ZIBO EASTMED HEALTHCARE PRODUCTS CO.，LTD

CE TECHNICAL FILE

Sterile Infusion Sets for Single Use

April, 2016

Prepared by:	Audited by:	Approved by:

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1 General

1.1 Company Profile

Zibo Eastmed Healthcare Products Co., Ltd. is a professional company in disposable medical device area and devotes itself to researching, exploiting and manufacturing an extensive range of medical devices and healthcare products such as: disposable syringes and needles, disposable infusion sets and blood transfusion sets, gloves, airway management, feeding and drainage tubes, IV therapy and vascular access products, wound care products, products for urology, nonwoven products and surgical products. Accuracy, professionalism, efficiency are exactly what you can expect from us. As evidence of our efforts, our facilities have obtained ISO13485 certification and our products have received CE certification. It allows our medical goods to meet standards approved all over the world: South Asia, Middle East, Europe, South and Central America as well as Africa. We deliver the highest quality service and products with professionalism, knowledge and personal attention. We are always upgrading the product design and quality using advanced manufacturing technologies to satisfy your demands.

1.2 Products description and intended use

Sterile infusion sets for single use is intended for clinical intravenous infusion liquid.

1.3 Classification

Base on intended use and definition of categorization, and according to 93/42/EEC, Annex IX, rule 6, this product is in Class IIa.

1.4 Conformity Assessment Procedure

According to 93/42/EEC, the conformity assessment procedure of annex V is applicable to this product.

1.5 Manufacturer and EC Authorized Representative

The information about manufacturer

Manufacturer: Zibo Eastmed Healthcare Products Co., Ltd.

Address: No.118 Huaguang Road, Zhangdian District, Zibo 255000, Shandong China

Tel: +86-533-5201297

Fax: +86-533-5201298

WEB: http://www.eastmedcn.com/

European Authorized Representative info.:

Humiss Beratung GmbH

Address: Gneisenaustraße 8 40477 Düesseldorf, Germany

2 EC Declaration of Conformity

EC Declaration of Conformity

Manufacturer:
Zibo Eastmed Healthcare Products Co., Ltd.
Address: No.118 Huaguang Road, Zhangdian District, Zibo 255000, Shandong China

whose single Authorized Representative:
Humiss Beratung GmbH
Address: Gneisenaustraße 8 40477 Düesseldorf, Germany

We, the manufacturer, herewith declare that the products

Sterile infusion sets for single use

UMDNS-Code: **15781**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.
Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

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

Certificate No.:

Issue date:

Expiry date:

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Zibo Eastmed Healthcare Products Co., Ltd.
Address: No.118 Huaguang Road, Zhangdian District, Zibo 255000, Shandong China

Place, date *Legally binding signature, Function*

3 Comprehensive description of the product and production process

3.1 Intended use

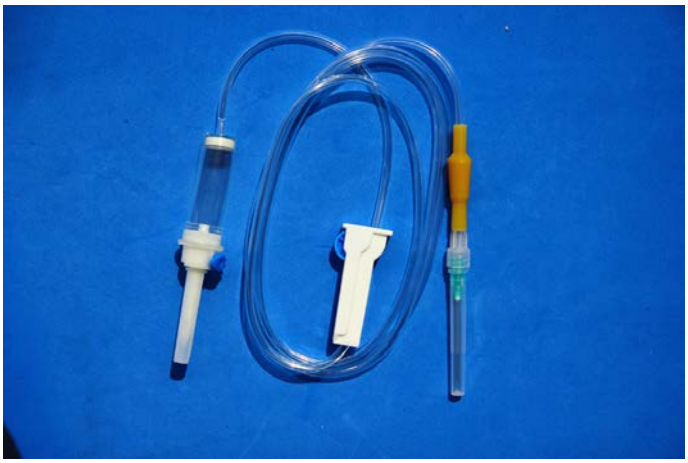
Sterile infusion sets for single use is intended for clinical intravenous infusion liquid.

3.2 Structure and specification

Sterile Infusion set for single use consists of puncture closure devices, protective cover, air filter, hoses, dropper, drip bucket, flow regulator, liquid filter, and comprising intravenous infusion needle.

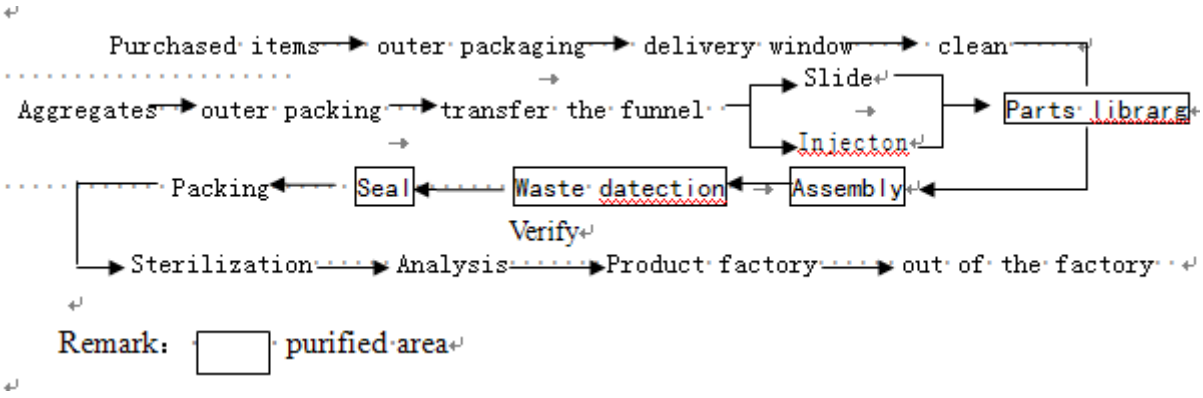
Specification: IS-V, IS-NV.

3.3 Picture and material



Number	Name	Material	Production process
1	Pipeline	PVC	Slide technology
2	Bucket drops	PVC	Drip bottle technology
3	Protection kit	polypropylene	Injection process
4	Puncture closure device	polypropylene	Outsourcing
5	Air filter	polypropylene	Injection process
6	Outside cone joint	PVC	Injection process
7	Flow regu lator	polypropylene	Injection process

3.4 Production process



4 Labelling

	DATE OF MANUFACTURE		Manufacturer
	Do not reuse		Batch code
	Sterilized using Ethylene Oxide		Warning, please refer to the instructions in the annex
	Do not use if package is damaged		Consulting Instructions for use
	Authorized representative in the European Community		The product meets the basic requirements of European medical devices directive 93/42/EEC

Sample for package labelling:

Primary package:

EASTMED

Sterile Infusion Set for Single Use

CE 0197

Size: YYYY-MM-DD LOT YYYYMMDD YYYYMMDD

STERILE EO For single use only Do not use if package is damaged

Non-toxic & Pyrogen Free, Discard after use

Zibo Eastmed Healthcare Products Co., Ltd.
No.118 Huaguang Road, Zhangdian District, Zibo 255000, Shandong

EC REP **Humiss Beratung GmbH**
Address: Gneisenaustraße 8 40477 Düesseldorf, Germany

Middle package:

EASTMED

Sterile Infusion Set for Single Use

CE 0197

pcs YYYY-MM-DD LOT YYYYMMDD YYYYMMDD

STERILE EO For single use only Do not use if package is damaged

Non-toxic & Pyrogen Free, Discard after use

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No.118 Huaguang Road, Zhangdian District, Zibo 255000, Shandong

EC REP **Humiss Beratung GmbH**
Address: Gneisenaustraße 8 40477 Düesseldorf, Germany

Outer package:

EASTMED

Sterile Infusion Set for Single Use

CE 0197

pcs YYYY-MM-DD LOT YYYYMMDD YYYYMMDD

STERILE EO For single use only Do not use if package is damaged

Non-toxic & Pyrogen Free, Discard after use

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EC REP **Humiss Beratung GmbH**
Address: Gneisenaustraße 8 40477 Düesseldorf, Germany

5 Instruction for Use

User Manual

[Product Name] Sterile Infusion Set for Single Use
Sterile Infusion Set for Single Use (hereinafter referred to as infusion set) is intended for clinical intravemous infusion solution.

[Specification]

IS-V, IS-NV.

[Structure and Character]

1. Infusion set consists of puncture closure devices, protective cover, air filter, hoses, dropper, drip bucket, flow regulator, liquid filter, comprising intravenous infusion needle.
2. Syringe sterilized by EO, should be sterile, non-toxic, pyrogen-free, non-hemolytic reaction.

[Methods]

1. Immediately use after unsealed, First remove the two sets of side protection, puncture device will be inserted into infusion bottles (bags), the schednle despite the gas and then venipuncture.
2. Use flow regulator, fluid flow in accordance with requirements.
3. Before use, intravenous infusion needle to the needle seat cover filter liquid tight joints to prevent leakage.

⚠ **[Notice]**

1. For single use only, discard after use.
2. Use before checking, do not use if the packaging is damaged, defiled.
3. The operation should be under professionals..

[Shelf life] 3 years

[Storage] Store in the relative humidity of no more than 80%, as well as non-corrosive and well-ventilated room.

Zibo Eastmed Healthcare Products Co., Ltd.
No.118 Huaguang Road, Zhangdian District, Zibo 255000, Shandong China

STERILE EO

CE 0197

EC REP **Humiss Beratung GmbH**
Address: Gneisenaustraße 8 40477 Düesseldorf, Germany

Date: Apr. 15, 2016 Version: A/0

6 Applied Standards

Item	Standard	Revision	Description
1	MDD93/42/EEC including Directive 2007/47/EC	2007	Medical Device Directive
2	EN ISO13485	2016	Medical device - Quality management system - requirements for regulatory
3	EN ISO14971	2012	Medical Device Application of Risk Management in Medical Device
4	EN ISO 15223-1	2012	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements.
5	EN1041	2008	Terminology, Symbols and Information Related to Medical Devices –Information Provided by Manufacturers of Medical Devices
6	EN 556-1	2001/ AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
7	EN ISO10993-1	2010	Biological Evaluation of Medical Device – Part 1: Test & Evaluation
8	EN ISO10993-5	2009	Biological Evaluation of Medical Device – Part 5: Cytoxicity Test – in vitro method
9	EN ISO10993-7	2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
10	EN ISO10993-10	2010	Biological Evaluation of Medical Device –Part 10: Irritation and Sensitization Test
11	EN ISO10993-11	2009	Biological evaluation of medical devices - Part

			11: Tests for systemic toxicity
12	EN ISO11607-1	2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
13	EN ISO11607-2	2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
14	ISO 11135	2014	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
15	ISO 8536-9	2015	Infusion equipment for medical use - Part 9: Fluid lines for single use with pressure infusion equipment
16	ISO 8536-10	2015	Infusion equipment for medical use - Part 10:Accessories for Fluid lines for single use with pressure infusion equipment

7 Essential Requirements checklist

Summary: After checking the product in compliance to the Annex I Essential Requirements, relevant requirements are all met.

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
I.	**GENERAL REQUIREMENTS**				
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 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	EN ISO 15223-1 EN ISO 14971 EN ISO 10993-1 EN ISO 10993-5 EN ISO 10993-10 EN ISO11607-1 EN ISO11607-2 ISO 8536-9 ISO 8536-10	Labeling Risk analysis report Test report	**ok**
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	A	ENISO14971 EN ISO 15223-1	Risk analysis report Labeling	ok

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
	alarms if necessary, in relation to risks that cannot be eliminated, - Inform users of the residual risks due to any shortcomings of the protection measures adopted.				
3.	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.	A	EN ISO 15223-1 EN ISO 10993-1 EN ISO 10993-5 EN ISO 10993-10	Labelling Test report	**ok**
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 condition 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	ENISO14971 EN ISO 15223-1	Risk analysis report Labeling	**ok**
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	EN ISO 15223-1 ENISO 14971	Labeling Risk analysis report	**ok**
6.	Any undesirable side effects must constitute an acceptable risk when weighed against the performances intended.	A	EN ISO 14971	Risk analysis report	**ok**
6a.	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	A		Part B.4 Clinical evaluation report	**ok**
II.	**REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION**				

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
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 toxicity and, where appropriate flammability, • the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device. - Where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.	A	EN ISO10993-1 EN ISO10993-5 EN ISO10993-10 EN ISO11607-1 EN ISO11607-2 ISO 8536-9 ISO 8536-10	Test report	**ok**
7.2	The devices must be designed, manufactured and packed in such a way as to minimise 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 the duration and frequency of the exposure.	A	EN ISO 14971	Risk Analysis Report	**ok**
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 those products and that their performance is maintained in accordance with the intended use.	A	EN ISO 15223-1 ENISO14971 EN ISO10993-1 EN ISO10993-5 EN ISO10993-10 EN ISO11607-1 EN ISO11607-2	Labeling Risk Analysis Report Test Report	**ok**

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
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 [1] 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.	NA			
	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 this 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.	NA			

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1). Regulation as last amended by Regulation (EC) No 1901/2006.

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
	Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on 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[2] of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[3].	NA			
	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,	NA			

[2] Internal note: replaced by (EC) 1272/2008

[3] OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850).

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
	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.				
7.6	The 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.	NA			
8.	Infection and microbial contamination				
8.1	The devices and their 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, minimise contamination of the device by the patient or vice versa during use.	A	EN ISO 14971	Risk Analysis Report	**Ok**
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.	NA			

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
	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.				
8.3	Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure 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.	NA			
8.4	Devices delivered in a sterile state must have been manufactured and sterilised by an appropriate, validated method.	NA			
8.5	Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions.	NA			
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 sterilised prior to use, minimise the risk of microbial contamination. The packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer.	NA			
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.	NA			
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 performance of the	NA			

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
	devices. Any restrictions on use must be indicated on the label or in the instruction for use.				
9.2	Devices must be designed and manufactured in such a way as to remove or minimise as far as possible: • the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional, and where appropriate the 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 the materials used or loss of accuracy of any measuring or control mechanism.	NA			
9.3	Devices must be designed and manufactured in such a way as to minimise 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 which could cause combustion.	NA			
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	NA			

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
	manufacturer.				
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.	NA			
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[4].	NA			
11.	Protection against radiation				
11.1 11.1.1	*General* Devices shall be designed and manufactured such 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.	NA			
11.2 11.2.1	*Intended radiation* 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.	NA			
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.	NA			

[4] OJ No L 39, 15. 2. 1980, p. 40. Directive as last amended by Directive 89/617/EEC (OJ No L 357, 7. 12. 1989, p. 28).

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
11.3 11.3.1	*Unintended radiation* 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 be reduced as far as possible.	NA			
11.4 11.4.1	*Instructions* The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	NA			
11.5 11.5.1	*Ionising radiation* Devices intended to emit ionising 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 uses.	NA			
11.5.2	Devices emitting ionising 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 minimising radiation exposure of the patient and user.	NA			
11.5.3	Devices emitting ionising 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 the radiation.	NA			
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 their intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to	NA			

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
	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.	NA			
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.	NA			
12.3	Devices where the safety of the patient depends on an external power supply must include an alarm system to signal any power failure.	NA			
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.	NA			
12.5	Devices must be designed and manufactured in such a way as to minimise the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	NA			
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 that the devices are installed correctly.	NA			
12.7 12.7.1	*Protection against mechanical and thermal risks* 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.	NA			

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
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.	NA			
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.	NA			
12.7.4	The 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 minimise all possible risks.	NA			
12.7.5	Accessible parts of devices (excluding any parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	NA			
12.8 12.8.1	Protection against the risks posed to the patient by energy supplies or substances 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.	NA			
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	NA			

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
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.	NA			
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 supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instruction leaflet is needed for devices in Class I or Class IIa if they can be used completely safely without any such instructions.	A	EN1041 EN ISO 15223-1	Instruction of use Label	**Ok**
13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	A	EN 1041 EN ISO 15223-1	Instruction of use Label	**Ok**

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
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;	A	EN ISO 15223-1 EN1041	Labeling Instruction of use	**Ok**
	c) where appropriate, the word "STERILE";	NA			
	d) where appropriate, the batch code, preceded by the word "LOT", or the serial number;	A	EN 1041 EN ISO 15223-1	Instruction of use, Label	**Ok**
	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;	A	EN ISO 15223-1	Label	**ok**
	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;	NA			
	j) any special operating instructions;	NA			
	k) any warnings and/or precautions to take;	A	EN ISO 15223-1		**ok**

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
				Label	
	l) year of manufacture of active devices other than those covered by e). This indication may be included in the batch or serial number;	A	EN ISO 15223-1	Label	**ok**
	m) where applicable, method of sterilisation. n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative."	NA			
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	EN 1041 EN ISO 15223-1	Instruction of use Label	**Ok**
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.	NA			
13.6	Where appropriate, the instructions for use must contain the following particulars: a) the details referred to in 13.3, with the exception of d) and e) b) the performances referred to in section 3 and any undesirable side effects;	A	EN 1041	Instruction of use	**Ok**

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
	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;	NA			
	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;	NA			
	e) where appropriate, information to avoid certain risks in connection with implantation of the device;	NA			
	f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;	NA			
	g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilisation	NA			

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
	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 he device to be resterilized, and any restriction on the number if 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;	NA			
	i) details of any further treatment or handling needed before the device can be used (for example, sterilisation, final assembly, etc.)	NA			
	j) in the case of devices emitting radiation for medical purpose, details of the nature, type intensity and distribution of this radiation The instruction 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:	NA			
	k) precautions to be taken in the event of changes in the performance of the device;	A	EN 1041	Instruction of use	Ok

Checklist according to annex I of the Medical Device Directive (MDD)		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Ok or failure
	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.;	NA			
	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;	NA			
	n) precautions to be taken against any special, unusual risks related to the disposal of the device;	NA			
	o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;	NA			
	p) degree of accuracy claimed for devices with a measuring function.	NA			
	q) date of issue or the latest revision of the instructions for use.	A	EN 1041	Instruction of use	Ok

8 Risk Analysis

Identification of qualitative and quantitative characteristics (acc.to EN ISO 14971:2012, cl. 4.2)

Questions	Answer
C.2.1 What is the intended use and how is the medical device to be used?	Used for clinical intravemous infusion solution f
C.2.2 Is the medical device intended to be implanted?	NO.
C.2.3 Is the medical device intended to be in contact with the patient or other persons?	Contact with a patient
C.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Medical polymer materials
C.2.5 Is energy delivered to or extracted from the patient?	NO.
C.2.6 Are substances delivered to or extracted from the patient?	According to the patient's situation, supply, nutrient solution
C.2.7 Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	NO.
C.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	Yes, E.O. sterilized.
C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user?	NO.
C.2.10 Is the medical device intended to modify the patient environment?	NO.
C.2.11 Are measurements taken?	NO.
C.2.12 Is the medical device interpretative?	NO.
C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	NO.
C.2.14 Are there unwanted outputs of energy or substances?	NO.
C.2.15 Is the medical device susceptible to environmental influences?	Store in the relative humidity of no more than 80%, as well as non-corrosive and well-ventilated room.
C.2.16 Does the medical device influence the environment?	NO.
C.2.17 Are there essential consumables or accessories associated with the medical device?	NO.
C.2.18 Is maintenance or calibration necessary?	NO.
C.2.19 Does the medical device contain software?	NO.
C.2.20 Does the medical device have a restricted shelf-life?	YES,3 years
C.2.21 Are there any delayed or long-term use effects?	NO.
C.2.22 To what mechanical forces will the medical device be subjected?	NO.
C.2.23 What determines the lifetime of the medical device?	Lifetime determined by the product materials, Three yeas

C.2.24 Is the medical device intended for single use?	YES. single use
C.2.25 Is safe decommissioning or disposal of the medical device necessary?	NO.
C.2.26 Does installation or use of the medical device require special training or special skills?	Using by trained doctors or nurses.
C.2.27 How will information for safe use be provided?	Manual.
C.2.28 Will new manufacturing processes need to be established or introduced?	NO.
C.2.29 Is successful application of the medical device critically dependent on human factors such as the user interface? C.2.29.1 Can the user interface design features contribute to use error?	NO.
C.2.29.2 Is the medical device used in an environment where distractions can cause use error?	NO.
C.2.29.3 Does the medical device have connecting parts or accessories?	NO.
C.2.29.4 Does the medical device have a control interface?	NO.
C.2.29.5 Does the medical device display information?	NO.
C.2.29.6 Is the medical device controlled by a menu?	NO.
C.2.29.7 Will the medical device be used by persons with special needs?	NO.
C.2.29.8 Can the user interface be used to initiate user actions?	NO.
C.2.30 Does the medical device use an alarm system?	NO.
C.2.31 In what way(s) might the medical device be deliberately misused?	NO.
C.2.32 Does the medical device hold data critical to patient care?	NO.
C.2.33 Is the medical device intended to be mobile or portable?	Yes, portable
C.2.34 Does the use of the medical device depend on essential performance?	NO.

No	Hazard General	Identify hazards	Risk Evaluation S	 O	 D	 RL	Risk Reduction Measure	Evidence	NH	ALOR
D2. Energy Hazards										
1	Electricity	N/A								
2	Heat	N/A								
3	Mechanical force	N/A								
4	Ionizing radiation	N/A								
5	Non Ionizing radiation	N/A								
6	Electromagnetic fields									
7	Moving parts	N/A								
8	Suspended masses	N/A								
9	Patient support device failure	N/A								
10	Pressure(vessel rupture)	N/A								
11	Acoustic pressure	N/A								
12	Vibration	N/A								
13	Magnetic fields(e.g. MRI)	N/A								
D3. Biological hazards										
1	Bio-contamination	1.Bad control of the production environmental. 2.Not sterilized Well 3.The package is damaged. 4.Incorrect operation.	3	3	1	9	1. Production in 100000 class clean room. 2. Follow the sterilization operation requirements. 3. Warning on the labeling.	Test report Labeling Instructions.		Acc
2	Bio-incompatibility	The product may cause the user uncomfortable if the material is not OK	3	3	1	9	Inspection of the raw material and production after confirmation.	See test report		Acc
3	Incorrect formulation(chemica	NA								

No	Hazard General	Identify hazards	Risk Evaluation S	O	D	RL	Risk Reduction Measure	Evidence	NH	ALOR
	l composition)									
4	Toxicity	The product may cause the user uncomfortable if the material is not OK	2	4	1	8	Choose raw materials of fabrics with cyto toxicity meeting the requirements	See test report		Acc
5	Allergenicity	The product may cause the user uncomfortable if the material is not OK	2	4	1	8	Choose raw materials of fabrics with cyto toxicity meeting the requirements	See test report		Acc
6	Mutagenicity	N/A								
7	Oncogenicity	N/A								
8	Teratogenicity	N/A								
9	Carcinogenicity	N/A								
10	Re-and/or cross-infection	The product is single use product and could not be re used. Re use may cause cross-infection	2	3	2	12	Ensure that the products are for single use shall be shown on the instruction of use and labels.	Instruction of use and Labels		Acc
11	Pyrogenicity	The product may cause the user uncomfortable if the material is not OK	2	3	1	6	Ensure that microb content in the production environment meets the requirements.	Products operating instructions		Acc
12	Inability to maintain hygienic safety	The product may cause the user uncomfortable if the material is not OK	2	3	2	12	Ensure that microb content in the production environment meets the requirements.	Products operating instructions		Acc
13	Degradation	N/A								
D4. Environmental hazards and contributory factors										
1.	Electromagnetic fields	N/A								
2.	Inadequate supply of power or coolant	N/A								
3.	Susceptibility to electromagnetic interference	N/A								

No	Hazard General	Identify hazards	Risk Evaluation S	 O	 D	 RL	Risk Reduction Measure	Evidence	NH	ALOR
4.	Emissions of electromagnetic interference	N/A								
5.	Inadequate supply of power or coolant	N/A								
6.	Inadequate supply of coolant	N/A								
7.	Storage or operation outside prescribed environmental conditions	Storage condition does not fulfill requirements.	3	2	1	6	Specify the storage requirements on the packaging.	User manual Labeling		Acc
8.	Incompatibility with other devices	N/A								
9.	Accidental mechanical damage	NA								
10.	Contamination due to waste products and /or device disposal	Do not discard after use.	3	2	2	6	Specify on the label and insturctions,single use only.	Labeling		Acc
D5. Hazards resulting from incorrect output of energy and substances										
1.	Electricity	NA								
2.	Radiation	NA								
3.	Volume	NA								
4.	Pressure	NA								
5.	supply of medical gases	NA								
6.	supply of anaesthetic agents	NA								
D6. Hazards related to the use of the device and contributory factors										
1	Inadequate labeling	The inadequate labeling may cause	3	2	1	6	Strengthen amending the	Refer to		Acc

No	Hazard General	Identify hazards	Risk Evaluation S	O	D	RL	Risk Reduction Measure	Evidence	NH	ALOR
		misuse.					label for warning	label.		
2	Inadequate operating instructions	The inadequate operating instructions may cause misuse.	3	2	1	6	Strengthen on the operating instructions.	See instruction of use		Acc
2.1	Inadequate specification of accessories	NA								
2.2	Inadequate specification of pre-use checks	The device may be damaged.	2	2	1	4	To strengthen pre-use checks.	See instruction of use		Acc
2.3	Over-complicated operating instructions	N/A								
2.4	Inadequate specification of service and maintenance	N/A								
3	Use by unskilled/untrained personnel	Operation not skilled, operating errors.	2	3	1	6	To strengthen training	See the instruction of use		Acc.
4	Reasonably foreseeable misuse									
5	Insufficient warning of side effects									
6	Inadequate warning of hazards likely with re-use of single use devices	Repeated use cause cross infection.	3	3	1	9	To strengthen in the Packaging	See Labeling.		ACC
7	Incorrect measurement and other metrological aspects	NA								
8	Incompatibility with consumables/accessories/other devices	N/A								
9	Sharp side									

No	Hazard General	Identify hazards	Risk Evaluation S	 O	 D	 RL	Risk Reduction Measure	Evidence	NH	ALOR
D7. Complicated operation										
1	Mistakes and judgement errors	NA								
2	Lapses and cognitive recall errors	NA								
3	Slips and blunders (mental or physical)	NA								
4	Violation or abbreviation of instructions, procedures, etc.,	NA								
5	Complex or confusing control system	NA								
6	Ambiguous or unclear device state	NA								
7	0Ambiguous or unclear presentation of settings, measurements or other information	NA								
8	Mispresentation of results	NA								
9	Insufficient visibility, audibility or tactility	NA								
10	Poor mapping of controls to action, or of displayed information to actual state	NA								
11	Controversial modes	NA								

No	Hazard General	Identify hazards	Risk Evaluation S	 O	 D	 RL	Risk Reduction Measure	Evidence	NH	ALOR
	or mappings as compared to existing equipment									
D8. Hazards arising from functional failure, maintenance and ageing										
1	Erroneous data transfer	NA								
2	Lack of , or inadequate specification for maintenance including inadequate specification of post maintenance functional checks	NA								
3	Inadequate maintenance	NA					Strengthen management	See instruction of use		Acc
4	Lack of adequate determination of end of device life	Do not specify the expiry date.	3	3	1	9	Strengthen on the packaging and label.	See Labeling.		Acc
5	Loss of mechanical integrity	N/A								
6	Inadequate packaging(contamination and /or deterioration of the device)	The lifetime of the device may be reduced	3	2	1	5	Confirm the packing and expiry date.	See use manual and labeling.		Acc
7	Re-use and / or Improper re-use	Do not clearly specify single use only.	3	3	1	9	Strengthen on the packaging and label.	See Labeling.		Acc
8	Deterioration in function (e.g.	NA								

No	Hazard General	Identify hazards	Risk Evaluation S	 O	 D	 RL	Risk Reduction Measure	Evidence	NH	ALOR
	gradual occlusion of fluid/gas path, or change in resistance to flow, electrical conductivity) as a result of repeated use.									
B2. Additional hazards to in vitro diagnostic medical devices										
1	Batch inhomogeneity, batch-to-batch inconsistency	NA								
2	Common interfering factors	NA								
3	Carry-over effects	NA								
4	Specimen identification errors	NA								
5	Stability problems (in storage, in shipping, in use, after first opening of the container)	NA								
6	Problems related to taking, preparation and stability of speciments	NA								
7	Inadequate specification of prerequisites	NA								
8	Inadequate test characteristics	NA								

Abbreviations used

RE	Risk Evaluation
S	Severity (9 –very severe, 0 –not severe)
O	Occurrence (9 –often, 0 –never)
D	Detection (9 –impossible to detect before risk occurs, 0 –will be certainly detected before risk occurs)
RL	Risk Level = Severity × Occurrence × Detection 1-9: Neglectable risk, no further actions; 9-24: Moderate: minimal risk, preventive action recommended; 25-48: Moderate risk, preventive action required; >48: Risk is usually not acceptable
RRM	Risk Reduction Measure
NH	New hazard generated (no/ yes - if yes, then number of new hazard indicated)
ALOR	Acceptable Level of Risk

Conclusion:

The report analyze the overview, product description, intended use, instruction for use, considerations, identification of characteristics related to the safety of the medical device, hazards that may exists, risk evaluation standard, residual risk evaluation, and evaluation on production and post-production information of single-use sterile stomach catheter according to the requirements of ISO14971 and "Risk Management Control Procedure", the drawn conclusion is that the risk of Sterile infusion sets for single use can be reduced to an acceptable level in clinics after taking pertinent measures.

9 Test Report

The product was manufactured and inspected by our company carried out biocompatibility test by third party inspection institute. The quality management system established and conformity assessment has been audited by TUV Rheinland.

10 Sterile method and validation

The product was manufactured and sterilized by using Ethylene Oxide according to EN ISO 11135: 2014. The factory has established quality management system and its conformity assessment has been audited by TUV Rheinland.

11 Packaging verification

To ensure the effectiveness of the packaging after sterilization, our company conducted the packaging verification test. All data demonstrates conformity with requirements of EN ISO 11607. The factory has established quality management system and its conformity assessment has been audited by TUV Rheinland.

12 Clinical evaluation

To prove the safety and effectiveness of the product, our company conducted the clinical evaluation. All data demonstrates conformity with relevant essential requirements and risks associated with the use of the device are acceptable when weighed against the benefits to the patient. The factory has established quality management system and its conformity assessment has been audited by TUV Rheinland.

13 Control Procedure of Vigilance System

Company set up vigilance procedure based on MDD 93/42/EEC.

5.1 Purpose

To reduce the re-occurrence of the similar accidents in different places at different times, to improve the safety and health protection of patients of users, to assess all reported accidents and issue information likely for the prevention of the re-occurrence of the similar accidents or alleviate the accidents results.

Scope

Applicable to the dealing of medical device accidents caused by all products with CE mark within CE territory.

Responsibility

5.2 CE authorized representative shall contact timely with the administration concerned and the company involved upon the receipt of accident report.

3.2 Distributor shall timely deliver the customer complaints and accident report to company and be responsible for protecting the record of sales.

5.3 Safety engineer shall be responsible for collecting the accident information and delivering it to all functioning departments and reversely delivering the measures of the accident taken by company to distributor and CE authorized representative and, to patients or user when necessary.

Procedure

5.4 Business section shall timely report safety engineer upon the receipt of information of accident report from CE authorized representative, distributor and user. Safety engineer shall call in personnel concerned to discuss and analyze the information delivered. Once any of the following points is determined, administration concerned and company involved shall be reported to.

5.4.1 Type of accident, significant accident (e.g. patients died or state of illness severely deteriorated.

5.4.2 Whether the accident is related with company product. In the case of such accident is directly related with company product, report to the administration of the country where accidents happened, whereas, no report is needed but record shall be placed and reason be recorded.
5.4.3 Whether the accident arises any hindrance or possibly aroused by the information defects (e.g. insufficient or incorrect contents of instruction of use) of the company or products. If such defects did bring the accident, report to the administration of the country where accidents happened, whereas, no report is needed but record shall be placed and reason be recorded.
5.5 Accidents which shall be reported to the administration of the country where accidents happened
5.5.1 Accident that caused the death of patients or user
5.5.2 Accident that severely damaged the health of patients or user
Disease or damage that severely threaten life
Damage to body function or permanent damage to body structure
Loss of body function or permanent damage of body structure can only be prevented by means of medical means or operation.
5.5.3 Death or severely-deteriorating health will be caused under normal conditions but fortunately have not develop into accident (ready accident)
5.6 Material shall be reported
5.6.1Opinions of doctors (based on the obtained evidence)
Preliminary evaluation result provided by company;
Evidence of former similar accident;
Other evidence held by company.
5.6.2 Material regarding accident includes:
Product performance and major malfunction or deteriorating status of the performance;
No product failure or deterioration. But in the case of certain property may lead to accident, report it as a ready accident;
The instructions for use for the product are not so specified, or have neglects or shortages.
5.6.3 Report the materials regarding the accident along with the accident
5.7 Preliminary reporting time of accident or potential accident
5.7.1 Safety engineer present fundamental report within the following time upon the receipt of accident notice and submit it to legal organization through CE representative.
Accident ： within 10 days.
Potential accident (ready accident): within 30 days.
5.8 Administration bureau of medical device that shall be reported to
5.8.1 Report to the national administration bureau where the medical device accident happened if in CE member countries.
5.8.2 If not in CE member countries
For Class I or above Class I, report to the country's the administration bureau where the notification institutes;
For Class I device, report to the country's administration bureau where the CE authorized representative is.
5.8.3 When appropriate, under the vigilance system, company shall inform the authorization representative and representatives of other bodies of accident reporting. At the same, company shall report to the notification institute.
5.9 Recall of Medical Device
5.9.1 The decision of recalling all of the medical devices in terms of technical or medical problems is notified to administration bureau concerned by company through CE authorized representative.

5.9.2”Advisory Notice” shall be issued when recalling products and be sent to administration bureau concerned.
5.9.3 Safety engineer organized personnel for collecting authentic materials and are authorized with the final decision-making right of notice issuing and product recalling.
5.10 Product recalling shall be reported to legal body
5.10.1 Safety engineer, in compliance with the requirements in annex of “Vigilance System Rules for Medical Device” submit the preliminary report to the legal institute of the country where accident happened through CE authorized representative.
5.10.2For device of Class I or above, if the quality accident happened not in CE member country and resulted the adopting of corrective action, such accident report shall be submitted to and notified the legal institute of the country concerned.
5.11 The detailed contents of the preliminary report shall be filled in “preliminary accident report”; make an analysis whether risk mitigating measures leads to new hazard.
5.12 Work after Preliminary Report
5.12.1 Safety engineer together with CE authorized representative shall investigate the accident according to preliminary report and report the process timely to legal institute.
5.12.2 If company is unable to investigate the accident, such situation shall be reported to legal institute without any delay.
5.13 Investigation Result and Corresponding Measures
5.13.1 Company takes appropriate measures subject to investigation result, e.g. consult with legal institute, recall product, etc.
5.13.2 Safety engineer, with the help of CE authorized representative, fill in the Final Accident Report which shall include the investigation result and appropriate measures taken and be submitted to legal institute by CE representative.
5.13.3 Appropriate measures as below after investigation shall be included:
No measures and reason of no measures;
Test and follow up the device under use;
Provide the user with information, e.g. issue notice (advisory notice)
Take action on successive products;
Recall product
5.14 Contact CE Authorized Representative about Detailed Rules
5.14.1 To guarantee the amendment to company technology document and the issue of medical device notice, CE authorized representative shall be noted with the effective ways of documents or other issues specified in the agreement signed by CE representatives.
5.14.2 Safety engineer shall fax any amendment to company document in no time to CE authorized representative and send it to CE representatives within on e week.

Annex 1 Document change history

S/N	Changed section	What was changed	Revision number	Change person	Approval person	Change date
	/	Initial edition	A/0	/	/	/