CE Technical Documents

- Yankauer Handle

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1 Document Change Record

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2 Declaration of Conformity

Manufacturer name: Ningbo Shengyurui Medical Appliances Co., Ltd.
Manufacturer address:
No.138 Binghai Road,Hangzhou Bay New Zone,315336,Ningbo City,China

EC REP

EC-Representative name: Shanghai International Holding Corp., GmbH (Europe)
EC-Representative address: Eiffestrasse 80, 20537 Hamburg, Germany

Products: Yankauer Handle

Classification: IIa (Rule 6 of Annex IX of MDD)

UMDNS Code 13325

Conformity certification route Annex V.3 of MDD 93/42/EEC

Date CE-mark starting to affixed: not start

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directive and Standards (MDD/93/42/EEC). The products meet prospective uses and all supporting documentation are retained under the promise of manufacturer.

DIRECTIVES

General Applicable Directive:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical device (MDD 93/42/EEC)

Notify Body: SGS

EC-certificate No.: _____
EC-certificate issuing date: _____
EC-certificate use by date: _____

Place, Date: _____, _____

Signature: _____
Name: Hui Hu
Position: General Manager
Place: Ningbo, China

3 Introduction of product

1. Company information:

Company name: Ningbo Shengyurui Medical Appliances Co., Ltd.

Company address: No.138 Binghai Road,Hangzhou Bay New Zone,315336,Ningbo City,China

2. EC-representative

2.1 Authorizing representative within EU

Name: Shanghai International Holding Corp., GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

2.2 Agreement between manufacturer and EC-representative

The agreement with EC-representative was signed

3. Products name: Yankauer Handle

The Yankauer handle is made from the raw material of medical grade materials, have such good performances as the tube with appropriate hardness, excellent biocompatibility.

The end of yankauer handle is connected to suction connection tube, then attach the tube to suction machine. During the operation, surgeon uses such device to remove the gore, body liquid and so on.

Yankauer handle is made from PVC or PP. Yankauer handle is used widely in Europe and America.

4. Intended uses of products:

Yankauer handle is intended to suck the residual liquid in the human body after connected with sucking machine or other sucking system.

5. Cautions: Check if the sterile packaging is damaged. If it is damaged, do not use the product and make sure the product is in valid period.

For single use only and please use it immediately after package opened and destroy it after use.

6. **Classification of products:** IIa (Rule 6 of Annex IX of MDD)

7. Conformity certification route

The company applies for auditing pathway of CE products in accordance with Annex V.3 of requirements of MDD93/42/EEC.

8 Models and specifications:

9 Structure and materials:

9. Production environment and sterilization method

The products are produced and assembled in 100, 000-class clean room which is meet requirement. The products are sterilized with ethylene oxide.

10. List of law and standards in point:

S/N	Document No.	Edition No.	Document Title
1	MDD 93/42/EEC	Amended by 2007/47/EC	Medical Device Directives
2	EN ISO 13485	2012	Medical devices — Quality management systems — Requirements for regulatory purposes
3	EN ISO 14971	2012	Medical devices — Application of risk management to medical device
4	EN ISO 10993-1	2009	Biological evaluation of medical devices - Part I: Evaluation and testing within a risk management process
5	EN ISO 10993-5	2009	Biological evaluation of medical devices ----- Part V:Cytotoxicity test – In vitro method
6	EN ISO 10993-7	2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization Residuals
7	EN ISO 10993-10	2010	Biological evaluation of medical devices ----- Part X: Irritation and sensitivity test
8	EN 980	2003	Graphics and symbols used in label of medical devices
9	EN 1041	2008	Terms and graphics information concerning medical device — information provided by manufacturer of medical device
10	EN ISO 15223-1	2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
11	EN ISO 11607-1	2009	Packaging for terminally sterilized Medical Device Part 1: Requirement for materials, sterile barrier systems and packaging systems
12	EN ISO 11607-2	2006	Packaging for terminally sterilized Medical Device——Part 2: Validation Requirement for forming, sealing and assembly process
13	EN ISO 14155	2011	Clinical investigation of medical devices for human subjects
14	EN ISO 11135-1	2007	Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
15	EN ISO 11138-2	2009	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
16	EN ISO 11737-1	2006	Sterilization of Medical Device-Microbiological methods——part 1: Determination of population of microorganisms on products
17	EN ISO 11737-2	2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

4 Essential Requirement Check List

Essential Requirements	A - N/A	Standards	Manufacturer compliance
1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, 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 intended 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	ENISO14971	Risk management report Clinical Evaluation Report
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 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.	A	ENISO14971	Risk management report
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 (2) (a), as specified by the manufacturer.	A	ENISO11607	Pre-clinical research Total performance test report Package validation report
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	ENISO11607	Package validation report
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	ENISO11607	Package validation report
6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended. 6a. Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	A	ENISO14971	Risk management report Clinical data
II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION			
7. **Chemical, physical and biological properties**	A	ENISO10993-1	Biocompatibility test

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'. Particular attention must be paid to: — 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 modeling research whose validity has been demonstrated beforehand.'			report Package validation report Package validation report
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		Product for single use
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 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.	A	Product standard	Test report
'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 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 21.9.2007 EN Official Journal of the European Union L 247/43 account the data related to the usefulness of	N/A		

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 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 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.	A	Product standard	Test report
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	Product standard	Manufactured in Class 100,000 cleanliness room, Prevent of foreign substrates
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, where necessary, minimize contamination of the device by the patient or vice versa during use.	A		Product for single 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 transmissible 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	A	ENISO11135-1	Sterilization validation

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.		ENISO11607	report Package validation report
8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	A	ENISO11135-1 ENISO11607	Sterilization validation report Package validation report
8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.	A	ISO13485	Program of environmental control
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 sterilization 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.	N/A		
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 instructions for use.	N/A		
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.	N/A		
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 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.	N/A		
10.2. The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	N/A		
10.3. The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1).	N/A		
11. **Protection against radiation**	N/A		

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.			
11.2. *Intended radiation* 11.2.1. 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 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* 11.3.1. 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		
12. **Requirements for medical devices connected to or equipped with an energy source** 12.1. Devices incorporating electronic programmable systems must be 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. 12.1a 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. 12.1b 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 principals 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		
12.5. Devices must be designed and manufactured in such a way 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 a way 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	N/A		

mechanical risks connected with, for example, resistance, stability and moving parts. Page 11 sur 33 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. 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, 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. 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.			
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. 12.8.2. Devices must be fitted with the means of preventing and/or indicating any inadequ acies 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 information must be understandable to the user and, as appropriate, the patient.	N/A		
13. **Information supplied by the manufacturer** 13.1. Each 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 data 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 sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet and 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 I or IIa if they can be used safely without any such instructions.	A	ENISO15223-1 EN980 EN1041	Labels and language samples

13.2. Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	A	ENISO15223-1 EN980 EN1041	Labels and language samples
13.3. *The label* must bear the following particulars: '(a) the name or trade name and address of 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 the authorised representative where the manufacturer does not have a registered place of business in the Community;' '(b) the details strictly necessary 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; (j) 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 serial number; Page 12 sur 33 (m) where applicable, method of sterilization; (n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.	A	ENISO15223-1 EN980 EN1041	Labels and language samples
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	ENISO15223-1 EN980 EN1041	Labels and language samples
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.	N/A		
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;	N/A		

(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 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. The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: (k) precautions to be 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.'			
13.7 The Commission, in accordance with the procedure referred to in Article 7 (2), may, where duly justified, adopt measures allowing instructions for use to be provided by other means.	N/A		
13.8 For Class IIb and Class III devices, the manufacturer must make available data giving a summery of the characteristics of the device The procedures implementing this requirement and in particular the data to be available and the conditions under which it shall be available, shall be adopted in accordance with the procedure laid down in Article 7(2).	N/A		

4 Risk Management Report

4.1 Foreword

This document describes the risk management about Yangkauer handle. Determine the possible hazard and contributing factors. Estimate the severity of the potential harm and probability of each factor. To the unacceptable risk, take the requisite measure, and estimate that adopts the surplus risk level after this measure.

Result: After taking these measurements, all known or foreseeable hazards associated with the medical device in both normal and fault conditions have been reduced to an acceptable level, included overall risks.

4.2 Purpose

Determinate hazards associated with the Yangkauer handle. Expatiate on necessary actions to reduce each hazard to an acceptable level. And improve our products' quality through taking appropriate actions against risks.

4.3 Scope

The products listed in the risk management: Yangkauer handle

4.4 Reference

4.4.1 Standards:

1. MDD 93/42/EEC
2. EN ISO 14971 Medical devices- Application of risk management to medical devices

4.4.2 Products' criterion

Refer to Products' criterion introduction: JCQ-T-S10006 Product Specification of Yangkauer handle

4.5 Risk management object

Intended use: Yangkauer handle is mainly applied to suck the residual liquid in the human body after connected with sucking machine or other sucking system.

4.6 Risk management process

4.6.1 step 1:Intended use/intended purpose and identification of characteristics related to the safety of the medical device.

4.6.1.1 Risk management of life cycles

Risk management must be carried out through the whole life cycle of product, from the plan, research and development to supplying the product, to feed back all information in time. Primary Risk Management should be carried out in the period of design. Requirements of Control measures to reduce risks must be advanced. Validate if any new harm appears in the very period of development and the effectiveness of harm ness and its occurrence probability. Rework it when necessary. Estimate the integrality and correctness of risk management after development. Collect information about security from production and usage and revalidate risk management. Rework it when necessary.

4.6.1.2 The assignment of trained personnel:

Name	Position	Duty
	General Manager	Leader: Responsible for the coordination of risk management activities; organize risk management review; approve risk management plan and report.

	R&D Department	Vice Leader:Develop risk management plan and goal; Participate in risk analysis; Prepare risk management report.
	QA Department Product Department Foreign Trade Department Management Representative	Group members: Estimate the probability of failure on The technology side Determine the possible existence of manufacturing defects on the technology side Assess the risk from view of application Collect, analyze the clinical data and thesis. And audit risk plans and reports.

4.6.1.3 Determination of Intended use/intended purpose and identification of characteristics related to the safety of the medical device(see Annex A)

4.6.2 Step 2:Identification of known or foreseeable hazards

These kinds of hazards are marked with "H_…"

Origin:

Risk analysis report available for a similar medical device

Identification of the person(s) and organization which carried out the risk analysis

Opinion from experts

Analysis FDA report

Study correspond control measures of similar medical devices

Scene information, service report, customer complaint and advisory notice from the similar medical device.

Relative latency hazards

Relative foreseeable hazards listed below by risk management group:

(1)harms to sufferer

H_P1Biological hazards

H_P1.1product with bacterium infect sufferer, causing user's skin infecting or allergic

H_P2 product is not compatible with body's organize

H_P2.1 material is not compatible with body's body

H_P2.2 package material is not compatible with body's body

H_P3product with eye winker, hair or metal, etc. which harm to sufferer(such as inflammation)

H_P4 raw materials, package materials have toxicity

H_P5 products, package with pyrogen

H_P6 error use by wrong or less information in the label or in the attention

H_P7error operation by person who are not professional doctor or nurse

H_P7.1 for other use

H_P7.2 use for sufferer by person who are not professional doctor or nurse

H_P8error use because user doesn't operation according to the use manual

H_P9 reuse the disposable product

H_P10 treatment intention has not been reached

H_P10.1 leakage

H_P10.2 break of package;

H_P10.3 product attaint;

H_P10.4 package aging.

H_P11 other harm chemistry

H_P11.1 products with acid or alkali causes stimulation

H_P11.1 EO residual

H_P12 mechanical forces

H_P12.1 During the clinical use, due to the inappropriate operation, the urethra mucous membrane may be hurt to cause the pain or blooding.

(2)harm to user(such as:doctor)

H_O1 microorganism infection

H_O1.1 products with pathogen infect doctor or nurse

H_O1.2 doctor or nurse will be infected by sufferer

(3)harm to other person(such as:nurse)

H_A1 microorganism infection

H_A1.1 products with pathogen infect doctor or nurse

H_A1.2 doctor or nurse will be infected by sufferer

H_A1.3 contamination from products which are not destroyed in time after use;

4.6.3 Determination of the risk(s) for each hazard

Risk estimation can be quantitative.

NO	Strictness degree	Probability of risk	Example
1	Neglect able	Occasionally	Immediate nausea and ache
2	Common	More harmness	Part red and gummy;
3	Strict	GBH or die	Shock or die for infection when touching thrill material
4	Calamitous	Many GBH or die	Dead virus diffuses largely and make many patients infect

4.6.4 Determination of possible hazards and contributing factors

Risk management personnel search possible factors through their knowledge.

All factors searched should be recorded in the risk management files and marked with “C…”.

4.6.5 Estimation probability of each factor

Risk estimation incorporates an analysis of the probability of occurrence and the consequences. Besides, certain elements of the risk estimation process may need to be considered:

Application experience of similar products, such as statistical data.

Approbatory technical criterion.

Its life span research

Experts’ judgments

These estimations have been listed below in 6 kinds:

No.	Probability of risk	Description	Example
1	Beyond brief	Never occurrence	products with pathogen after sterilization
2	Unnecessarily possibly	Appear once in the lifespan	Some electrical components failure
3	Few	Appear once every 100 treatment times	Some cable break;mechanical damage by the handle of electrical knife
4	Occasionally	Appear once every 10 treatment times	Gas apparatus empty
5	Very probably	Appear in every treatment	Special tools drop to the ground
6	Frequently	Appear many times in every treatment	Step on the cable

4.6.6 Step 3:Estimation of the risk(s) for each hazard (before risk control measure(s))

There are two factors in the first hazard: Severity levels, occurrence probability and hazards derived from it. Risks can be categorized into the following three regions according to ISO14971.

Intolerable region

Broadly acceptable region

ALARP(As Low As Reasonably Practicable)

4.6.7 Risk evaluation (Step 4)

Probability of risk	Severity level			
	1:Neglect able	2:Common	3:Strict	4:Calamitous
6 Frequently	ALARP	NAC	NAC	NAC
5Very probably	ALARP	ALARP	NAC	NAC
4 Occasionally	ALARP	ALARP	ALARP	NAC
3 Few	AC	ALARP	ALARP	ALARP
2 Unnecessarily possibly	AC	AC	ALARP	ALARP
1 Beyond brief	AC	AC	AC	AC

NAC＝Unacceptable risk

AC＝Acceptable risk

ALARP＝As Low As Reasonably Practicable

Mark each hazard derived from every factor with the above risk regions (NAC/AC/ALARP)in the column "R" and record its control measures.

4.6.8 Step 5, 6:Implementation of risk control measure(s)

Implementation risk control measures to each cause of a hazard if the risk is unacceptable without taking control measures. If there are several control measures drawn out in the same time, the result is effectiveness of all the risk control measures.

The risk control measures shall be recorded in the corresponding column in the risk management table, and marked with "M…"

4.6.9 Step 7:Residual risk evaluation

Low harm ness degree or occurrence probability or both after taking control measures. Sometimes, quantitative judgment can not be made. All the risk management members summarize their analysis to do the Residual risk evaluation using their specialty.

Every change should be recorded in the column "Residual risk".

Determinant Residual risk of each hazard/cause and record it in its risk region(NAC/AC/ALARP).

4.6.10 Step 8: Risk/benefit analysis

ALARP does not mean to reach the goal, but mean to be acceptable .Technical practicability refers to the ability to reduce the risk regardless of cost. Cost and availability implications are considered in deciding what is practicable to the extent that these impact upon the preservation, promotion or improvement of human health. Major risks should normally be reduced even at considerable cost. If this evidence supports the conclusion that the medical benefits outweigh the residual risk, then the risk remains acceptable. Explain the cause of whether the risk is acceptable after taking further measures when the result is ALARP.

4.6.11 Step 9, 10, 11

Residual risks of each hazard listed in the risk management table have been reduced to the acceptable region or ALARP region and have explanations why not reduce the further risk for each ALARP. From the following two tables, you can see the differences between taking measures and not taking measures. This show，there are 22 ALARP and 1 NAC conditions under no measures. While there is no NACC and ALARP conditions left after taking measures and they are all below the ALARP region.

Not taking measures

		Harm degree			
		1	2	3	4
probability	6				
	5			1	
	4				
	3		1	13	
	2			8	
	1				

Taking control measures

		Harm degree			
		1	2	3	4
probability	6				
	5				
	4				
	3				
	2				
	1		1	22	

In this way, single residual risk can be acceptable.

4.7 Step 12:Result of risk management

Since The Yangkauer handle has been developed widely, its effect is obvious and excellence explanation is not necessary. Herein its residual risk is small; the medical benefits outweigh the risk.

4.8 Annex A:Questions that can be used to identify medical device characteristics that could impact on safety

1) What is the intended use and how is the medical device to be used?

Yangkauer handle is mainly applied to suck the residual liquid in the human body after connected with sucking machine or other sucking system.

2) Is the medical device intended to contact the patient or other persons?

The Yangkauer handle is intended to contact the mucous membranes.

3) What materials and/or components are incorporated in the medical device or are used with, or are in contact with, the medical device?

Made of medical grade PVC or PP material.

4) Is energy delivered to and/or extracted from the patient?

No.

5) Are substances delivered to and/or extracted from the patient?

Residual liquid in the humanbody.

6) Are biological materials processed by the medical device for subsequent re-use?

No such material.

7) Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?

Before shipping to the customer, the product has been sterilized by EO gas.

8) Is the medical device intended to be routinely cleaned and disinfected by the user?

No.

9) Is the medical device intended to modify the patient environment?

No.

10) Are measurement taken?

No.

11) Is the medical device interpretative?

No.

12) Is the medical device intended for use in conjunction with medicines or other medical technologies?

No.

13) Are there unwanted outputs of energy or substance?

No.

14) Is the medical device susceptible to environmental influences?

No.

15) Does the medical device influence the environment?

No.

16) Are there essential consumables or accessories associated with the medical device?

No.

17) Is maintenance and/or calibration necessary?

No.

18) Does the medical device contain software?

No.

19) Does the medical device have a restricted shelf-life?

Yes, it is 2 years.

20) Are there any delayed and/or long –term use effects?

No.

21) To what mechanical forces will the medical device be subjected?

No.

22) What determines the lifetime of the medical device?

Period of validity of sterilization and the aging character of the Rectal tube.

23) Is the medical device intended for single use?

Single use.

24) Is safe decommissioning or disposal of the medical device necessary?

No.

25) Does installation or use of the medical device require special training?

Yes, the Yangkauer handle is restricted to be used by the doctor or nurse.

26) Will new manufacturing processes need to be established or introduced?

No.

27) Is successful application of the medical device critically dependent on human factors such as the user interface?

No.

27.1) Does the medical device have connecting parts or accessories?

Yes, sometimes the Yangkauer handle is connected with tube.

27.2) Does the medical device have control interface?

No.

27.3) Does the medical device display information?

No.

27.4) Is the medical device controlled by a menu?

No.

28) Is the medical device intended to be mobile or portable?

No.

4.9 Annex B:Examples of possible hazards and contributing factors associated with medical devices

This annex provides a non-exhaustive list of possible hazards together with contributing factors which may be associated with different medical devices. This list can be used to aid in the identification of hazards associated with a particular medical device.

Energy hazards and contributory factors	Reasons
electricity	----
heat	----
mechanical force	----
ionizing radiation	----
non-ionizing radiation	----
moving parts	----
unintended masses	----
suspended masses	----

failure of patient-support device	----
pressure(e.g. vessel rupture)	----
acoustic pressure	----
vibration	----
magnetic fields(e.g. MRI)	----

biological hazards and contributory factors	Reasons
bio-contamination	The bio-burden on the product exceeds the limit (1) The large amount of microbes existing in the environment (2) The microbes on the body surface directly polluted the products (3) The microbes on the packaging material Imperfect sterilization cause the product micro-polluted. 3. Pollution in packing, storage and transport Unqualified packaging material and inadequate scaling offered the access of the bacterium into the product The dark, moist and non-ventilated conditions in the stock room allow bacteria to grow and propagate. In storage of transport, highly stowed packing are damaged and bacterial into products.
bio-incompatibility	Adopt non-proper materials to cover with the Yangkauer handles' surface, cause the allergic reaction.
incorrect formulation (chemical composition)	----
toxicity	----
allergenicity	Adopt non-proper materials to cover with the Yangkauer handles' surface, cause the allergic reaction.
mutagenicity	----
teratogenicity	----
oncogenicity	----
carcinogenicity	----
re-and/or cross-infection	----
pyrogenicity	----
inability to maintain hygienic safety	----
degradation	The material is degraded because of heat ,light and other reason.

Environmental hazards and contributory factors	Reasons
electromagnetic fields	----
susceptibility to electromagnetic interference	----
emissions of electromagnetic interference	----
inadequate supply of power	----

inadequate supply of coolant	----
storage or operation outside prescribed environmental conditions	the Yangkauer handle is degraded due to storage in hot, light or moist place.
incompatibility with other devices with which it is intended to be used	----
accidental mechanical damage	----
contamination due to waste products and/or medical device disposal	----

Hazards resulting from incorrect output of energy and substances	Reasons
electricity	----
radiation	----
volume	----
pressure	----
supply of medical gases	----
supply of anaesthetic agents	----

Hazards related to the use of the medical device and contributory factors	Reasons
inadequate labeling	Error information or inadequate information that will cause miss usage;
inadequate specification of accessories to be used with the medical device	----
inadequate specification of pre-use checks	Error information or inadequate information that will cause miss usage;
over-complicated operating instructions	----
inadequate specification of service and maintenance	----
use by unskilled/untrained personnel	use by unskilled/untrained personnel,
reasonably foreseeable misuse	----
insufficient warning of side effects	----
inadequate warning of hazards likely with re-use of single-use medical devices	Mark of single use is not obvious.
incorrect measurement and other metrological aspects	----
incompatibility with consumables/accessories/other medical devices	----
sharp edges or points	----

Inappropriate, inadequate or over-complicated user interface (man/machine communication)	Reasons
mistakes and judgment errors	----
lapses and cognitive recall errors	----
slips and blunders (mental or physical)	----
violation or abbreviation of instructions procedures, etc	----
complex or confusing control system	----
ambiguous or unclear device state	----
ambiguous or unclear presentation of settings, measurements or other information	----
misrepresentation of results	----
insufficient visibility, audibility or tactility	----
poor mapping of controls to action, or of displayed information to actual state	----
controversial modes or mappings as compared to existing equipment	----

Hazards arising from functional failure, maintenance and ageing and contributory factors	Reasons
erroneous data transfer	----
lack of, or inadequate specification for maintenance including inadequate specification of post-maintenance functional checks	----
inadequate maintenance	----
lack of adequate determination of the end of life of the medical device	No specific period of validity.
loss of electrical/mechanical integrity	----
inadequate packaging (contamination and/or deterioration of the medical device)	The seal of packaging is bad.
re-use and/or improper re-use	----
deterioration in function (e.g..gradual occlusion of fluid/gas path, or change in resistance to flow, electrical conductivity) as a result of repeated use.	----

4.10 Annex C:Summarization of risks reducing measures

M1 Maintain the workshop relatively clean, inspects the product and the pack to ensure there are no other matters.

M2 Strictly controls every procedure of the receiving material, process and finished product to ensure that the population of microbes is under the control scope.

M3 Select the material according to the regulated safety index, ensure that there is no procedure affecting safety of material.

M4 Strictly carry out the standards of ISO11135， enact sterilization parameter, make validity confirmation to ensure sterilization effect; Make asepsis examination.

M5 Package validation(set seal parameters);transportation test, fall test; “Do not use if package is broken, products are contaminated or broken” is denoted on package and instruction manual of products.

M6 Select proper packing material according to the standards; research of package performance.

M7 “Do not store at extreme temperatures and humidity. avoid direct sunlight” is printed on package

M8 Use medical grade materials.

M9 clarify the acceptable standards of product, ensure the used material is up to grade, and strictly control the quality of every procedure.

M10 Strengthen management of printing and carry out process inspection

M11 Strictly control issue of the labels

M12 “Only for specialty doctor and nurse operation and use” is printed on package and instruction manual

M13 Intended use is printed on package and instruction manual.

M14 “single use only” is printed on package and instruction manual.

M15 Set output guideline of products, Ensure that there is no working procedure in processing which will affect the performance of tube materials.

M16 Carry out period of validity validation, storing environment and period of validity of products are printed on package and instruction manual of products

M17 Use Product immediately after package opened

M18 Production is processed strictly in accordance with standard of products and inspection is strengthened

M19 Set output guideline of EO and ECH residua volume

M20 “Destroyed after use” is printed on package and instruction manual.

4.11 risk management table

Harm degree(S)	occurrence probability (P)
1＝Neglect able	1＝Beyond brief
2＝Common	2＝Unnecessarily possibly
3＝Strict	3＝Few
4＝Calamitous	4＝Occasionally
	5＝Very probably
	6＝Frequently

H_P1 microorganism infection

ID cause	Before taking actions			ID control measures	Residual risk		
	S	P	R		S	P	R
C1.1 The bio-burden on the product exceeds the limit (1)The large amount of microbes existing in the environment (2)The microbes on the body surface directly polluted the products (3)The microbes on the packaging material	3	3	ALARP	M1 Maintain the workshop relatively clean, inspects the product and the pack to ensure there are no other matters. M2 Strictly controls every procedure of the receiving material, process and finished product to ensure that the population of microbes is under the control scope. M3 Select the material according to the regulated safety index, ensure that there is no procedure affecting safety of material. M17 Use Product immediately after package opened	3	1	AC
C1.2Imperfect sterilization cause the product micro-polluted.	3	2	ALARP	M4 Strictly carry out the standards of ISO11135，enact sterilization parameter, make validity confirmation to ensure sterilization effect; Make asepsis examination.	3	1	AC
C1.3 Pollution in packing, storage and transport (1)Unqualified packaging material and inadequate scaling offered the access of the bacterium into the product (2)The dark, moist and non-ventilated conditions in the stock room allow bacteria to grow and propagate. (3)In storage of transport, highly stowed packing are damaged and bacterial into products.	3	3	ALARP	M5 Package validation(set seal parameters);transportation test, fall test; “Do not use if package is broken, products are contaminated or broken” is denoted on package and instruction manual of products. M6 Select proper packing material according to the standards; research of package performance. M7 “Do not store at extreme temperatures and humidity. avoid direct sunlight” is printed on package	3	1	AC

H_P2 products incompatible with human body

ID cause	Before taking actions			ID control measures	Residual risk		
	S	P	R		S	P	R
C2.1 material is not compatible with body's organize C2.1.1 material are not for C2.1.2 impurity entered in the production;	3	3	ALARP	M1 Maintain the workshop relatively clean, inspects the product and the pack to ensure there are no other matters. M3 Select the material according to the regulated safety index, ensure that there is no procedure affecting safety of material.	3	1	AC
C2.2 package material are not for medical	3	3	ALARP	M8 Use medical grade materials.	3	1	AC

H_P3 product with eye winker, hair or metal, etc. which harm to sufferer(such as inflammation))

ID cause	Before taking actions			ID control measures	Residual risk		
	S	P	R		S	P	R
C3 product with eye winker, hair or metal, etc.	3	3	ALARP	M1 Maintain the workshop relatively clean, inspects the product and the pack to ensure there are no other matters. M2 Strictly controls every procedure of the receiving material, process and finished product to ensure that the population of microbes is under the control scope.	3	1	AC

H_P4 material\package materials have toxicity

ID cause	Before taking actions			ID control measures	Residual risk		
	S	P	R		S	P	R
C4 material\package material are not for medical	3	5	NAC	M8 Use medical grade materials. M9 clarify the acceptable standards of product, ensure the used material is up to grade, and strictly control the quality of every procedure.	3	1	AC

H_P5 products\package has pyrogen

ID cause	Before taking actions			ID control measures	Residual risk		
	S	P	R		S	P	R
C5 products have too much microorganism	3	3	ALARP	M1 Maintain the workshop relatively clean, inspects the product and the pack to ensure there are no other matters. M2 Strictly controls every procedure of the receiving material, process and finished product	3	1	AC

				to ensure that the population of microbes is under the control scope.			

H_P6 error use by wrong or less information in the label or in the attention

ID cause	Before taking actions			ID control measures	Residual risk		
	S	P	R		S	P	R
C6.1 error label design	3	3	ALARP	M10 Strengthen management of printing and carry out process inspection	3	1	AC
C6.2 error label use	3	3	ALARP	M11 Strictly control issue of the labels	3	1	AC

H_P7 error use by personnel who is not doctors or nurse

ID cause	Before taking actions			ID control measures	Residual risk		
	S	P	R		S	P	R
C7.1 for other uses	2	3	ALARP	M13 Intended use is printed on package and	2	1	AC
C7.2 use by personnel who is not doctors or nurse	3	3	ALARP	M12 “Only for specialty doctor and nurse operation and use” is printed on package and	3	1	AC

H_P8 error use by not use according to use instruction

ID cause	Before taking actions			ID control measures	Residual risk		
	S	P	R		S	P	R
C8.1 error operate by doctors or nurse	3	2	ALARP	M13 Intended use is printed on package and instruction manual.	3	1	AC

H_P9 re-use the single use products

ID cause	Before taking actions			ID control measures	Residual risk		
	S	P	R		S	P	R
C9.1 error operate by doctors or nurse	3	2	ALARP	M14 “single use only” is printed on package and instruction manual.	3	1	AC

H_P10 miss treatment objective

ID cause	Before taking actions			ID control measures	Residual risk		
	S	P	R		S	P	R
C10.1 break of package	3	2	ALARP	M5 Package validation(set seal parameters);transportation test, fall test; “Do not	3	1	AC
C10.2 product destroyed	3	2	ALARP		3	1	AC

C10.3 package aging	3	2	ALARP	use if package is broken, products are contaminated or broken" is denoted on package and instruction manual of products. M6 Select proper packing material according to the standards; research of package performance. M7 "Do not store at extreme temperatures and humidity. avoid direct sunlight" is printed on package M15 Set output guideline of products, Ensure that there is no working procedure in processing which will affect the performance of tube materials. M16 Carry out period of validity validation, storing environment and period of validity of products are printed on package and instruction manual of products	3	1	AC
C10.4 leakage (1)The thickness for the first layer is not so enough. (2)Missing when inspection. (3)Such factors will cause the leakage as the sealing of the one-way valve is too thin and lack of elasticity; and there is bulbs.	3	3	ALARP	M9 clarify the acceptable standards of product, ensure the used material is up to grade, and strictly control the quality of every procedure. M15 Set output guideline of products, Ensure that there is no working procedure in processing which will affect the performance of tube materials. M18 Production is processed strictly in accordance with standard of products and inspection is strengthened	3	1	AC

H_P11 other harmful chemistry

ID cause	Before taking actions			ID control measures	Residual risk		
	S	P	R		S	P	R
C11.1 production with acid or alkali	3	3	ALARP	M18 Production is processed strictly in accordance with standard of products and inspection is strengthened	3	1	AC
C11.2 EO residual	3	3	ALARP	M19Set output guideline of syringe EO residua volume	3	1	AC

H_P12 mechanical forces

ID cause	Before taking actions			ID control measures	Residual risk		
	S	P	R		S	P	R
C11.1 During the clinical use, due to the	3	3	ALARP	M12 "Only for specialty doctor and nurse operation and use" is printed on package and	3	1	AC

inappropriate operation, the urethra mucous membrane may be hurt to cause the pain or blooding.				instruction manual			

H_O1 microorganism infection

ID cause	Before taking actions			ID control measures	Residual risk		
	S	P	R		S	P	R
C1 products with pathogen	3	2	ALARP	M1 Maintain the workshop relatively clean, inspects the product and the pack to ensure there are no other matters. M15 Set output guideline of products, Ensure that there is no working procedure in processing which will affect the performance of tube materials.	3	1	AC

H_A1 microorganism infection

ID cause	Before taking actions			ID control measures	Residual risk		
	S	P	R		S	P	R
C1 products with pathogen	3	2	ALARP	M1 Maintain the workshop relatively clean, inspects the product and the pack to ensure there are no other matters. M15 Set output guideline of products, Ensure that there is no working procedure in processing which will affect the performance of tube materials. M20 “Destroyed after use” is printed on package and instruction manual.	3	1	AC

Result of the risk analysis

As displayed on the risk management table, the residual risk of each hazard/reason is reduced to the degree of AC. In this way, the total number of residual risk can be considered acceptable. Because the Yangkauer handle is broadly used worldwide for many years, and the clinical effect of the Yangkauer handle is obvious.

6 Clinical evaluation

1 Product name: Yankauer Handle

2. Material and performance description

a. This products are made of PP and non-toxicity in met the requirements of ISO10993.5 and ISO 10993.10
b. The products are sterilized by EO
c. There is no toxicity, no potential skin irritation, and no sensitization;
d. Period of validity is 5 years since being manufactured.

3 Intended use: Yankauer handle is intended to suck the residual liquid in the human body after connected with sucking machine or other sucking system.

4 Applications: For single use, do not reuse.

5. Product statuses: the QMS of our company is complying with ISO 13485 standard, manage in detail, improve continuously, and try to form the management system accord with the standard as well as with characteristic of company. The quality of products is safe, effective, and being elevated steadily. The products gained users' recognition and good comment in long-term clinical uses.

6. Clinical probation result

The products are sterile. There is no toxicity, no potential skin irritation, and no sensitization; No harm to the patients.

7. Result:

People accept the products because the ink is non-toxic. The quality of products is safe, effective, and being elevated steadily. The products gained users' recognition and good comment in long-term clinical uses.

7 Pre-clinical Study

1 Biological compatibility tests

The company carries out biological compatibility test in accordance with ISO 10993-5 and ISO 10993-10 standards. The tests are consigned to Testing Center of Radiation Medicine Research Institute, Soochow University for cytotoxicity, sensitivity and irritation test.

1) Cytotoxicity test
   a) Take growing-well cell of strain L-929 to prepare cell soliquiod with concentration of 4×10^4 counts/ml in culture bottles. Proceed to next step after the cell grows up to monolayer.
   b) Discard the liquid in culture bottles. In these culture bottles. Take testing group, add con 50% sample solution, the positive control solution and the negative control solution. They are all incubated at 37^0C. After 2 and 4 days incubation respectively, conduct the morphology evaluation and cell counting.

Conclusion:

By the experiment incubating L-929 cell using culture medium with sample solution, the RGR of testing group is determined as above Grade 1 and 0.This means the testing sample has no toxicity to L-929 cell.

2) Delayed Contact Sensitization Study (A Maximization Method)In the Guinea Pig
   a) Intradermal induction phase I:

Make a pair of 0.1ml intradermal injections of each of the following, into each animal, at the injection sites(A, B, C)as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50: 50(volume ratio)stable emulsion of Freund`s complete adjuvant mixed with the chosen solvent. Use physiological saline(equivalent)for water-soluble alone.

Site B: The test sample (undiluted extract); inject the control animals with the solvent alone.

Site C: The test sample at the concentration used at site B, emulsified in a 50: 50 volume ratio stable emulsion of Freund`s complete adjuvant and the solvent (50%); inject the control animals with an emulsion of the blank liquid with adjuvant.

   b) Topical induction phase Ⅱ:

Seven days(±1days) after completetion of the intradermal induction phase, administer the test sample by topical application to the intrascapular region of each animals, using a patch of area approximately $8cm^2$(filter paper or absorbent gauze), so as to cover the intradermal injection sites. Use the concertration selected in Intradermal induction phase I for site B. If the maximum concentration that can be achieved in Intradermal induction phase I dose not produce irrition, pretreat the area with 10% sodium dodecyl sulfate massaged into the skin 24h±2h before the patch is applied. Secure the patches with an occlusive dressing. Remove the dressings add patches after 48h±2h.

Treat the control animals similarly, using the blank liquid alone.

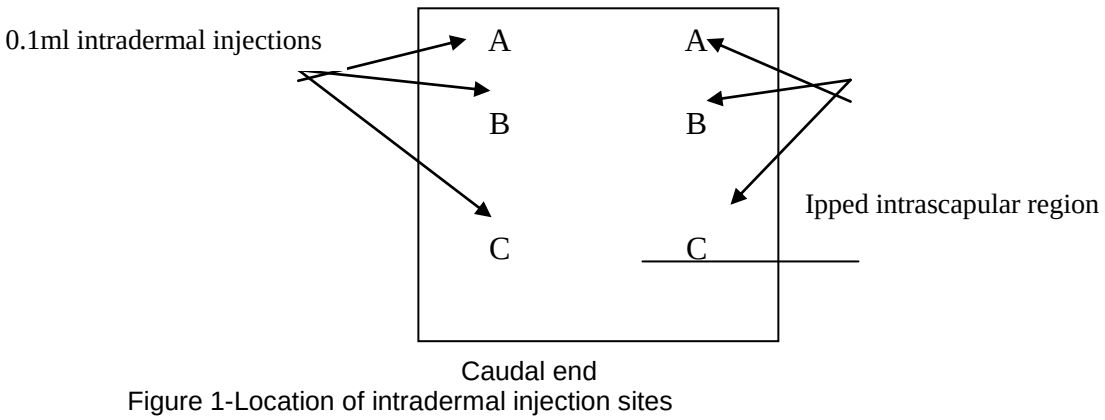


Figure 1-Location of intradermal injection sites

c) Challenge phase:

At 14days (±1day) after completetion of the topical induction phase, challenge all test and control animals with the test sample. Administer thetest sample and a vehicle control by topical application to sites that were not treated during the induction stage, such as the upper flank of

each animal, using appropriate patches or chambers soaked in the test sample at the concertration selected in Intradermal induction phase I for site C. Dilution of this concerntration may also be applied to other untreated sites in a similar manner. Secure with an occlusive dressing. Remove the dressings and patches after 24h±2h.

Conclusion:

Under the condition of this study, the as test article extract and the test article showed no significant evidence of causing delayed dermal contact sensitization in the guinea pig.

3) Skin Irritation test

Clean the rabbit`s naked skin with 75% alcohol. Choose ten points at 2cm intervals on one side of rabbit back and inject 0.2ml leached solution at each point. Similarly, on the other side of rabbit back. Choose five points at 2cm intervals and inject 0.2ml control solution at each point. Observe and wire down the skin responses of injection sites in 24h, 48h and 72h respectively after injection. The skin response include erythema, odema and necrosis as well. From weak to serious, the responses are differentiated by grade 0, 1, 2, 3, 4 on the basis of its extent. See table 1.

Table.1 Classification System for Skin Reaction

Reaction	Numerical Grading
Erythema and Eschar Formation:	
No erythema	0
Very slight erythema(barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Sever erythema(beet redness)to eschar formation preventing grading of erythema	4
Edema Formation:	
No edema	0
Very slight edema(barely perceptible)	1
Well-defined edema(edges of area well-defined by definite raising)	2
Moderate edema(raised approximately 1mm)	3
Moderate edema(raised more than 1mm and extending beyond exposure area)	4
Total possible score for irritation	8

Conclusion:

The test result shows that leached solution of sample does not induce irritation to skin.

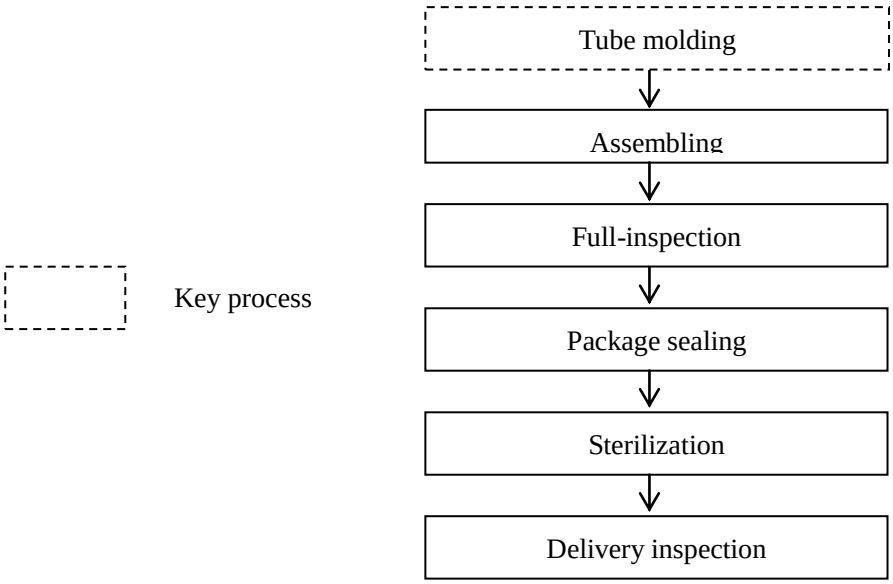
Annex:

Cytotoxicity Test	
Delayed Contact Sensitization Study (A Maximization Method) In the Guinea Pig	
Skin Irritation Test	

8 Description of Production Process

1. Picture of product

2. Flow chart of production techniques



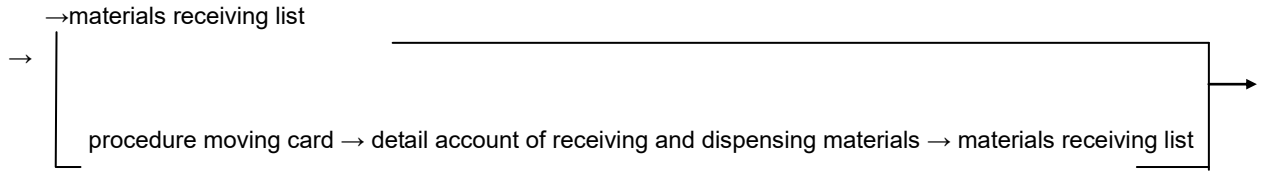
3. Identification and traceability

the traceability is carried out by pathway described below:

Products → sell account → products list of put out storage → final products account

→ sterilization batch records → products qualification certification

→ detail batch records of materials receiving and dispensing



→ detail account of materials receiving and dispensing → materials put in storage list

4. **Description of Environmental Control**

a) Production and assembling of accessories and components of Infusion set are completed in 100000-grade cleanliness workshop.

b) control requirements of 100000 grade cleanliness workshop:

Monitoring items	Technical requirements		Monitoring method	Monitoring frequency
Temperature	(18℃～28℃)		ISO14644-3	Once a shift
Humidity	(45～65%RH)		ISO14644-3	Once a shift
Wind speed (Times of aeration)	≥0.25m/s (15 times/hour)		ISO14644-3	Once a month
Static pressure difference	≥5Pa(Between cleanliness rooms (areas) with different cleanliness classes)		ISO14644-3	Once a month
	≥10Pa(Between inner and outer of cleanliness rooms (areas))			
	≥5Pa(Between cleanliness room (area) and non-cleanliness room (area))			
Dust particles	≥0.5 μm	≥5 μm	ISO14644-3	Once a quarter
	≤3,500,000 particles/m3	≤20,000 particles/m3		
Sediment microorganism	≤10 cfu/plate		ISO14644-3	Once a week

5. Annex: Report of environmental monitoring

9 Validation of Packaging Process

1. Sterility validation and qualification certification

1.1 setting of sterilization techniques

See work instruction of sterilization

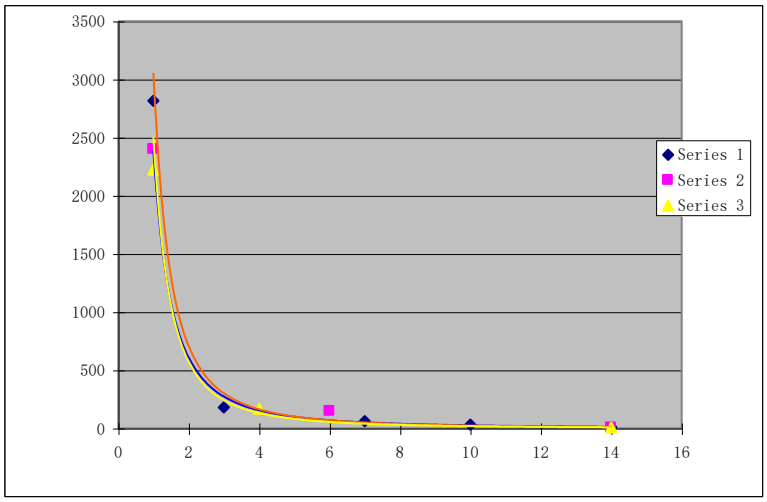
1.2 sterility validations:

The company carries out sterility validation in accordance with requirements of EN ISO 11135-1 standard to ensure that the sterility technique can meet the practice requirements and ensures reach sterility assurance level (SAL) of 10^{-6}. The biological indicator of ATCC9372 (10^{6}, D value in 2.5min~5min) is used in sterility validation and routine sterilization.

1.3 Residua of EO

The company monitors and determinate the residua of EO to ensure prescribed resolving days. For detail see table and figure below.

Sample NO.	After a few days						
	1day	3days	4days	6days	7days	10days	14days
1	2816	180	—	—	62	32	11
2	2400	—	—	148	—	—	7
3	2224	—	169	—	—	—	8



1.4 Annex: Report of sterility validation

2. Package validation and qualification certification

The company validates the sealing process of sterile package to ensure products sterility in little package.

2.1 seal validation

Hold speed and interval of capper and adjust the temperature.

Sealing temperature:

Trail-produce between the upper and lower limit. Half of preproduction samples are used for peeling off test and pressure break test, another half are used for peeling off test and pressure break test after aging. The result indicates all qualified.

2.2 Annex: Package validation report

3. Validation of period of validity of products and qualification certification

The company validates the shelf life of transfusion system.

3.1 Origin of samples: Sampling products from final products

3.2 Approach of validation

Validate sampling products in three year of validity and one year after period of validity.

1) Validation in first year of period of validity

Validation result: a. there is no aging and fragile on package; b. there is no blooming out on latex piston; c. There is no break and leakage on package; d. There is no color changing on syringe body.

Inspection conclusion: Meet requirements.

2) Validation in second year of period of validity

Inspection result: a. Appearance: qualified; b. Sterility: qualified; c. pyrogen: qualified

Inspection conclusion: Meet requirements

3) Validation in third year of period of validity

Inspection result: appearance: qualified; sterility: qualified; pyrogen; qualified; easily oxidization substrates: qualified; heavy metal: qualified; pH: qualified; abnormal toxicity: qualified; hemolysis: qualified; intracutaneous stimulation: qualified.

Inspection conclusion: Meet requirements

4) Validation in the first year after period of validity

Inspection result: a. Appearance: qualified; b. sterility: qualified; c. pyrogen: qualified

Inspection conclusion: Meet requirements

3.3 inspection conclusions: The quality assurance department carries out long-term appearance, sterility and pyrogen about each batch of sampling products in three year of period of validity, and carries out total performance test about emphasis sampling products in three years after period of validity. The result indicates its qualification. These results indicate that three years of period validity of Infusion set is scientific and reliable. Alternately, the history of Infusion set production is more than ten years and the annual production is about tens of millions pieces. There is no bad feedback in clinical uses. Each guideline is good and meets prospective uses.

10 Quality Control of Products

1. Stock inspection

   The quality assurance department inspect and validate sampling stock and take out inspection report in accordance with《Purchasing control procedure》.

   Frequency: Each batch.

2. Process inspection

   The quality assurance department and production department carry out process inspection separately in accordance with requirements of product standard.

   Frequency: Each batch

3. Final products inspection

   The quality assurance department carry out leaving factory inspection and take out inspection report in accordance with requirements of product standard.

   Frequency: Each batch

11 Validation of sterilization process

1. Purpose

Sterilization of medical products for single use is the necessary procedure to make the medical instruments free from bacteria. To verify and monitor the effectiveness and reasonable of sterilization procedure is to ensure the products to be non-bacteria. So the EO sterilizing procedure of Yankauer Handle by this company will be verified as the following processes:

2 Relative documents

EN ISO 11135-1 2007 Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

EN ISO 11138-2 2009 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes

EN ISO 11737-1 2006 Sterilization of Medical Device-Microbiological methods——part 1: Determination of population of microorganisms on products

EN ISO 11737-2 2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

EN ISO 10993-7 2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization Residuals

3. Sterilized products

3.1 Yankauer Handle for single use is the sterilized product to be verified this time. It is packed in two layers: inside is the PE membrane bag with holes, and outside is ventilating paper/PE compounded pouch.

3.2 Unloading and pattern

According to requirements of 3.1, the packages of sterilized products are put into plastic-box.

3.3 The assembling and package of Yankauer Handle is in the class 10^5 clean room. The normal environment control is according to 《Environment Control of Clean Area》and《Environment Control of Normal Producing Area》, so that the bioburden is assured to be controlled less than 100 cfu/piece·.

3.4 According to EN ISO 11737-1 2006 Sterilization of Medical Device-Microbiological methods——part 1: Determination of population of microorganisms on products, test the bioburden on the products before sterilization. Result sees <Bioburden Test Report>. It can be seen from the result that the bioburden of the products before sterilization are controlled between 10 to 100 cfu/piece·, which is conform to the requirement of EN ISO 11737-1.

4 Sterilizer

4.1 The sterilizer to be verified this time is HMG-$6M^3$ sterilizer produced by Jiangyin Huaqing machining Co., Ltd. It was produced in March 2002 and was purchased in May 2002. All data of the equipment can be set, and the whole processes are controlled and administered by computer. The main designed function of this equipment is as the following:

4.1.1 Temperature homogeneity of racing: maximum range of temperature ≤±3℃

4.1.2 Temperature homogeneity of fully loaded: maximum range of temperature ≤10℃

4.1.3 Speed in vacuum: degree of vacuum -15Kpa, ≤ 6min; degree of vacuum -50Kpa, ≤ 30min

4.1.4 Negative pressure leakage speed: ≤ 0.1Kpa/min

4.1.5 Positive pressure leakage speed: ≤ 0.1Kpa/min

4.1.6 Moisten: It can effectively moisten. Max. 85%.

4.2 All the equipment measuring temperature, pressure and weight has been checked and verified by technique monitor department before the verification.

5. Gaseous sterilant:

20%EO produced by Hangzhou Bailang auxiliary Co., Ltd., which is ISO and CE certified.

6. Bio-indicator

B.S. ATCC 9372 from Hangzhou Future Bio-technology Co., Ltd.is used as B.I. with lot number: 030620. Its bioburden is not less than 1.0×10^6 cfu. The B.I. is packed the same way with the sterilized products.

7. Verification team and responsibility

Name	Department	Position	Responsibility
	Production Department	Operator	Operate and maintenance the machine
	Quality Department	Examiner	Perform microorganism test

8. Verification content and method

8.1 There should be verification of equipment installation, equipment physical function, sealing and microorganism function this time.

8.2 Verification of equipment installation

8.2.1 Verification of temperature homogeneity of racing:

20 well-distributed temperature probes (distribution see figure 1) are used to measure the temperature distribution inside the sterilizer when racing, to make sure whether it is suitable for the requirement of 4.1.1.

8.2.2 Verification of temperature of homogeneity fully loaded:

The sterilized products are put according to 3.2, also the 20 temperature probes are put according to figure 1, to measure the temperature distribution when fully loaded, to make sure whether it is suitable for the requirements of 4.1.2.

8.2.3 Validation of the time needed for the probes reaching the set temperature:

Load 100 circles products according to the pattern of figure 2, and place 20 temperature probes according to figure 1, record the time needed from heating starts till the last probes reaching the set temperature.

8.3 Validation of physical function of sterilizer

8.3.1 Verification of physical speed in vacuum

Shut the door of incoming material under the normal pressure, remove the air to -15KPa and -50KPa, record the time needed, then count the speed in vacuum, to make sure whether it is pressure, count the speed of leakage, to make sure whether it is suitable for the requirements of 4.1.3.

8.3.2 Verification of leakage under negative pressure

Maintain for 60min after removing the air to -50Kpa. Record the maximum changing number of pressure, and count the speed of leakage to make sure whether it is suitable for the requirements of 4.1.4.

8.3.3 Verification of leakage under positive pressure

Maintain for 60min after increasing pressure to +50Kpa. Record the maximum changing number of pressure, and count the speed of leakage, to make sure whether it is suitable for the requirements 4.1.5.

8.3.4 Verification of humidity effectiveness

Record the initial relative humidity inside sterilizer chamber. When the steam pressure inside humidity system reaches 0.05MPa, the humidify system is started. When the steam pressure decreases to 0.0MPa, humidifying is stopped. Keep the status for 12min. Then record the relative humidity at that time. Compare with the initial humidity to make sure whether the humidity changes a lot.

8.4 Sealing verification

Under a certain sterilizing condition, verify the reliability and safety of package sealing, the detail method see <Verification Report on Packing>.

8.5 Verification on physical function of microorganism

8.5.1 Loading pattern of B. I.: 30 pcs B.I. are placed in this verification. Loading pattern see figure 3. And the positive and negative contrasts are done.

8.5.2 Determination of sterilizing parameter

According to the structure, packing form, pattern of the sterilized products loaded and the former sterilization experience, the sterilizing parameter is determined as the following:

- Time to preheat: According to 405min (Temperature pre-set is 54℃), the arrange permitted is 20 min.
- Exposure temperature: 54±2℃
- Exposure pressure for sterilization: 45±2 KPa
- Temperature of carburetor: 49-55℃
- Pre-vacuum degree: -50±2KPa
- Humidity: 30-85%RH
- Density of EO inside sterilizer chamber: 320+20mg/1 (16kg/10m^3)
- Weight of sterilant added: 1.6±0.1 kg/m^3
- Speed in vacuum: 3±0.5KPa/min
- Speed of sterilant added: 8±1KPa/min
- Speed of air added: 12±2KPa/min
- Gas renew vacuum degree: -30Pka
- Pressure for cleaning air added: Normal pressure
- Cleaning times: 3 times

8.5.3 Half time circulation

According to the former sterilization experience, the exposure time begins from 6 hours, and decreases by 1 hour, until there is bacterium growing on the B.I., so that the critical exposure time can be determined initially. Verify twice according to this time. If there is no bacterium growing on the B.I., the critical exposure time can be defined at last. Twice the time is the exposure time.

8.5.4 Effectiveness of B.I. and the culture way of microorganism

8.5.5 The B.I. should be in its validity period when it is used in the test, and it is well stored. The B.I. should be cultured immediately after take out.

8.5.6 The EO residuals of products sterilized within the defined exposure time are inspected according to the required method in ISO10993-7.

9. Fulfilling of verification on sterilization

9.1 Verification of equipment installation

9.1.1 Temperature homogeneity of racing:

Use the method of 8.2.1, place the 20 temperature probes as per figure 1, and the time needed for heating is 370 min. Record the temperature measured by the 20 temperature probes. The set temperature is 50℃, the highest temperature is 52.8℃ and the lowest is 49.4℃. The up deviation is 2.8℃, and the down deviation is 0.6℃.

9.1.2 Temperature homogeneity of fully loaded:

Use the method of 8.2.2, load the 100 circles products as per figure 2, then record the temperature measured by the 20 temperature probes. The set temperature is 54℃, the highest temperature is 55.4℃ and the lowest is 48.6℃. The max rang of temperature is 6.8℃.

9.1.3 Temperature per-set is 54℃, and air temperature is 29℃. It take 370 min for all the temperature probes to reach 54℃.

9.2 Verification of physical function of sterilizer

9.2.1 Speed in vacuum

Use the method of 8.3.1; close the feeding door in normal pressure. Vacuum the sterilizer to reach -15KPa and -50KPa respectively. And the time needed is 4 min and 13 min.

9.2.2 Leakage speed of negative pressure

Using the method of 8.3.2, vacuum the sterilizer to –50Kpa and them maintain for 60 min. The pressure in the sterilizer chamber is measured, which is –50Kpa. And the leakage speed of negative pressure is measured, which is 0.

9.2.3 Leakage speed of negative pressure

Use the method of 8.3.3, raise the pressure to +50Kpa and maintain 60 min. And the pressure inside the sterilizer chamber are measured, which is +49.8Kpa. And the max. pressure changing point is 0.2Kpa, the leakage speed of negative pressure is 0.0037Kpa/min.

9.2.4 Effectiveness of humidity

Start the humidify system. When the steam pressure of the humidify system reach 0.15Kpa, record the initial humidity which is 40%. Meanwhile tern on the humidify switch. When the steam pressure reaches 0Kpa, stops humidify. After 12min, the humidity shows is 70.2%.

9.2.5 Sealing verification: See <Verification Report on Packing>.

9.3 Verification of function of microorganism

9.3.1 Placed the sterilized products and B.I. as shows in figure 2, sterilize according to the parameter or 8.5.2. The preheating time is 420 min. Culture the B.S. immediately after sterilization, and the culturing time is 7 days. Provided the package structure, packing, and loading pattern unchanged, test result is as the following:

Exposure time to sterilant	Number of B.I. exposed	Number of test B.I. showing no growth	Test environment	
			Temperature	Humidity
2.0hr	30	26	30℃	72%RH
3.0hr	30	30	30℃	70%RH
3.0hr	30	30	30℃	70%RH
3.0hr	30	30	30℃	70%RH
4.0hr	30	30	28℃	72%RH
5.0hr	30	30	30℃	72%RH
6.0hr	30	30	26℃	72%RH

9.3.2 During the above processes of verification, no pouch breakage occurred.

9.3.3 EO residual

Sample sterilized specimen for 6h, and test the EO residual. Result see <EO Residual Verification Report>

Evaluation of Verification

Equipment: EO sterilizer		Type: HMG -6	Sterilant: 20% (EO/CO_2)	
Bio-indicator: B.S. ATCC 9372			Quantity: 30 pcs	
Sterilized products: Yankauer Handle				
Circle Loaded: 100				
Bioburden: See <Test Report of bioburden of Verification Report>				
Verification Item		Result	Requirement	Judgment
Installation	Racing	The range of temperature is 3.4℃	≤±3℃	Conform

Confirmation	Full Load	The range of temperature is 6.8℃	≤±10℃	Conform
Confirmation of Physical Properties	Vacuum Speed	When Vacuum to –15Kpa and-50Kpa, speed are 3.75 Kpa/min and 3.8 Kpa/min respectively	≥2.5Kpa/min	Conform
	Leakage speed under negative pressure	0Kpa/min	≤0.1Kpa/min	Conform
	Leakage speed under positive pressure	0.0033Kpa/min	≤0.1Kpa/min	Conform
	Humidifying	RH from 40% to 70.2%		Conform
Effectiveness of Sterilization		When the exposure time is 6h, 5h, 4h, 3h, 3h, 3h, B.I. being cultured are all negative. When the exposure time is 2h, 4pcs of B.I. are positive.		Critical exposure time is 3h.

Technical parameter of sterilization	● Time to preheat: According to 405min (Temperature pre-set is 54℃), the arrange permitted is 20 min. ● Exposure temperature: 54±2℃ ● Exposure pressure for sterilization: 45±2 KPa ● Temperature of carburetor: 49-55℃ ● Pre-vacuum degree: -50±2KPa ● Humidity: 30-85%RH ● Density of EO inside sterilizer chamber: 320+20mg/1 (16kg/10m^3) ● Weight of sterilant added: 1.6±0.1 kg/m^3 ● Speed in vacuum: 3±0.5KPa/min ● Speed of sterilant added: 8±1KPa/min ● Speed of air added: 12±2KPa/min ● Gas renew vacuum degree: -30Pka ● Pressure for cleaning air added: Normal pressure ● Cleaning times: 3 times
Conclusion	1. The installation and physical property conform to the design requirement. 2. When the above technical parameter, products and B.I. loading pattern in sterilizer chamber do not change, the critical exposure time is 3h. According to the half time circulation, the exposure time is 6h. The sterilization is effective and the EO residuals comply with the relevant standard. 3. Verification on sterilization shall be proceed again in the following condition: ● Changing of sterilant, supplier or density of EO ● Changing of packing material or packing style of products or loading pattern. ● Changing or repairing of critical component of sterilizer ● Changing of technical parameter of sterilization ● Fail to sterile 2 to 3 times successively

Figure 1:

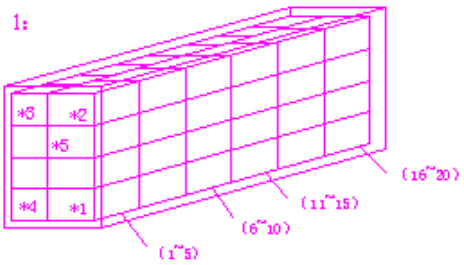
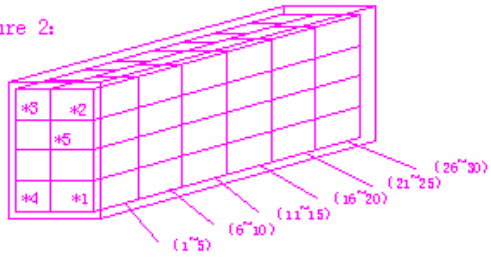


Figure 2:



12 Label and Language Sample

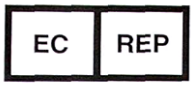
1. Label design

The label, instruction manual, blueprint and characters of products should usually contain these contents:

1.1 Symbol, name and address of manufacturer


xxxxxx

1.2 Symbol, name and address of EC-representative



xxxxxx

1.3 characters and symbol denote “do not use repeatedly”:

① characters: For singe use only;

② symbol: 

③ the symbol denotes that it is only for single use.

1.4 characters and symbol denote “expiry”:


2007-02-01

① characters: Expiry;

② symbol:

③ the date and 4-digit year, 2-digit month is in the wake of symbol, it denote the products should be used before this date.

1.5 characters and symbol of “lot”:

① characters: LOT;

② symbol: 

20020201

③ 8-digit production lot is in wake of symbol

1.6 characters and symbol of “date of manufacture”:

① characters: DATE OF MANUFACTURE

② symbol:  2002-02-01

③ 8-digit date is in wake of symbol

1.7 characters and symbol of “caution”

① characters: Caution;

② symbol: 

1.8 CE mark

1.9 characters of “STERILE”:

① figure:

② size and location of characters are not prescribed.

1.10 Do not use if package is damaged

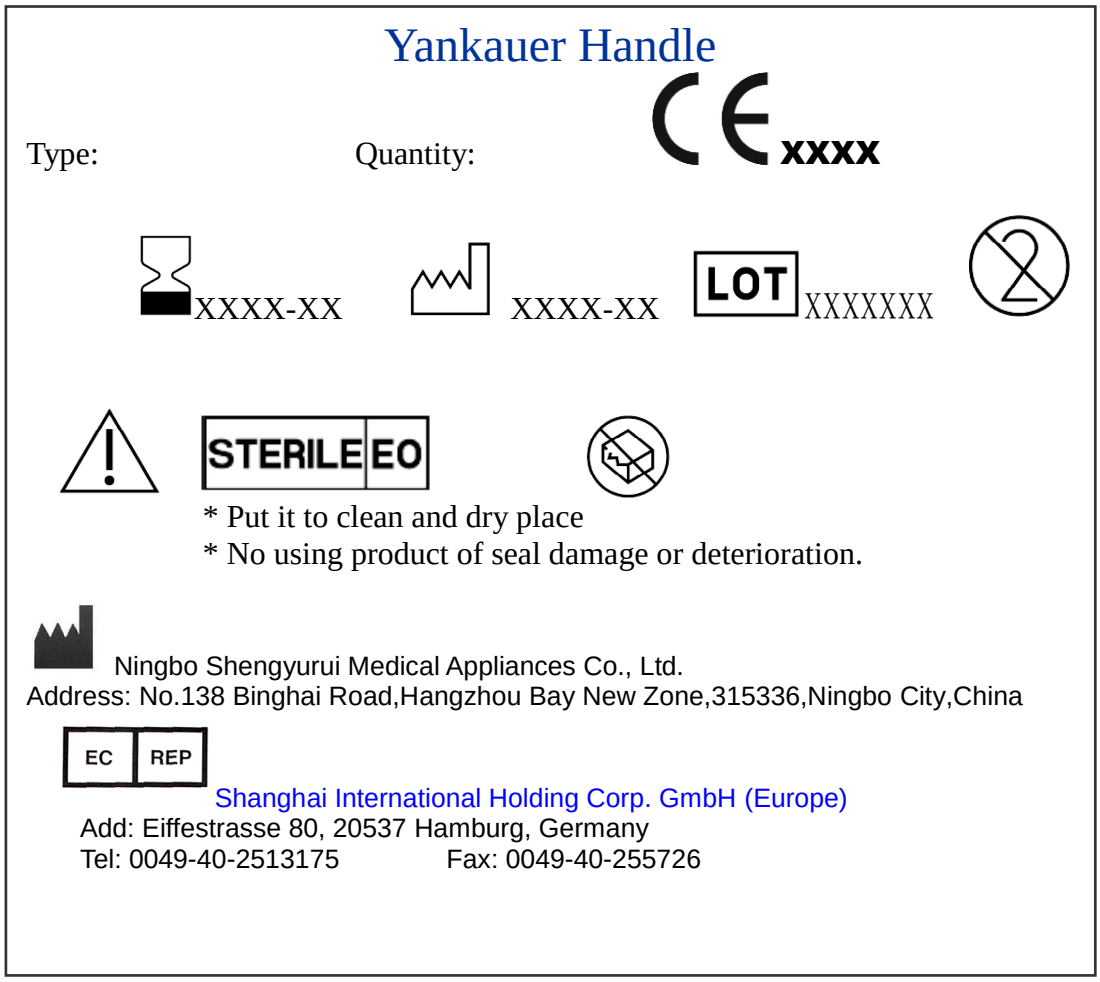
2. The typeface, symbol, size and location on label are not prescribed. But the handwriting should be clear, obvious and durable.

3. If there is a special requirement on label from Customers, the Company should design and manufacture label in accordance with requirements of customers or mark from customers.

4. Language on label should be up to requirements of European countries and ensure the accuracy.

5. Samples of label and language:

12 Label sample of primary package of Yankauer Handle:



Label sample of outer package of Yankauer Handle:

Yankauer Handle

Type: Quantity: CE XXXX

XXXX-XX XXXX-XX LOT XXXXXXX

STERILE EO

* Put it to clean and dry place
* No using product of seal damage or deterioration.

Ningbo Shengyurui Medical Appliances Co., Ltd.
Address:No.138 Binghai Road,Hangzhou Bay New Zone,315336,Ningbo City,China

EC REP

Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany
Tel: 0049-40-2513175 Fax: 0049-40-255726

(Side mark)

Quantity:
Gross Weight: KG
Net Weight: KG
Size: CM