

2.4.1 EC-Representative Name：Shanghai International Holding Corp. GmbH (Europe)

Address：Eiffestrasse 80,20537 Hamburg,Germany

2.4.2 Notified Body

Name：SGS United Kingdom Limited

Address：Unit 202B,Worle Parkway,Weston-super-mare,Somerset,BS22 6WA

2.4.3 Agreement between Manufacturer and EC-Representative

Agreement between Manufacturer and EC-Representative see 《Annex 1: Agreement between Manufacturer and EC-Representative》.

2.5 Overview of Product and Intended Use

2.5.1 Intended use of the product :

The Simple Oxygen Mask is used for the emergency oxygen, and hypoxia in patients with oxygen inhalation.

2.5.2 Structure of Product:

The simple Oxygen mask consists of Connector、Tubing、Interface、Mask、Aluminum card、Ribbon。

2.5.3 Classification of Product

According to MDD 93/42/EEC Annex IX, Rule 2, the product is classified as Class IIa device.

2.5.4 Certification route of product

According to MDD 93/42/EEC conformity evaluation process and certificate, the certification route was confirmed as Annex II and Annex VII.

2.6 Instructions and Precautions

- Open the package and take out the Mask; connect the parts as per the following figure 2 , one tubing end to the bottom of nebulizer jar, and the other to the oxygen (or compressed air)source port.

1-Connector

2-Tubing

3-Interface

4-Mask

5-Aluminum card

6-Ribbon

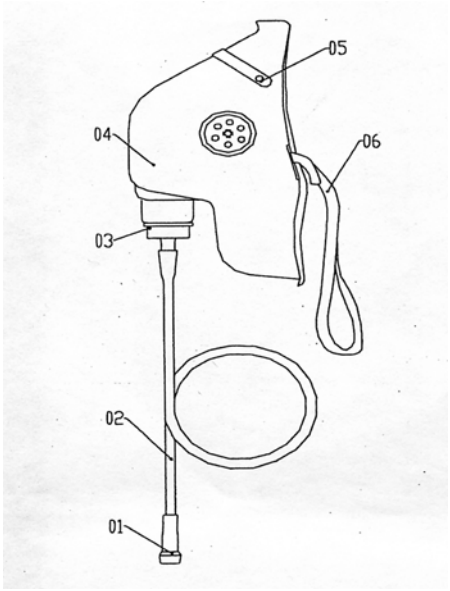


Figure 2 SIMPLE OXYGEN MASK structure drawing

- signle use only
- The product is not allowed to use if the package is broken.
- The product is not allowed to use if the sterilization validity is expired.

2.7 List of EU harmonized standards and international standards

2007/47/EC:2007	Directive amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market
93/42/EEC:1993	Medical Devices Directive
ISO13485:2003	Medical devices - Quality management systems -- Requirements for regulatory purposes
ISO14971:2009	Medical devices - Application of risk management to medical devices
ASTM F 1980-07	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
EN1041:2008	Information supplied by the manufacturer of medical devices
EN980:2008	Graphical symbols for use in the labeling of medical devices
ISO10993-1:2009	Biological evaluation of medical devices —Part 1:Evaluation and testing within a risk management process
ISO10993-10:2010	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
ISO10993-5:2009	Biological evaluation of medical devices —Part 5: Tests for in vitro cytotoxicity
ISO1135-1:2007	Sterilization of health care products — Ethylene oxide —Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO11607-1：2006	Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems
ISO14644-1	Cleanrooms and associated controlled environments-Parts 1 :Classification of air cleanliness.
ISO15223-1:2007	ANSI/AAMI/ISO 15223-1:2007,Medical devices —Symbols to be used with medical device labels , labeling, and information to be supplied —Part 1: General requirements Amendment 1
MEDDEV. 2.7.1:2003	Guidelines on medical devices evaluation of clinical data: A guide for manufacturers and notified bodies

3.0 CHECKLIST FOR ESSENTIAL REQUIREMENTS

Product Name: SIMPLE OXYGEN MASK

Primary classification of products:

Whether passive medical device or not: ☐No ■Yes

Whether active medical device or not: ■No ☐Yes

Whether sterile products or not: ☐No ■Yes

Whether take measurement function or not:: ■No ☐ Yes

Whether contains any drug or other matters or not: ■ No ☐ Yes

Whether used in drug injection or not: ■No ☐Yes

Whether contains matters from animals or other species or not: ■No ☐Yes

Whether takes irradiation function or not: ■No ☐Yes

Whether contains vibration resource or not: ■No ☐Yes

Whether contain noise resource or not: ■No ☐Yes

Whether contains pyrogen or not: ■No ☐Yes

Whether release energy toward human body or not: ■No ☐Yes

Whether have period of validity or not: ☐No ■Yes

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include: ---reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used(design for patient safety), and ---consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	A	ISO14971:2009	Risk Analysis Report (RMR002)	Office
2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: - eliminate or reduce risks as far as possible (inherently safe design and construction), - where appropriate take adequate	A	ISO14971:2009	Risk Analysis Report (RMR002)	Office

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
protection measures including alarms if necessary, in relation to risks that cannot be eliminated, -inform users of the residual risks due to any shortcomings of the protection measures adopted.				
3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (a) of the above-mentioned Council Directive, as specified by the manufacturer.	A	ISO11607-1：2006 YZB/Zhe 1938-2011	Test repot Z20112167	Office
4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	A	MEDDEV. 2.7.1:2003 ISO11607-1：2006 ASTM F 1980-07	Clinical Data(11-001) Product Ageing Test 03-VS-016	Office
5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	A	ISO11607-1：2006 ASTM F 1980-07	Product Ageing Test 03-VS-016	Office
6. Any undesirable side effect must constitute an acceptable risk when weighed against the performances intended.	A	MEDDEV. 2.7.1:2003	Clinical Data（11-001）	Office
6 a Demonstration of conformity with the essential requirements must include a	A	MEDDEV. 2.7.1:2003	Clinical Data（11-001）	Office

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
clinical evaluation in accordance with Annex X of the above-mentioned Council Directive				
7. Chemical, physical and biological properties 7.1 The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General requirements'. -the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, -the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device. -where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand	A	ISO10993-1:2009 ISO10993-5:2009 ISO10993-10:2010	Test repot Z20112167	Office
7.2 The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.	A	ISO14971:2009	Risk Analysis Report (RMR002)	Office
7.3. The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the	A	ISO10993-1:2009 ISO10993-5:2009	Test repot Z20112167	Office

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.		ISO10993-10:2010		
7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 (*) on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data	N/A			

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where a device incorporates,as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on				

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
the established benefit/risk profile of the addition of the substance in the medical device. When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.				
7.5 The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (*). If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or	A	ISO15223-1 :2007	Operation Instructions	Office

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.				
7.6.Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	A	ISO14971:2009	Quality Control Plan SYR-Z-002 Risk Analysis Report (RMR002)	Office
8. Infection and microbial contamination 8.1.The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and,	A	ISO15223-1:2007	Operation Instructions	Office

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
where necessary, minimize contamination of the device by the patient or vice versa during use.				
8.2.Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Notified bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	N/A			
8.3. Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.	A	ISO11607-1: 2006 ASTM F 1980-07	Product Ageing Test 03-VS-016 Sterilization Package Validation 03-VS-005	Office
8.4.Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	A	ISO1135-1:2007	Sterilization Validation 03-VS-011 Sterilization Work Instruction 03-WI-A181/03-WI-A023	Office

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.	A	ISO14644-1 YY0033-2000	Clean room environment Validation (03-VS-012) Clean room Inspection report (Z20112498) Clean room Standard Operation Procedure (SOP-06)	Office
8.6. Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterili-zation indicated by the manufacturer.	N/A			
8.7. The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	A	EN980:2008	Label and language Standard Operation Procedure (SOP-27)	Office
9. Construction and environmental properties 9.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the	A	EN980:2008	Label and language Standard Operation Procedure (SOP-27) Operation Instruction	Office

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
instructions for use.				
9.2. Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: - the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features, - risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration. -the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given, -risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	A	ISO14971:2009 ASTM F 1980-07	Risk Analysis Report (RMR002) Product Ageing Test 03-VS-016	Office
9.3.Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	N/A			
10. Devices with a measuring function 10.1.Devices with a measuring function	N/A			

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by, the manufacturer.				
10.2The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	N/A			
10.3The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC	N/A			
11. Protection against radiation 11.1 General 11.1.1. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	N/A			
11.2.Intended radiation 1. Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant	N/A			

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
variable parameters.				
11.2.2. Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	N/A			
11.3. Unintended radiation 1. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.	N/A			
11.4 Instructions 11.4.1 The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	N/A			
11.5.Ionizing radiation 11.5.1. Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geo-metry and QC of radiation emitted can be varied and controlled taking into account the intended use. 11.5.2. Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	N/A			
11.5.3. Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable	N/A			

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.				
12. Requirements for medical devices connected to or equipped with an energy source 12.1.Devices incorporating electronic programmable systems must he designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	N/A			
12.1.a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification	N/A			
12.2.Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	N/A			
12.3.Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	N/A			
12.4. Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	N/A			

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
12.5. Devices must be designed and manufactured in such away as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	N/A			
12.6.Protection against electrical risks Devices must be designed and manufactured in such away as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.	N/A			
12.7.Protection against mechanical and thermal risks 12.7.1. Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	N/A			
12.7.2. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	N/A			
12.7.3. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise,	N/A			

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
particularly at source, unless the noise emitted is part of the specified performance.				
12.7.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.	N/A			
12.7.5 Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	N/A			
12.8. Protection against the risks posed to the patient by energy supplies or substances 12.8.1. Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	N/A			
12.8.2. Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	N/A			
12.9. The function of the controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such in-	N/A			

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
formation must be understandable to the user and, as appropriate, the patient.				
13. Information supplied by the manufacturer 13.1Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the details on the label and the ta in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the practicable, the information must be set out in the leaflet sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class Ⅰor Ⅱa if they can be used safely without any such instructions.	A	EN980:2008 EN1041:2008	Label and language Standard Operation Procedure (SOP-27) Operation Instruction	Office
13.2.Where appropriate, this information should take the form of symbols. Any symbol or identification color used must conform to the harmonized standards. In areas for which no standards exist, the symbols and collors must be described in the documentation supplied with the device.	A	EN980:2008 EN1041:2008	Label and language Standard Operation Procedure (SOP-27) Operation Instruction	Office
13.3.The label must bear the following particulars: (a)the name or trade name and address of	A	EN980:2008 EN1041:2008	Label and language Standard	Office

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
the manufacturer. For devices imported into the Community, in view of their distribution in the community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of either the person responsible referred to in Article 14 or of the authorized representative where the manufacturer does not have a registered place of business in the Community. (b)the details strictly necessary for the to identify the device and the contents of the packaging especially for the users; (c)where appropriate, the word 'STERILE'; (d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number (e) where appropriate, an indication of the date by which the device should be used, in safety.'. expressed as the year and month; (f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community; (g) if the device is custom-made, the words 'custom-made device'; (h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations'; (i) any special storage and/or handling conditions;any special operating instructions; (j) where appropriate, any special operating instructions (k)any warnings and/or precautions to take; (l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or			Operation Procedure (SOP-27) Operation Instruction	

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
serial number; (m) where applicable, method of sterilization.				
13.4. If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	A	EN980:2008 EN1041:2008	Label and language Standard Operation Procedure (SOP-27) Operation Instruction	Office
13.5.Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components	**A**	EN980:2008 EN1041:2008	Label and language Standard Operation Procedure (SOP-27) Operation Instruction	Office
13.6. Where appropriate. the Instructions for use must contain the following particulars: (a) the details referred to in Section 13.3, with the exception of (d) and (e); (b) the performances referred to in Section 3 and any undesirable side-effects; (c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination (d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;	A	EN980:2008 EN1041:2008	Label and language Standard Operation Procedure (SOP-27) Operation Instruction	Office

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
(e) where appropriate, information to avoid certain risks in connection with implantation of the device; (f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; (g) the necessary(g) instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization; (h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I; If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request (i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.); (j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.				

GENERAL REQUIREMENTS according to Council Directive 93/42/EEC (2007)	**A-N/A (applicable or not applicable)**	**Standards referred to and year of edition**	**Manufacturer's compliance**	**Location**
The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions tohe taken. These details should cover in particular: (k) precautions to he taken in the event of changes in the performance of the device; (l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.; (m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered; (n) precautions to be taken against any special, unusual risks related to the disposal of the device; (o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4 (p) degree of accuracy claimed for devices with a measuring function. (q) date of issue or the latest revision of the instructions for use				

4.0 RISK MANAGEMENT REPORT OF PRODUCT

ITEM: SIMPLE OXYGEN MASK

The First Chapter – Summary

4.1 Product overview

4.1.1 Intended use of product:

The Simple Oxygen Mask is used for the emergency oxygen, and hypoxia in patients with oxygen inhalation.

4.1.2 Components of the product

The simple Oxygen mask consists of Connector、Tubing、Interface、Mask、Aluminum card、Ribbon。

4.1.3 Product status:

Sterile

4.1.4 User :

Patient

4.1.5 Using environment

Clinical or others

4.1.6 Product Structure

1-Connector

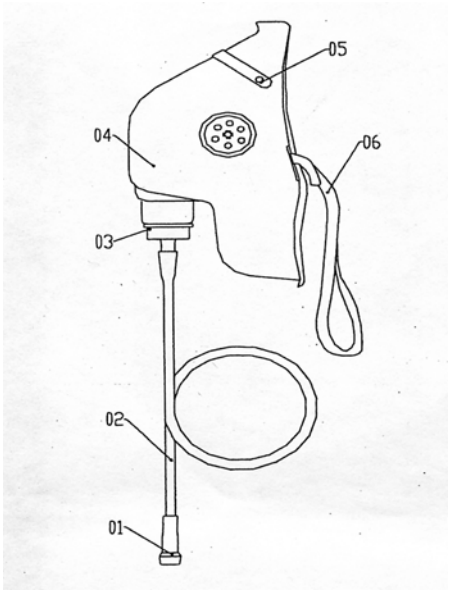
2-Tubing

3-Interface

4-Mask

5-Aluminum card

6-Ribbon



4.2 Risk management plan and process

- The SIMPLE OXYGEN MASK project started in year 2008. At the same time, we began the risk management activities, and formulated the risk management plan.
- The risk management plan defines the risk acceptable criteria for the SIMPLE OXYGEN MASK project. It also covers the risk management activities from the design, development stages to the evaluation of the method to obtain production and post-production information.
- The company formed a risk management team and appointed the person in charge of it, thus to ensure that the risk management activities can be carried out effectively in accordance with plan.

4.3 The purpose of risk management review

The purpose of this risk management review is evaluate the risk management activities in each stage before the Simple Oxygen Mask to market, make sure that the plan can be completed successfully. It covers through the analysis of the product risk management, risk evaluation, risk control and the residual risk

acceptable evaluation to confirm that the risk of product has been managed and controlled within acceptable limits.

4.4 The risk management review team and its responsibilities

Reviewers	Department	Position	Responsibilities
Mr. Jiang BS	Engineering Department	Manager	From a product technical point of view to determine the possible defects
Mr. Zhang XD	Project Management Department	Manager	From the design and development point of view to determine the possible defects
Miss. Luo LN	QC/QA Department	Manager	From the quality inspection point of view to determine the possible defects
Mr. Duan WH	Assembly Department	Supervisor	From the productive process point of view to determine the possible defects
Mr. Wan KF	Manufacturing Department	Manufacturing Director	From the productive process point of view to determine the possible defects
Mr. Yuan NP	/	Quality Director	From the quality control and medical point of view to estimate damage.

The Second Chapter - Risk Management Review Input

4.5 The risk acceptable criteria

- According to the risk management control procedure document SOP-07

4.6 The risk management documents

- Risk management plan
- Product safety features issue list
- The initial damage judgment and initial risk control protocol analysis
- The risk assessment sheets and the risk control measures record

4.7 Related laws, regulations and standards

- EN980:2008 Graphical symbols for use in the labeling of medical devices
- GB/T2828.1-2003 Sampling procedures for inspection by attributea-Part1:Sampling schemes indexed by acceptance quality limit(AQL) for lot-by-lot inspection
- GB/T2829-2002 Sampling procedures and tables for periodic inspection by attributes (Apply to inspection of process stability
- GB/T 14233.1-2008 Infusion, transfusion, injection equipment, test methods Part I: Methods for chemical analysis

- GB/T14233.2-2005 Infusion, transfusion, injection equipment, test methods Part II: Biology test methods
- ISO1135-1:2007 idt GB18279-2000 Sterilization of health care products — Ethylene oxide —Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO10993-1:2009 Biological evaluation of medical devices —Part 1:Evaluation and testing within a risk management process
- ISO10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
- ISO10993-5:2009 Biological evaluation of medical devices —Part 5: Tests for in vitro cytotoxicity
- IS014971:2007 Medical devices -- risk management--Application of risk management to medical devices

4.8 Related documents

- The risk management control procedure File No :SOP-07
- The design and development control procedure File No :SOP-09
- Ethylene oxide sterilization process validation and routine control procedures File No：SOP-24

The Third Chapter - Risk Management Review

4.9 The completion status of risk management plan

- The review team has checked the completion status of the risk management plan one by one. After checking the related documents, the Simple OXYGEN MASK project risk management plan has basical implemented.

4.10 Residual risk acceptable review

The review team has comprehensively analyses the residual risk, fully considered the influence of all residual risk function, the result of the review is: product overall residual risk is acceptable. Detailed evaluation:

- Has the single risk of the risk control found any conflicting requirements? Conclusion: have not found yet
- The warning review (including if warning is too much?) Conclusion: warning prompts is clear, and in line with norms.
- Operation manual review (Is there any conflicting clause? Or is it hard to follow?)

Conclusion: The opearion manual conforms to the state Drug Administration’s 10th order and product special safety standards requirements. The product safety clause stated in the manual is clear and easy to read to users.

- Comparison with other company's similar product

The product has compared with Ningbo Meidikang medical equipment Co., LTD's SIMPLE OXYGEN MASK, our preference is that the product performance and appearance is better than Meidikang's products.

Conclusion: the risk management review team analyses all above aspects, and communicate well with clinical application experts , we concluded that the overall residual risk of the product is acceptable.

4.11 Production and production information

- Production and production information acquisition methods refer to《the production and production information acquisition method table》

Production and production information	Acquisition	Responsible departments
Regulatory changes	Regularly receives	Quality Assurance Department
Adverse event （inside、outside）	Regularly receives	Quality Assurance Department
Notice / recall （inside、outside）	Regularly receives Notice / recall process	Quality Assurance Department， Engineering Technology Department
Customer complaints	Feedback summary of information,analysis and assessment results	Sales Department， Quality Assurance Department
Design changes	Design review of changes	Engineering Technology Department
Changes in the procurement of quality of the product	Procurement product quality analysis	Quality Assurance Department， Engineering Technology Department
Manufacturing process	CPAP	Manufacturing department
Product test results	Product test results analysis report	Quality Assurance Department
Stay in the analysis of sample products	Product quality analysis report	Quality Assurance Department
Monitor the results of product storage	Product inventory report	Warehouse

- The team reviewed the suitablility and effectiveness of《the production and production information acquisition method table》,and believe that the method is appropriate and effective. Production and production information acquisition methods of SIMPLE OXYGEN MASK project can use it.

- The project in charge should responsible to manege the production and production information, when necessary, risk management review team will participate and implement the risk management activities.

4.12 The risk management accredited ducuments

The final risk management document after the review are:

- 《product risk management plan》
- 《Product safety features issues list》
- 《The initial damage judgment and initial risk control scheme analysis》
- 《Risk assessment sheets and risk control measures record sheets 》
- 《PFMEA analysis and the results》

The Fouth Chapter - Conclusion

The risk management plan has been properly carry out; The overall residual risk is acceptable.

The company has proper methods to get the related production and production information.

All residual risk of the Simple Oxygen Mask project is controlled in a acceptable range and be benefited more than risk. The team approves the mass production of the SIMPLE OXYGEN MASK and launches the product to market.

5. 0 GENERAL DESCRIPTION OF PRODUCT

The simple Oxygen mask consists of Connector、Tubing、Interface、Mask、Aluminum card、Ribbon.The Simple Oxygen Mask is used for the emergency oxygen, and hypoxia in patients with oxygen inhalation.

Number	Flow chart move △ / Quality control point □ / Special process ⊕ / Key processes ⬡ / General procedure ✳	Process name
1		Feed testing
2		Raw material storage
3		Picking
4		njection/Extrusion
5		Semi-finished sampling
6		Semi-finished products storage
7		Receive semi-finished products
8		Mask mounted interface
9		Oxygen tube bonding head, aluminum card
10		The mask wearing Baotou with
11		Mask intubation, coil fitted plastic bag sealing
12		Package
13		Transported to the sterilization room
14		Sterilization
15		Sterilizing effect of verification
16		Finished product storage
17		Finnal inspection

6.0 BIOCOMPATIBILITY TEST

6.1 Overview

The company subcontract Zhejiang Province Hangzhou Medical Device Supervising & Test Center to perform the biocompatibility test according to ISO 10993 and other applicable standards, the test items including Delayed-type Hypersensitization test, Skin Irritation test, Cytotoxicity tets.

6.2 Brief Introduction of Biocompatibility Test:：

6.2.1 Delayed-type Hypersensitization test

In this test a certain volume of extractable solution of product was injected into the body of rabbit, observe the reaction of local skin, and evaluate the irritation effect of testing sample on contacting tissue,the test no. is Z20112167.

6.2.2 Skin Irritation test

In this test, a certain extractable solution of product was used to contact with skin of guinea pig to test if the testing sample causes contacting skin abnormality reaction.

6.2.3 Cytotoxicity test

In this test a certain volume of extractable solution of device was added in L—929 cell solution, after growth and reproduction, evaluate the potential toxicity effect of testing sample on cell.

6.3 Conclusion

According to the requirements of ISO 10993-5:2009《Biological evaluation of medical devices—Part 5:Test for virto cytotoxicity》,there was slight cytotoxicity; And according to the requirements of ISO 10993-10:2010《Biological evaluation of ,medical devices—Part 10:Tests for irritation and delayed—type hypersensitivity》,there was no skin irritation and delayed—type hypersensitization.

7.0 CLINICAL DATA

Simple Oxygen Mask, manufactured by NingBo Shengyurui Medical Appliances Co., Ltd. Simple Oxygen Mask is made of PVC.

The Simple Oxygen Mask is used for the emergency oxygen, and hypoxia in patients with oxygen inhalation.

7.1 Intended use of the product

- Soundway Medical:

The Simple Oxygen Mask is used for the emergency oxygen, and hypoxia in patients with oxygen inhalation.

- Well Lead -Medical:

The Simple Oxygen Mask is used for the emergency oxygen, and hypoxia in patients with oxygen inhalation.

7.2 Raw materials

- Soundway Medical:

  The major raw materials of Simple Oxygen Mask is PVC.

- Well Lead -Medical:

  The major raw materials of Well Lead -Medical's product are also medical PVC

In summary, we believe the raw materials our company's product are the same as that of the Well Lead -Medical company's.

7.3 The basic structure & principle (including composition)

- Soundway Medical:

  The simple Oxygen mask consists of Connector、Tubing、Interface、Mask、Aluminum card、Ribbon。

- Well Lead -Medical Company:

  The simple Oxygen mask also consists of Connector、Tubing、Interface、Mask、Aluminum card、Ribbon。

By the above comparison shows the Simple Oxygen Mask, manufactured by NingBo Shengyurui Medical Appliances Co., Ltd., In Intended use of the product、Raw materials and structure are the same as Well Lead -Medical Company.

8.0 PRODUCT PACKAGING QUALIFICATION

8.1 Overview

The CE marked product manufactured in our company, uses primary package which is produced with Paper Pouch or PE plastic bag. The packaging materials and packaging process were validated according to requirements of EN 868-1.

8.2 Packaging Material Qualification

8.2.1 Packaging bag bioburden test

The document is included in Sterilization Validation Report (03-VS-011 Annex 2)

8.2.2 Compatibility of packaging materials and sterilization process

The document is included in Sterilization Validation Report (03-VS-011)

8.2.3 Biocompatibility of packaging materials

Quality Assurance Certificates supplied by pacgaing materials supplier, The document is included in Sterilization Validation Report (03-VS-005 and 03-VS-003)

8.3 Packaging Process Validation

Primary package is packed by Paper Pouch or PE plastic bag.

The packaging process validation was carried out with 3 steps:

1. Installation qualification（IQ), to validate the conopenence of equipment itself and determine if it can meet technique requirements；

2. Operation qualification （OQ), to determine the appropriate the sealing technique and failure or limit conditions, and evaluate the stability of techniques；

3. Performance qualification （PQ), to evaluate the technique stability between batch and batch, and the stability of product performance.

The packaging qualification is performed according to ISO 11607:2003 and EN 828-1. The final packaging qualification report （03-VS-006 and 03-VS-005）is established accordingly .

The packaging qualification proved that the packaging technique is:

1. Continuous automatic bagger (model：FRB-770）or Continuous automatic bagger with ink（model：FRM-980）；

2.Packing technique parameters are:

Machine Name	Machine Type	Thermal temperature(℃)	Sealing time（transforming speed) （roll/minute)
Continuous automatic bagger	FRB-770	150±10	The fastest speed
Continuous automatic bagger with ink	FRM-980	200±10	The fastest speed

9.0 STERILIZATION VALIDATION REPORT

9.1 Overview

To ensure the sterilization of our product Anexflex Mask meeting specified requirements, the sterilization validation according to ISO11135《EO sterilization validation For Medical Instruments and routine control》 was performed, and the relevant work instructions were established according to technical parameters obtained in validation, which used to control the sterilization process.

9.2 Sterilization conditions

The product shall be sterilized with the following validated parameters.

- Gas type: Ethylene Oxide (EO)100%
- Temperature: 45±1℃
- Relative humidity: 64~80%
- Thermal Time: 120min
- Pressure：-20kpa
- EO Volume: 12Kg

- Time: 360 min
- Washing Vacuum Pressure：-10Kpa
- Washing times：6 times
-

9.3 sterilization validation and control

9.3.1 Sterilization validation

9.3.1.1 The sterilization validation shall be performed according to ISO11135

9.3.1.2 Equipment needing to perform sterilization validation: HXD-20/CE EO sterilizer.

9.3.1.3 Requirements of sterilization validation

- ·ensure the sterilization effectiveness achieving 10-6 sterility assurance level
- ·physical performance of product can meet requirements of 《Company Standard》

9.3.1.4 Items of sterilization validation:

- ·validation of sterilization parameters；
- ·evaluation of physical performance conformity
- ·evaluation of microorganism performance conformity

9.3.1.5 Method of sterilization validation

Set the sterilization validation parameters scope based on technical data of sterilizer and experience data. Search the shorten sterilization time with half-cycle method, and determine the sterilization effectiveness under upper and lower limit conditions （physical performance conformity , microorganism performance conformity etc.)

9.3.1.6 Result of sterilization validation

- ·Equipment qualification (empty load) is conforming, for detail see 《EO Sterilization Validation Report》 (03-VS-002)；
- Physical performance validation (empty load) is conforming, for detail see 《EO Sterilization Validation Report》(03-VS-002)；
- Microorganism performance validation (loading) is conforming, for detail see 《EO Sterilization Validation Report》；(03-VS-011)；
- Product performance （including physical performance, Sterile examination) validation（loading) is conforming, for detail see 《EO Sterilization Validation Report》(03-VS-011)。

9.3.2 Sterilization control

9.3.2.1 Data such as temperature, humidity, pressure, EO concentration, processing time etc. shall be recorded batch by batch.

9.3.2.2 According to requirements of ISO 11138-1 and ISO 11138-2, uses Bacillus subtilis ATCC9372 as BI, each BI contains 106 cfu microorganism.

For each sterilization batch, sufficient quantity of BIs shall be laid in sterilizer according to requirements of ISO 11135. The sterility test shall be carried out after sterilization.

9.3.2.3 After sterilization, the replacement of gas will lower the EO concentration in package, and the products shall be laid in warehouse for aeration. To ensure the EO concentration in product ,6 times of -15Kpa pressure is used.

10. PRODUCT LABEL AND LANGUAGE SAMPLE

10.1 Label design

The following content shall be addressed in label:

Name and address of manufacturer and EC-Representative；

a）Company Name, Address

symbol:

b）Trademark

symbol:

c）Production license

d）Proudction standards

e）Product name and model

f）Registered Number

g）Quantity

h）Production date

- The production date with six digits composition, which is be in the right of the symbols or below.The first four digits indicates the year of production,and others indicate the month of production.
- Symbol:

Eg.2007-06 means products in Jun ,2007 production

i）lot

- Symbol

- Lot number follows on the right side or below the symbol with 6 digits, the 1st and 2nd digit indicates year,others indicates the production order
- size and location of symbol and lot

Eg. LOT 110602

Indicate： In 2011, the order number or task order for 0602 of a batch of products

j）symbol of “valid period”and wriiten characters (USE BY)

- Symbol  XXXX-XX

- Date follows on the right side or below the symbol with 4 digits of year, and 2 digits of month.
- size of symbol and date is not specified.
- this symbol and date indicates that the product shall be used before this date.

Eg.  2011-06

Indicate：Use before 30 Jun 2011

K）word and symbol of “Please consult instructions”

- word ： caution
- symbol:

l）Word and symbol of ”Do not reuse”

- symbol:

- this symbol indicates the product is for single use
- this symbol can be arbitrara,but it must ensure that zoom-in symbols of clear

m）Word ”sterile ” and characters of “EO Sterilization”

- symbol:

STERILE | EO

- size of symbol and date is not specified

n）symbol and content of “Please consult instructions”

- Symbol:

- background of this symbol shall be yellow, the outline of symbol is black, size of this symbol is just OK once it can be observed.
- Content for warning shall be followed behind this symbol;

O）Instruction of product and notes (including storage condition,etc.)

10.2 Instruction of product also should have the following main contents

a）product main performance

b）Applicable scope

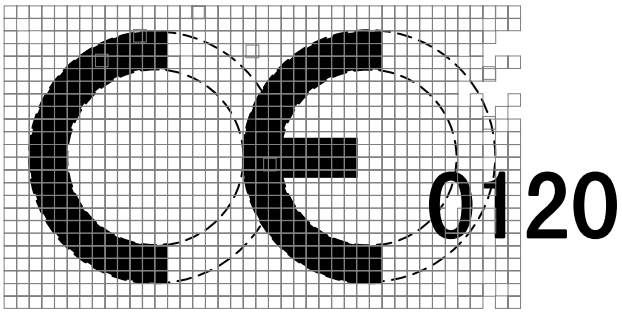
c）Use method and the matters needing attention

d）The storage and transpotation,storage requirements

e）After-sales service commitment

10.3 label control of CE Marking

a)Symbol



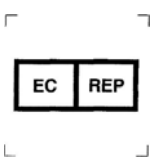
b) Diameter of symbol shall not less than 5mm.

c) On bottom right of CE mark the register number of Notified Body shall be indicated.

d) CE mark shall be readable, clear and durable.

10.4 EC-Representative Name, Address

symbol:



10.5 Special requirements

If there is special requirements on label（or mark) by customer, other than the customer's requirements, the other requirements shall be conforming to above mentioned content.

10.6 Relevant literatures

MDD93/42/EEC Annex clauses 13 and Ⅶ.

EN980

EN1041

10.7 Annex

Annex1: Instructions Manual for The simple Oxygen mask.