Epidural Anaesthesia Kit

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Content

Introduction

1About company

Zhejiang Sujia Medical Device Co., Ltd (Sujia) is the first joint stock enterprise in medical devise industry of Zhejiang. It started as Sujia Medical Devise Factory in 1992. Now it is located at 168 Zhenxing Road, Jiaxing Economic Developing Zone, covering an area of 40196sqm, with a construction area of 31944sqm. The garden makes up 37.8% of the plant. It is a modern and garden-style medical device manufacturer. Sujia specializes in disposable devices. It has gotten the certificates of ISO9001:2000 and ISO13485:2000.

2 About products

2.1The anaesthesia kit manufactured by our company consists of disposable L.O.R syringe,disposable epidural needle,disposable filter, catheter connector,and epidural cathether packed in a PVC tray and dialysis paper. It boasts fine biocompatibility and low sensitization. Sterilized for safe use.

Specification：16G, 18G

2.2 Pass the tests of in vitro cytotoxiciy, delayed contact sensitization, intracutaneous toxicity, and pyrogen reaction（Jinnan Medical Device Quality Monitoring and Inspection Center）conducted all the tests, see Inspection report for details）. No negative effect to human body. No calcium formed during the usage

3 Intented application

Used for human epidural anesthesia by puncturing and injecting the anesthesia fluid. This kit is for local anesthesia and stay in human body below 60 mins in clinical treatment.

4 Contradictions

a. Disposable, reuse is not allowed

b. Used as artificial trachea of patient, the staying time is no longer than 1hour.

c. Used products may cause potential pollution, dispose as the instruction or relating rules and law.

d. Not for use if the package is broken.

5 Classification

The kit is for clinical local anaesthesia, and the parts stay in human body no more than 1 hour. In accordance with the EU MDD 93/42/EEC Appendix Ⅸ,it falls into the class of Iib,rule6 of short-term used medical device.

6 Qualification

The assessment of product qualification abides by the EU MDD 93/42/EEC. Company apply for CE mark as the procedure of Appendix □ and□.

7 Reference

MDD93/42/EEC Appendix Ⅸ、Ⅶ、Ⅴ.

EU Medical Device Coordinator and International Standards List

No	Document No	Version	Document
1	93/42/EEC	1993.6.14	EU MDD
2	ISO13485	2003	Quality System—Medical Device—regulation requirements
3	EN14644-1 EN14644-2	1999 2000	Guideline for Cleaning Workshop
4	EN ISO14971:2000 +A1:2003	2000 2003	Risk Analysis for Medical Device
5	EN550	1994	Sterilization of Medical device： ETO Confirmation and Regular Control
6	EN556-1	2001	Requirements for Sterilization
7	EN980	1996.5	Graphical symbols used in the labelling of Medical Device
8	EN1041	1994.8	Terms, marks and information of Medical Devices
9	EN1174-1	1996.2	Sterilization of Medical Device—Microbe assessment for product—Part I: Basic requirements
10	EN1174-2	1996.11	Sterilization of Medical Device—Microbe pollution assessment for product—Part I： Instruction
11	EN1174-3	1996.11	Sterilization of Medical Device—Measure of Bacteria—Part III: Instruction on bacteria calculation
12	ISO594-1 ISO594-2	1986 1998	Standard Luer Connector
13	ISO11737-1 ISO11737-2	2006 1998	Sterilization of Medical Device—Assessment of microbe of product—Part I: General Requirement Sterilization of Medical Device—Assessment of microbe pollution of product—Part II: Application guideline
14	ISO10993-1	1997	Assessment of Microbiology for Medical Device—Part I: Instruction for Test alternatives
15	ISO10993-4:	2002	Hemolysis Test
16	ISO10993-5	1993	Biological Assessment of Medical Device—Part V: In Vitro Cytotoxicity

17	ISO10993-7	1995	Residual ETO

18	ISO10993-10	1995.3.15	Biological Assessment of Medical Device—Part X：Irritation and Sensitization tests
19	ISO10993-11	1995	Systematic Toxicity
20	YY0321.1 YY0321.2 YY0321.3	2000	Disposable Anaesthesia Kit
21	EN868-1	1997.2	Packing material and System of Sterilized Medical Device—Part I：General Requirement and Test Method
22	ISO11607	2003	Sterilized Medical Packing Material Requirement
23	ISO7886-1	1993	Disposable Sterilized Syringe
24	ISO9626:1991 +Amd1:2002	1991 2002	Medical Grade Stainless Steel Needle

Basic Requirements Checking List

Essential Requirements	A-N/A	Standards	Manufacturers Compliance	Place
1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	A	EN1782:1998 MDD93/42/EEC ISO 13485:2003	Test report No.Y2003010606 Quality Manual GYJ2005 No.063	QA Dept
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. -inform users of the residual due to any defection of the protection measures adopted.	A	EN1782:1998 MDD93/42/EEC ISO 14971:2000 ISO 13485:2003	Risk Analysis SJ-CE-10-05 Clinical Data SJ-CE-10-06	QA Dept
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(a), as specified by the manufacturer.	A	EN868-1	Test report No.Y2003010606 Quality Manual GYJ2005 No.063	General engineer office
4.The characteristics and performances referred to in Sections 1,2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the devices as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	A	EN550	Preclinical Study SJ-CE-10-06 Sterilization validation report SB-7.5.2.1	General engineer office

5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and provided by the manufacturer.	A	EN868-1-1998	Package qualified certification SJ-CE-10-10	General engineer office

Essential Requirements	A-N/A	Standards	Manufacturers Compliance	Place
6. Any undesirable side effect must constitute an acceptable risk when weighed against the performances intended.	A	ISO14971:2003	Risk Analysis SJ-CE-10-05 Clinical Data SJ-CE-10-07	General engineer office
II.REQUIREMENTS REGARDING DESIGN AND CONSTRUCION 7.Chemical, physical and biological properties 7.1 The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section 1 on the General requirements'. Particular attention must be paid to: The choice of materials used, particularly as regards to cellular toxicity and, where appropriate, flammability. The compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended use of the device.	A	EN30993	Test report No.Y2003010606 Biocompatability GYJ2005 No.063	General engineer office
7.2 The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.	A	EN868-1	Test report No.Y2003010606 GYJ2005 No 063	General engineer office
7.3 Devices must be designed, manufactured and packed in such a way that they can be used safely with the materials, substances and gases with which they enter into contact 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 intended use.	A	EN30993	Test report No.Y2003010606 Biocompatability GYJ2005 No.063	
7.4 Where a device incorporates, as an integral part,	N/A			

substance which, if used separately, may be considered to be a medicinal product as defined in Article of Directive 65/65/EEC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified,				

Essential Requirements	A-N/A	Standards	Manufacturers Compliance	Place
taking account of the intended purpose of the device, by analogy with the appropriate methods specified in Directive 75/318/EEC.				
7.5 The device must be designed manufactured in such a way as to a minimum the risks posed by substances from the device.	A	EN30993	Test report No.Y2003010606 GYJ2005 No.063	
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 the device and the nature of the environment in which is intended to be used.	N/A			
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, and third parties. The design must allow easy handing and, where necessary, minimize contamination of the device the patient or vice during use.	A	EN30993	Test report No.Y2003010606 GYJ2005 No.063	General engineer office
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 the geographical origin of the animals. Processing, preservation, testing and handing of tissues, cells and substances of animals origin must be carried out so s to provide optima; security. In particular safety with regard to viruses and other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation the course of the manufacturing process.	N/A			
8.3 Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and /or according to appropriate procedures to	A	EN550 EN868-1	Sterilization Validation SB-7.5.2.1	General engineer office

ensure that they are sterile when placed on the market and remain sterile, under he storage and transport conditions lard down, until the protective packaging is damaged or opened.				
8.4 Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	A	EN550 EN868-1	Sterilization Validation SB-7.5.2.1	General engineer office

Essential Requirements	A-N/A	Standards	Manufacturers Compliance	Place
8.5 Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	A	ISO13485:2003 ISO14644-1/-2 DREN1632	The Enviroment Controling System verification report No（2002）（326）	General engineer office
8.6 Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of 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 indicated on the label or in the instructions for use.	A		Test report No.Y2003010606 GYJ2005 No.063	
9.2 Devices must be designed and manufactured in such a way as to remove or minimize as far as possible: -the risk of injury, in connection with their physical features including the volume/ pressures 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.	A		Test report No.Y2003010606 GYJ2005 No.063	
-the risks of reciprocal interference with other				

devices normally used in the investigations or the treatment given -risks arising where maintenance or calibration are not possible (as with implants), from aging of materials used or loss of accuracy of any mechanism.				
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.	N/A			

Essential Requirements	A-N/A	Standards	Manufacturers Compliance	Place
Particular attention must paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	N/A			
10. Devices with 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	N/A			
11.Protection against radiation 11.1 General 11.1.1 Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	N/A			
11.2 Intended radiation 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	N/A			

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.				
11.3 Unintended radiation	N/A			

Essential Requirements	A-N/A	Standards	Manufacturers Compliance	Place
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 reduced as far as possible.	N/A			
11.4 Instructions 11.4.1 The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protection the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	N/A			
11.5 Ionizing radiation 11.5.1 Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use. 11.5.2 Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user. 11.5.3 Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.	N/A			
12. Requirements for medical devices connected to or equipped with an energy source:	N/A			

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 eliminate or reduce as far as possible consequent risks.				
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			

Essential Requirements	A-N/A	Standards	Manufacturers Compliance	Place
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 mechanical risks connected with, for example, resistance, stability and moving parts. 12.7.2 Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	N/A			
12.7.3 Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the				

risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, 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 beat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	N/A			

Essential Requirements	A-N/A	Standards	Manufacturers Compliance	Place
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 indication any inadequacies in the flow-rate which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	N/A			
12.9 The function of the controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such 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 information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. 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	A	EN980:2003 EN1041	Labelling & Term SJ-CE-10-09	QA Dept

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 supplied with one or more devices. Instructions for use must be included in the packaging or every device. By way of exception, no such instructions for use are needed for devices in Class I or Iia if they can be safely without any such instructions				
13.2 Where appropriate this information should take the form of symbols. Any symbol or identification color used must conform to the harmonized standards. In areas for which no standards exit, the symbols and collars must be described in the documentation supplied with the device.	A	EN980 EN1041	Labelling & Term SJ-CE-10-09	QA Dept

Essential Requirements	A-N/A	Standards	Manufacturers Compliance	Place
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 vie of their distribution in the Community ,the label, or the outer packaging, or instructions' for use, shall contain in addition the name address of either the person responsible referred to in Article 14 or the authorized representative of the manufacturer established within the Community or of the importer established within the Community, as appropriate; b. The details strictly necessary for the user to identify the device and the contents of the packaging; 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; g. If the device is custom-made, the words' custom-made device ; Any special storage and/or handing conditions; Any special operating instructions; k. Any warnings and/or precautions to take;	A	EN980 EN1041	Labelling & Term SJ-CE-10-09	QA Dept

l. ar of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number;	N/A			
m. Where applicable, method sterilization.	A	EN980 EN1041 EN550	Labelling & Term SJ-CE-10-09	QA Dept
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.	N/A			
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:				

Essential Requirements	A-N/A	Standards	Manufacturers Compliance	Place
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 undesirable side-effects;	A	EN980 EN1041 EN550	Labelling & Term SJ-CE-10-09	QA Dept
c if the device must be installed with or other medical devices or equipment to order operate as required for 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; 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 events of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	N/A			

h. If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, desinfection, 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 III; i. Details of any further treatment or handing needed before the device can 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.				

Essential Requirements	A-N/A	Standards	Manufacturers Compliance	Place
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： -- Precautions be taken in the event of changes the performance of the device； -- Precaution 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.; -- Adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitation in the choice of substances to be delivered; -- Precautions to be taken against any special, unusual risks related to the disposal of the device; -- Medical substances incorporated into the device as an integral part in accordance with section 7.4; -- Degree of accuracy claimed for devices with a measuring function.				

14. Where conformity with the essential requirements must be based on clinical dada, as in Section 1, such data must be established in accordance with Annex X	A	MDD93/42/EEC Appendix X	Clinical Data SJ-CE-10-07	

Product Description

The Epidural Anaesthesia Kit in range of specifications are all made from the same raw materials by the same manufacturing procedures. So description to the kit is made consistently.

1. General description of Epidural Anaesthesia Kit

1.1 Classification ：in accordance to YY0321.1.2.3-2000.

1.2 Quality of finished product：：Comply with YY0321.1.2.3-2000 of Chinese Medical Device Industrial Association.

1.3 Manufacturing procedures：find details in Production Flow Chart SJ-CE-10-04

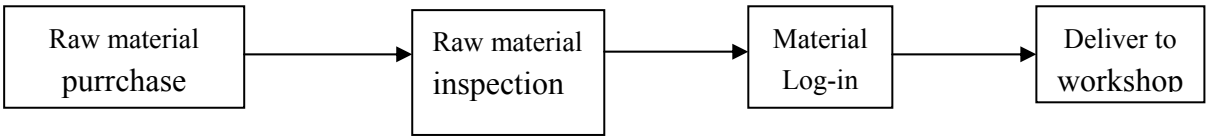
1.4 Specification:

Epidural Anaesthesia Kit

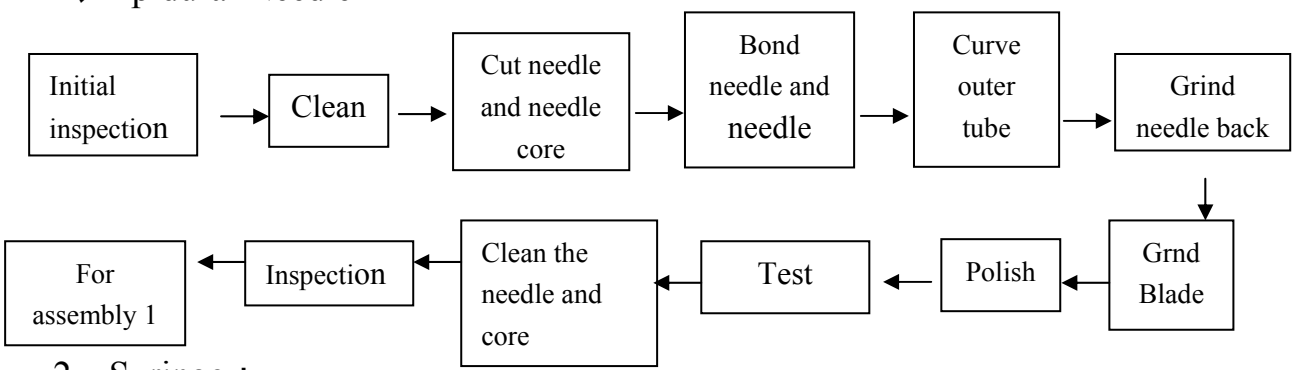
Unit：

Specification	L(mm)	Base Color
14 16 17 18 20	100	

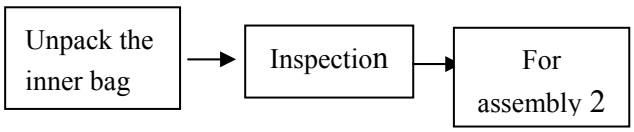
Production Flow Chart



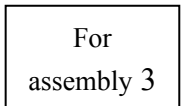
1、Epidural Needle：

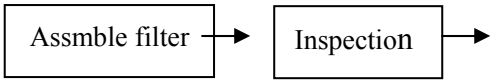


2、Syringe：

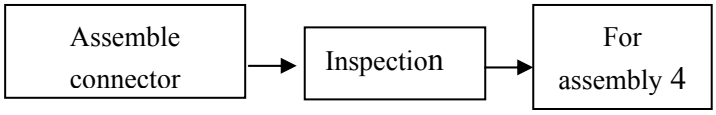


3、Filter：

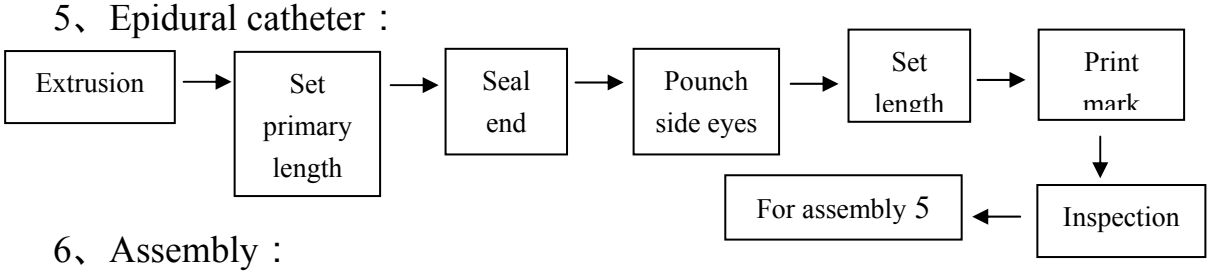




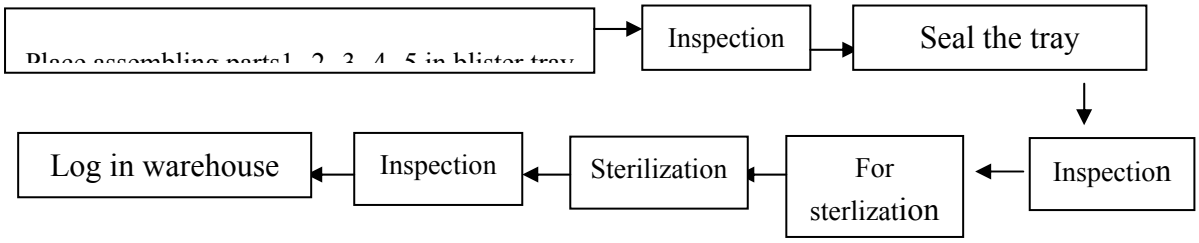
4、Catheter connector：



5、Epidural catheter：



6、Assembly：



Check Drawing SJ015A-000 for material list

Check Drawing SJ015A-000 for technical drawing

Title：Production Flow Chart Page 1 of 1

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Risk Analysis Report

As the requirements of MDD93/42/EEC EN1441:1997, and Procedure for Risk Analysis of Product, make analysis and evaluation to the potential risks of product to minimize the risk within an acceptable range for entry into market.

1 Intented Application

Disposable Epidural Anaesthesia Kit is used for the local anaestheia in clinical treatment, to prevent medical intra-infection effectively.

2 Identify the potential risk

Infection, pyrogen reaction, sensitization, toxicity, and irritation

3 Procedure for risk analysis and evaluation

The raw material quality, production process, package of finished products, sterilization, storage and delivery may cause the product risk. So the positive preventive actions shall be taken according to each step to maintain any possible risk in an acceptable degree, and do not affect the product purpose, and ensure the product safety. According to the analysis chart of Procedure for Risk Analysis, we make the risk evaluation in the process of production.

3.1 Infection to defective position：

3.1.1 Cause

3.1.1.1 Bacteria caused by non-complete sterilization or break of package.

3.1.1.2 Superscale bacteria in initial production, mainly include：

Bacteria in manufacturing environment, brought by operators (in convalescence with infective disease or dermatosis), microbe (including the culture medium for microbe) in bacteria-resisting packing material, product containers, and the ones in storage and transportation environment.

3.1.2 The infection in defective position is not allowed, and actions as following must be taken to minimize the risk in an acceptable degree：

3.1.2.1 Complete sterilization

Operate the sterilizing procedures and process, control the inspection and test devices strictly as the requirements of EN550. The finial inspection shall be conducted and released strictly to ensure complete sterilization.

3.1.2.2 Strictly control and minimize the bacteria in initial production in an acceptable degree.

3.1.2.2.1 Control the microbe in air

Do well on cleaning and disinfection. Strictly follow the requirements for productive environment control, to ensure the conformity on floor, wall and operating table in working area. Operators shall operate as the Environmental Control Procedure of workshop during working time to minimize the microbe.

3.1.2.2.2 Microbe control of human body

Operators of manufacture shall do well on self cleaning. The ones who are with infective diseases or dermatosis can not conduct the production or enter into cleaning room. The skin directly connecting to products shall meet the requirements of workshop.

3.1.2.2.3 Water source control

The water shall meet the national specification of pure water and injection water. And polluted water shall be prevented and drained.

3.1.2.3 Control the packing material

The log-in of each lot of packing materials shall be conducted as the Log-in Inspection Procedure. Make sure that the packages are complete without break. The operator shall

handle carefully and in certain area for inspection. Any microbe pollution to packing materials during inspection shall be avoided.

3.1.2.4 Control the microbe pollution in package, storage and delivery

3.1.2.4.1 Choose the qualified packing materials and pack strictly as the procedure. The seal must be hermetic to ensure the package quality. The label shall indicate as *No use with package damage.*

3.1.2.4.2 Place the products neatly in storage, keep airy and dry. The passage and exit of warehouse shall be free. The placement of products shall be as the sequence of log-in for convenience. Handle carefully to prevent any damage to package or product.

3.1.2.4.3 Pack firmly, the outer package shall be not broken and protect the inner package and bacteria-resisting package effectively.

3.1.2.4.4 In transportation, the products shall be placed neatly on the track. The track shall be clean and with shelter.

3.1.3 With the above actions and measures, our company have taken all the possibilities may cause pollution into consideration. And minimize the risk in an acceptable degree. Normally, no

pollution will occur.

3.2 Pyrogen reaction

3.2.1 Cause

Pollution to raw materials, water, manufacturing environment, and any other contrived pollutions.

3.2.2 No pyrogen reaction is allowed. The action shall be taken to minimize the risk in an acceptable degree.

3.2.3 Preventive actions

3.2.3.1 Disposal to raw materials, containers (circulating box, barrel, bag, box), and instruments

Purchase the raw materials from the qualified suppliers. The material may affect the pyrogen reaction directly shall be packed firmly, and log into warehouse in conformity with the Stock Inspection Procedure. The containers and instruments used in production shall be disposed firstly to meet the sanitation requirements.

3.2.3.2 Water processing

The water used in production shall be in conformity with the national specification for pure water or injective water.

3.2.3.3 Assistance of operators

The materials and workers shall be separated. To each production step, workers shall dress the costume compatible to working environment, and sanitation devices shall be equipped. Workers shall meet the sanitation requirements in working procedures.

3.2.3.4 Control the cleanness in working area

In accordance to medical industry specification of PRC YY0033-2000 *Sterilized Medical Device Production Regulation*, control the entire process of production from raw material log-in to finished product. The raw materials shall be double packed, and passed in to 100,000class cleaning room by 2-layer channel after being taken off the outer package.

The whole process shall be conducted in the 100,000class cleaning room, including, extrusion, injection, assembling, and packing. And necessary cleaning and sterilizing devices shall be equipped.

3.2.4 With the above mentioned actions and measures, the risk of pyrogen reaction will be minimized to an acceptable degree, and no pyrogen reaction will occur normally. The pyrogen inspection tested by Jinan Medical Device Quality Monitoring Institution is approved.

3.3 Sensitization and irritation

3.3.1 The sensitization and irritation is caused by the lecithin and protein in raw materials.

3.3.2 No sensitization and irritation is allowed, actions shall be taken as following：

Purchase the raw materials in conformity with National specification of PRC GB15593-1995 *Soft PVC for Transfusion Instrument*. Require the product report from supplier. The lab of company shall do the tests on sensitization and irritation to the raw materials.

3.3.3 With the actions and measures, the risk will be controlled effectively, and products will not cause sensitization and irritation. The sensitization inspection to our CE products tested by Jinan Medical Device Quality Monitoring Institution is approved.

3.4 Toxicity

3.4.1 Cause: heavy metal in productive materials.

3.4.2 Action：

Purchase the raw materials in conformity with National specification of PRC GB15593-1995 *Soft PVC for Transfusion Instrument*. Use the water which meet the requirements of pure water or injection in production to decrease the amount of heavy metal. The cytotoxicity inspection to our CE products tested by Jinan Medical Device Quality Monitoring Institution is approved.

4 Conclusion

So, with the risk analysis and evaluation to product, there is little possibility to have the potential risks mentioned above occur. The production process is under strict control, ensure the quality and meet the requirements of MDD 93/42/EEC. The product risk is within the acceptable degree. Normal usage under instruction will cause no damage to human body.

5 Relating/Supporting documents

MDD93/42/EEC

EN1174

Pre-clinical Study

1 Purpose：The appearance and function of product can meet the requirements of MDD/93/42/EEC before public to market.

2 Disposable Epidural anaesthesia kit

3 Predicted purpose of product

Disposable epidural anaesthesia kit is used for local anaesthesia in clinical treatment. It is used for human epidural anesthesia by puncturing epidural and injection anesthetic, to prevent intra-infection effectively.

4 The production of product is refered to specifications of：EN14644、EN ISO14971、EN550 EN556、EN980、EN1041、EN1174、ISO594、EN1174、ISO11737、ISO10993、EN868 ISO11607、ISO7886、ISO9626、YY0321

5 Bio-compatability of raw material and product
5.1 Raw materials: The out sourced stainless steel for needle and core comply with ISO9626:1991 Medical Grade Stainless Steel Needle. The plastic material for needle base, catheter connector and epidural catheter comply with the requirement for medical grade plastic.
5.2 Bio-compatability of product
5.2.1 In accordance with ISO10993-5, cytotoxicity Study on Tracheal Dissepiment conducted by Jinan Medical Device Quality Monitoring Institution is approved. Please find the No.Y2003010606 Cytotoxicity Study Report for details.
5.2.2 In accordance with ISO10993-10, intracutaneous toxicity and delayed contact sensitization studies conducted by Jinan Medical Device Quality Monitoring Institution is approved. Please find No.Y2003010606 Intracutaneous Toxicity and Delayed Contact Sensitization Study Report for details.
5.2.3 As required, pyrogen reaction study conducted by Jinan Medical Device Quality Monitoring Institution is approved. Please find the No.Y2003010606 Pyrogen Reaction Study Report for details.
5.3 All of the items mentioned above on biocompatibility are proved to meet the requirements and standard of CE by inspections and tests.
6 Technical conduct

6.1 Inspection requirement：all the inspections shall be conducted as the specifications

in Item 4 of this chapter.
6.2 Appearance requirement: No objects or defect dictated on needle or base by 2.5 times of normal vision distance.
6.3 Needle requirements shall comply with ISO9626:1991 *Stainless Steel Needle for Medical Device*, the results shall meet these requirements. See details in Test Report No.Y2003010606.
6.4 Base requirments shall comply with YY0321.2-2000, the results shall meet these requirements. See details in Test Report No.Y2003010606.
6.5 Needle tip requirments shall comply with YY0321.2-2000 the results shall meet these requirements. See details in Test Report No.Y2003010606.
6.6 Epidural catheter requirements shall comply with YY0321.1, the results shall meet these requirements. See details in the Test report No.Y2003010606.
6.7 Filter requirements shall comply with YY0321.1, the results shall meet these requirements. See details in the Test report No.Y2003010606.
6.8 The package material validation shall in comply with EN868-1.
6.8.1 Bacteria resisting inspection to packing material is subject to the study report by Jinan

Medical Device Quality Monitoring Institution.
6.8.2 Package seal inspection is subject to the inspection report by our company.
6.9 Sterilization inspection is operated as EN550, and the result is approved. Find inspection

document for details（SB7.5.2-01）.

All the inspections required by CE are approved. The other items are controlled as the EU standards. The variation is within the control. The inspections and operations all prove that our product meet all the requirements of CE. We can have the capability to meet the market demand.
7 Relating/supporting document

7.1 EN1782、ISO10993-1，EN550，EN1441，EN868-1，EN556，EN980、ISO5361：1999

YY0321.0-2000
7.2 Cytotoxicity Study Report, Pyrogen Reaction Study Report, Intracutaneous Toxicity Study Report, Delayed Contact Sensitization Study Report, Inspection Report of Epidural anaesthesia kit.

Clinical Information

1． About product

The anaesthesia kit manufactured by our company consists of disposable L.O.R syringe,disposable epidural needle,disposable filter, catheter connector,and epidural cathether packed in a PVC tray and dialysis paper. t boasts fine biocompatibility and low sensitization. Sterilized for safe use.

With the approved inspections on cytotoxicity, sensitization, intracutaneous toxicity, and pyrogen reaction (conducted by Jinan Medical Device Quality Monitoring Institution), product will not harm or cause any negative reaction to the skin and human body. It is excellent on biological characteristic.

2． Intended Application

Disposable epidural anaesthesia kit is used for local anaesthesia in clinical treatment. It is used for human epidural anesthesia by puncturing epidural and injection anesthetic. The duration of inside human body is no more than 60min.

3． Histroy of product

The manufacture and usage of disposable anaestheis kit have been decades. The epidural anaesthesia kits in various specifications which are composed of disposable syringe, epidural needle, catheter, connector and filter,are used commonly in Anaesthesia Section of hospitals. Until now, there is no report on any accident of patient serious hurt or death related to disposable epidural anaesthesia kits.

4． History of company

Since the establishment of Zhejiang Sujia Medical Device Co.,Ltd, it focuses on management, technology input, and investment. Now it is a specialist on the disposable anaesthesia kits in various specifications.

5． Sales status and customer feedback

The products manufactured by our company have been exported far to Europe and America and mid-east. We have never received any complaint on non-qualified products from customers since the establishment.

6． In the Risk Analysis of Product made by our company, each potential risk possibility has been analyzed and controlled by effective actions. The risk can be controlled in an acceptable degree.

All in all, the value of epidural anaesthesia kit manufactured by us is much more than the risk. They can be used as medical device.

7． Supporting document

1） Cytotoxicity Test Report

2） Sensitization Test Report

3） Skin contact—irritation Test Report

4） Pyrogen Test Report

5） Clinical Report

Biocompatibility Test Report

In accordance with ISO10993-1 and Biocompatibility Test Procedure, do test to the CE product (disposable epidural anaesthesia kit by our company) on four indexes. We consign Jinan Medical Device Quality Monitoring Institution to do the cytotoxicity test, intracutaneous toxicity test, skin contact sensitization test and pyrogen test.

1． Cytotoxicity test

1.1 This test adopts the technology of cell cultivation. Determine the impact of test device, article and/or its extract on the cell dissolution (death), and its growth.
1.2 As the above test requirements, add the extract of CE product into the cultivated cell solution, evaluate the potential toxicity of product according to the cell growth and reproduction.

2． Intracutaneous toxicity test

2.1 This test shall take a suitable model to be injected with the extract of test device and article into its part or skin to evaluate the potential irritative impact. The duration of experiment shall be the same as the one in actual usage.
2.2 As the above requirement, inject the extract of the CE product into domestic rabbit, and observe for local irritant effects to evaluate the irritation impact of product.

3． Sensitization test

3.1 This test shall take a suitable model to evaluate the potential sensitization by test article extract.
3.2 The extract of CE product is contacted with the mouse, and observed for sensitive effects to skin to evaluate the sensitization impact of product.

4． Pyrogen reaction test

In this test, the extract of test product is mainlined into the rabbit, and observed for fever to evaluate the pyrogen reaction.

Conclusion：

The CE product is tested by Jinan Medical Device Quality Monitoring Institution with extract on cytotoxicity, sensitization, irritation, and pyrogen reaction, and the results are approved that it is qualified on biocompatibility. Please check appendix for details.

5． Appendix

① Acute Cytotoxicity Test

② Intracutaneous Toxicity Test

③ Sensitization Test

④ Pyrogen Reaction Test

6． Relating/supporting document:

① ISO10993-1Medical Device Biological Evaluation Part I：Instruction on Test Options

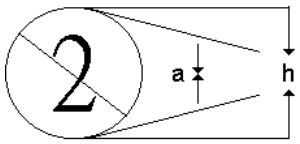
② Biocompatibility Test Procedure

Labelling and Term

1.Design of label
The label shall include:
1.1 Names and addresses of manufacturer and EU representative;
Manufacturer: Zhejiang Sujia Medical Device Co.,Ltd. 168# Zhenxing Rd, Jiaxing, Zhejiang, 314001, China.

EU Representative:Shanghai International Holding Gorp,GmbH(Europe),Eiffestrasse 80,20537 Hamburg Germany EC REP

1.Design of label
The label shall include:
1.1 Names and addresses of manufacturer and EU agency;



ID：a，OD：h，h=1.2a

1.3.2 The length of a is normally about 500MM.It can be as short as 3MM, but shall be clear enough.
1.3.3 The sign only can be used for once.
1.4 The sign of USE BY
1.4.1 Sign:

1.3.2 The length of a is normally about 500MM.It can be as short as 3MM, but shall be clear enough.
1.3.3 The sign only can be used for once.
1.4 The sign of USE BY

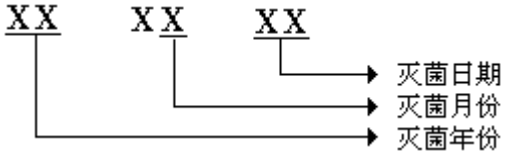
1.4.1Sign  2000-04 means used before april of 2000

1.5Sign of lot number（“BATCH CODE”、“LOT NUMBER”、 “BATCHNUMBER”）

1.5.1Sign:

1.5.2 The sign is followed by lot number, which is in 6 numbers indicates the sterilization date.

As following：



1.5.3 There is no specific prescription on the size and position of the sign and date.

1.5.4 Example： 

060808

It means that the product is sterilized on 8th Nov, 2006.

1.6 Sterile No.:

1.6.1The sign is followed by the sterilization sequence number in 6 numbers of YY/MM/DD.

1.6.2 There is no specific prescription on the size and position of the sign and date.

1.6.3Example：061108

It means the sterilization date is on 8th Nov, 2006

1.7Sign of DATE OF MANUFACTURE

1.7.1 Sign

1.7.2 The sign is followed by the manufacture date of YY/MM/DD.

1.7.3 There is no specific prescription on the size and position of the sign and date.

1.7.4Example:

00-05-22

It means manufacture on 22nd May, 2000

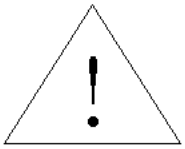
1.8 Sign of ETO sterilization（STERILE）：

1.8.1Sign:

1.8.2 There is no specific prescription on the size and position of the sign and date.

1.9 Please check the sign and content of cautions:

1.9.1 Sign:



1.9.2 The back colour of the sign is white, and the colour of sign and contour line is black. The size of sign shall be enough to note visually.

1.9.3 The content followed the sign shall attract the attention of users.

1.9.3.1 Usage (specific operating instructions)

1.9.3.2 Storage condition;

1.9.3.3 No use is allowed if package broken.

1.10 CE mark shall be printed if get CE certification

1.10.Sign

CE 0197

1.10.2 The diameter of the sign is no less than 5MM.

1.10.3 The auditing institution registering number shall be placed at the right corner of the CE mark 0197.

1.10.4 CE mark shall be notable, clear and durable

2 The language on the label shall meet the requirements of the Language for EU members (see matrix), and accurate.

3 Extra requirement

Beside the above designs, satisfy the customers' extra requirements for design on label or mark.

4 Relating documents

4.1 MDD93/42/EEC Annex I clauses 13 and Annex □

4.2 EN980:2002

4.3 EN1041:1994

Qualification of Package

The bacteria-resisting packing material of the CE product is sealed by the strengthened PP and medical grade dialytic paper. Do validation to the packing material as the requirements of EN868-1.

1．Qualified inspection to bacteria-resisting packing material

1.1 The specification, inspection report supplied by manufacturer.

1.2 The inspection of initial contamination of material：

When materials ship to plant, the inspection report shall be supplied. Check the outer package of material to make sure no damage.

2．Bacteria-resisting material and suitability of sterilization

Appendix Sterilized Product Inspection Report

3．Label

The label will not be obscure after sterilization （final product inspection）

4．Biocompatibility of sterile packing material

The sample for inspection conducted by Jinan Medical Device Quality Monitoring Institution is packed hermetically. The sample and package contact fully. The cytotoxicity test, intracutaneous toxicity test, sensitization test and pyrogen reaction test are done as required.

5．Seal of bacteria-resisting package

Appendix Report on Moulding Test and Temperature Setting of Bacteria-Resisting Packing Poly Bag

6．Maintenance of sterile

6.1 The sterile status of the product from sterilization to expiry date can be proved by the bacteria-resistance test.

Appendix Sterile Inspection Report

6.2Inspection on storage life/product aging

Appendix Report on Simulant Five-Year-Aging Test

The test conducted as EN868-1 proves that the sterile packing materials we adopt are qualified.

7．Relating/supporting document

EN868-1 Packing Material and System for Sterilized Medical Device—Part I: General requirements and inspection method; Package inspection procedure

Sterilization Report

The sterilization of CE product of our company is in comply with the requirements of EN550.

1．Our company establish the quality system as ISO9001、ISO13485 and implement strictly to minimize the initial contaminative bacteria before sterilization.

2．Choose and test of sterilizing medicine

Choose the medicine on the basis of plan and report of sterilization chamber install and test, and the amount absorbed by medical grade PVC. The used amount is about 7.5kg±6%. Inspect the products after sterilization to ensure the sterilization effect. Measure the amount each time after adding medicine.

3．Validation and maintenance of instruments

Validate and calibrate as the requirements of EN550. All the instruments used for installation qualification, operation qualification and workmanship control, shall be calibrate as the Inspection, Measurement and Experimental Instrument Control Procedure, to ensure the effect.

a) All the measurement shall be taken to make sure the proper sterilization to products. Personnel trained specifically shall take the responsibility of sterilization room management and operation to regulate the process.

4 . Confirmation

5.1 Identification of physical nature

Validate strictly as the requirements of EN550. During the preset time of 2 hours, the sterilizing temperature and humidity shall within 52□±2□,and 40%RH ~ 75%RH respectively. The time to add medicine is 30 ~ 45minutes, during when the temperature is stable. The pressure is rising from -30KPa to +25Kpa. These data are all within the regulation, and the gasification temperature is 45 ~ 55□ which makes the EO enter into the chamber in gasiform.

5.2 Identification of biological nature

Before pre-setting, place Biological indicator, the sterilization indicator, into the sterilizing load as regulated, and maintain it at the position during the whole process. After sterilization, the Lab tests to confirm the sterile status. It is proved by method of half time circulation that the best sterilization duration is 12hours.

5.3 Confirmation of sterilizing process

Place the products in the chamber as required and monitor specifically. The corresponding software will monitor the varying parameters in the process and make sure that they are within the effective range.

5.4 Workmanship regulation

Develop the operation document, which is regulating on products, package and sterilizing placement. The document shall also regulate the proper amount of EO applied, parameters in details. All the data shall be recorded and maintained.

5.5 Workmanship control

Control strictly as the Sterilization Operation Manual, and Control Procedure of Monitoring and Measuring Equipment.

5.6 The maintenance duration of the workmanship and process parameters is 5 years after the last lot of products leaving plant.

5.7 Confirmation of sterilization result

Make the functional inspection to the package of product after sterilized by the maximum amount of EO within allowance, and the result turns as qualified.

6. Relating/supporting document

a) EN550

b) EN1174

c) EO Validation Plan and Confirmation Report on EO Effect

d) Sterilization Operation Manual, Control Procedure of Monitoring and Measuring Equipment

e) Procedure of CE Technical Document Control

Declaration of Conformance

1. The quality system, procedures, technical documents plant, equipments, environmental control and workmanship process of the disposable epidural anaesthesia kit of our company have been evaluated and certified by TUV (Shanghai) Co., LTD. They approve that the current quality system, workmanship and equipments meet the requirements of ISO9001、

ISO13485 and MDD93/42/EEC， and certify our company the qualifications of ISO9001、ISO13485 and CE. And they are the proclaiming institution.

2. Description

2.1 The CE product of our company：Disposable Epidural Anaesthesia Kit

2.2 Production ：

a）The raw materials for production are gone through log-in inspection strictly.

b）The production is conducted as the requirements of YY0321.1,2,3.

c）Make the risk analysis as EN ISO14971，and take effective measurements to minimize the risks within an acceptable range.

d）The manufacturing environment meet the requirements of EN14644 and YY0033

e）The package of products meets the requirements of EN868-1.

f）Sterilize products by ETO as the requirements of EN550.

2.3 After service：

Develop the Medical Device Alerting System and After Service Management Procedure.

2.4 Quality：

Develop the quality system as ISO9001、ISO13485、MDD/93/42/EEC.

3. The disposable epidural anaesthesia kit manufactured by our company is in conformity with the instruction of EU MDD93/42/EEC.

We hereby declare：

The disposable epidural anaesthesia kit manufactured by our company with CE mark is in conformity with the MDD93/42/EEC. The products satisfy the predicted purpose. The CE documents have been approved by our company and the proclaiming institution, and guarantee the facticity.

4. Standards applied in production

MDD93/42/EEC	EN ISO9001	EN ISO13485	EN14644	EN ISO14971
EN550	EN556	EN980	EN1041	EN1174
ISO594	EN1174	ISO11737	ISO10993	EN868
ISO11607	ISO7886	ISO9626	YY0033	YY03211
YY0321.2	YY0321.3			

5. Appendix：Declaration of Conformance