NO: QF/GK-CE-01/0

《Nasal oxygen cannula》

Ningbo Shengyurui Medical Appliance Co.,Ltd **CE Document**

Approved the issuance date : April 8, 2012 **Versions of : B/0**

Technical file

(controlled)

Author: Youjun Lin and so on

Reviewed：Michael Yin

Approved：Haili Jin

Contents

Declaration of Conformity

Manufacturer：Ningbo Shengyurui Medical Appliance Co.,Ltd

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

European authorized representative:

Shanghai International Holding Corp GmbH

ADD: Eiffestrasse80,20537Hamburg，Germany

Product (including S/N/manufacturing date if there is same product without CE mark)：

Product : Nasal oxygen cannula

Model1 ：Nasal oxygen cannula series: including adult/ pediatric/ infant and newborn, nasal tips may be silicon or liquid PVC, PVC;

Model2 ：Humidifying series, including humidifying bottle;

Model3 ：Oxygen connecting tube;

Model4 ：Mouth-nasal cannula;

Model5 ：Suction connecting tube, yankauer handles, suction connecting tube with handles.

Classification (MDD, Annex/X): class Ⅱa medical device。

Conformity Assessment Route: according to appendix V.3 of MDD93/42/EEC.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES:

General applicable directives: 93/42/EEC of 14 June 1993 concerning medical devices (MDD93/42/EEC)

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD93/42/EEC) as mended by 2007/47/EC.

Standard Applied: See attached list of (harmonized-EN) standards for which documented evidence of compliance can be provided.

Notified Body: SGS United Kingdom Ltd
202B Worle Parkway, Weston-super-Mare, Somerset BS22 6 WA UK

Identification number: 0120

(EC)Certificate(s): CN 09/21829

Expire date of the Certificate:

Start of CE Marking: November 19, 2009

Place, Date of Issue:

Signature

Name ： Haili Jin

Position：Gernaral manager

Appendix 1: list of harmonized-EN standards

the listing of the harmonized-EN standards and international standards：

Serial NO	File NO	Version number	File name
1	93/42/EEC	2007	COUNCIL DIRECTIVE of medical device
2	EN11135	2007	Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization
3	EN980	2008	Graphical symbols for use in the labelling of medical devices
4	EN 1041	2008	Information supplied by the manufacturer with medical devices
5	ENISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:2009)
6	ENISO10993-5	2008	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2008)
7	ENISO10993-7	2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)
8	ENISO10993-10	2010	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity (ISO 10993-10:2010
9	ISO11607	2006	Packaging for terminally sterilized medical devices
10	ENISO13485	2003	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
11	ISO 15223	01-4-2000	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied
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Technical file	**Name and ADD of the Manufacturer**	QF/GK-CE-01/0-02
Edition No. B/0	Page 1 of 1	

Manufacturer Name: Ningbo Shengyurui Medical Appliance Co.,Ltd

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

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E-mail:andywu1912@163.com

Technical file	**Name and ADD of EU authorized representative company**	QF/GK-CE-01/0-03
Edition No. B/0	Page 1 of 1	

Name of EU authorized representative company: Shanghai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80, 20537 Hamburg，Germany

Tel: 0049-40-2513175

Fax：0049-40-255726

E-mail: shholding@hotmail.com

Production Area Name: Ningbo Shengyurui Medical Appliance Co.,Ltd

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

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Technical file	**Name and ADD of Notified Body**	QF/GK-CE-01/0-05
Edition No. B/0		Page 1 of 1

Name of Notified Body: SGS United Kingdom Ltd

Add: 202B Worle Parkway, Weston-super-Mare,Somerset BS22 6 WA UK

Tel: +41 22 739 91 11

Fax： +41 22 739 98 86

1 Product name: Nasal oxygen cannula（Hereinafter referred to nasal oxygen cannula）

Nasal oxygen cannulae is made of medical PVC material , which is used to supply the oxygen therapy, which adopt the oxygen cylinder and other oxygen

equipment as the driving force.

According to using, production, processing and other technical documents produced by the strict operating regulations. **Nasal oxygen cannula** is medical, stable material on the shelves so that their products have a good long time. It is an excellent clinical material for supply oxygen, nebulizer and therapy.

Oral mucous membrane irritation ,skin irritation ,cytotoxicity and sensitization of the product should be up to the according production standard. Biological compatibility performance is doing by performance testing center in Zhejiang medical equipment tested and approved, the product has been confirmed that excellent performance is safe and effective.

2 Intended use:

Nasal oxygen cannula mainly used to supply t oxygen in clinical using.

3 Classification grades:

Nasal oxygen cannula is classified as class Ⅱa sterile medical device in according with MDD93/42/EEC Annex IX rule 5..

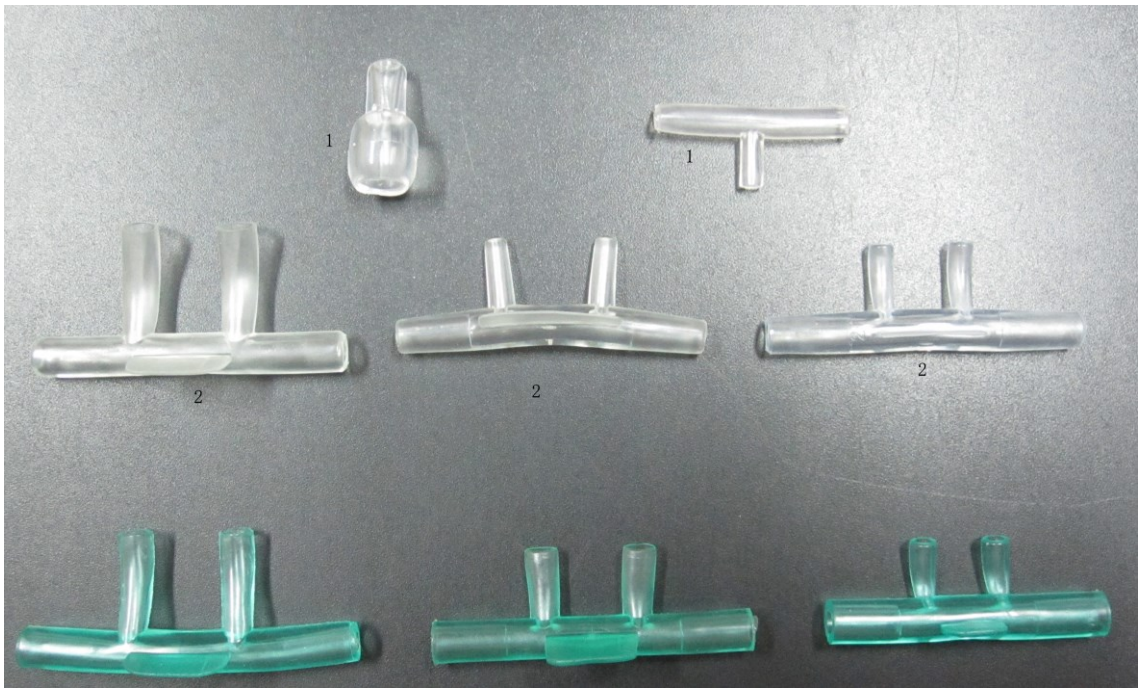
4 Certification pathway of CE products

Nasal oxygen cannula applys for CE marking by Annex V.3 of MDD93/42/EEC.

5 Model:

Product 1: Nasal oxygen cannula (Sketch map refer to Fig. 1-3)

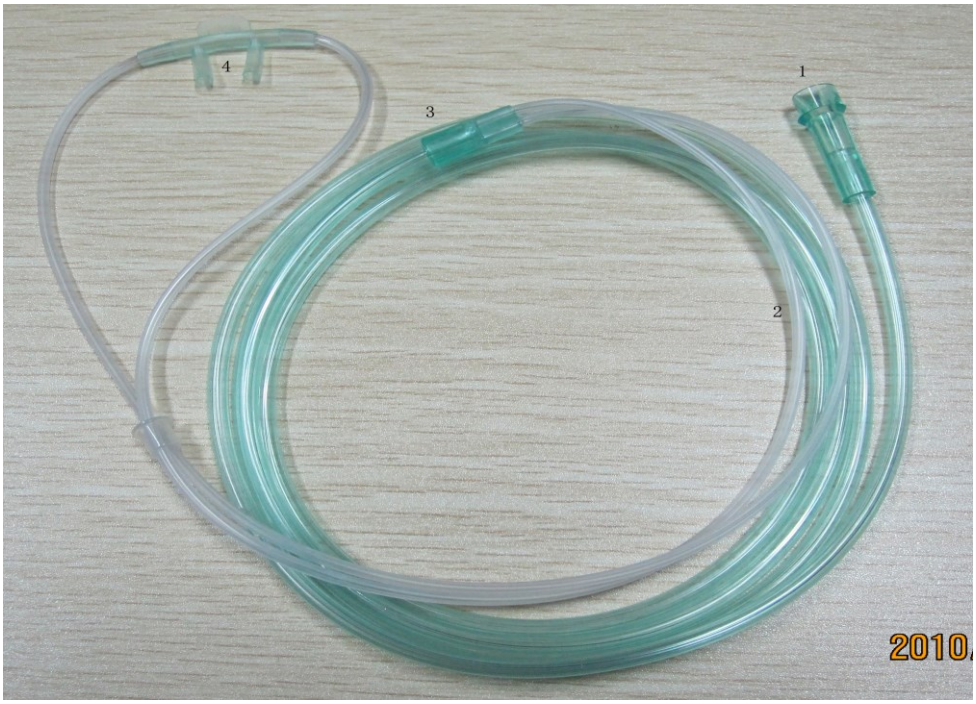
Model 1： adult/ pediatric/ infant



1 single nasal tip 2 double nasal tip

Fig. 1 Sketch map of The Nasal Oxygen Cannula

Fig. 2 Sketch map of humidification bottle



1、oxygen connecting tip 2、oxygen supply tube 3、double - hole connecting tip 4、the double - hole nasal tip

Fig. 3 Sketch map of The Nasal Oxygen Cannula

6 Structure, materials and performances

Nasal oxygen cannula is main made of medical PVC plastics. its structure of appearance is shown in Fig. 1. The plastic products belongs to medical PVC grades . which has good biological compatibility. And It is soft , flexible , smooth.

7 Production environment

Nasal oxygen cannula is required to be sterile， and It is single patient use.But it should be produced in a clean environment so as to reduce the possibility of cross pollution and biocontamination .The production place should be clean,and keep a grade of 100,000.

8 Technical parameter：

Nasal oxygen cannula designed and produced according to GB 15593 standard and <Disposible nasal oxygen cannulae > product standards.

- The every connecting tip of product should be firm , reliable , and can bear the static axial pulling force of 15N , lasting 15s, can't be taken off and ruptured etc. .
- The product should feel soft, flexible, color even luster, have none fly-sides, obvious impurity , spot and obvious machinery damage.

- The product should not have the phenomenon of leaking gas and stopping up.
- The product should have none obviously twisted.
- If product has been sterilized , before delivery , the remaining of EO should not be more than 10mg/kg.
- The product should be sterile.

8.1 Product 1: Nasal oxygen cannulae (**Model**：adult/ pediatric/ infant)

8.1.1 specification and constitution

Chart 1 specification and constitution of nasal oxygen cannulae

specification		Construction
NOC-1	NOC-1S	Be made of humidifying bottle, oxygen supply tube, oxygen connecting tip, double - hole connecting tip, the single - hole nasal tip and fixed ring.
	NOC-1DA、NOC-1DB、NOC-1DC	Be made of humidifying bottle, oxygen supply tube, oxygen connecting tip, double - hole connecting tip, the double - hole nasal tip and fixed ring.
NOC-2	NOC-2S	Be made of oxygen supply tube, oxygen connecting tip, double - hole connecting tip, the single - hole nasal tip and fixed ring.
	NOC-2DA 、NOC-2DB 、NOC-2DC	Be made of oxygen supply tube, oxygen connecting tip, double - hole connecting tip, the double - hole nasal tip and fixed ring.
NOC-3	NOC-3S	Be made of oxygen supply tube, double - hole connecting tip, the single - hole nasal tip and fixed ring.
	NOC-3DA 、NOC-3DB 、NOC-3DC	Be made of oxygen supply tube, double - hole connecting tip, the double - hole nasal tip and fixed ring.
NOC-4		Be made of oxygen supply tube, oxygen connecting tip, double - hole connecting tip.
NOC-5		Be made of humidifying bottle.
note：specific construction should production according to the requirement of customer。		

8.1.2 appearance

8.1.2.1 The product should be feet soft, and coloure and luster uniformity ,none flashing, none obvious impurity, besmirch ,and obvious mechanical damage.

8.1.2.2 The tube of nasal oxygen tube should be none obvious warping , flat, shriveled and so on.

8.1.3 Biology performance of Nasal oxygen cannulae.

8.1.3.1 It should be none mucosa stimulate.

8.1.3.2 It should be none cytotoxicity.

8.1.3.3 It should be none delayed-type hypersensitivity.

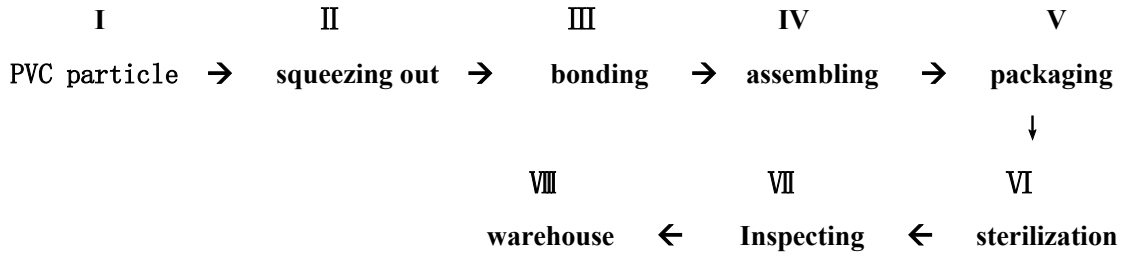
8.4 Package and label:

The primary packaging of product should be no laekage, and should have a instruction in it .The CE symbol and the name and address of the manufacturer should be marked on the primary package and the outer package.

9 Design drawing

the drawing of Nasal oxygen cannula sees fig 1-8.

10 production flowing chat

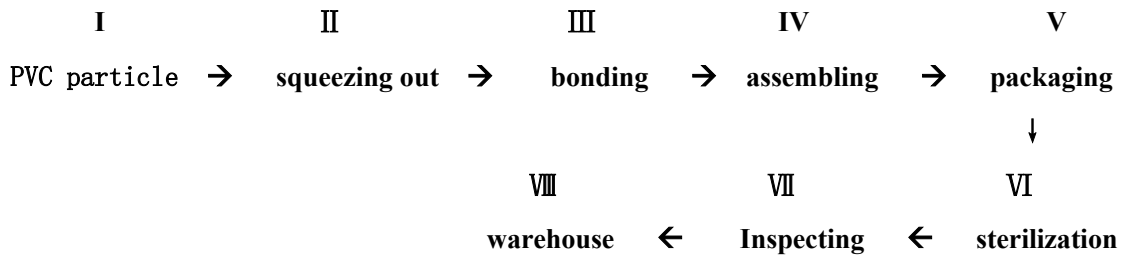


11 Materials, outsourcing pieces and providers

No.	materials	Specification	supplier	comments
1	PVC	medicine	Gaoyou city Hansheng macromolecular material Co., Ltd.	GB 15593
2	Elastic band		Haining city Xinchang Anshunda braid factory	
3	cyclohexanone	AR	Hangzhou Shuanglin huagong chemical reagent factory	

1 Production information document

(1) Production flow chart of Nasal oxygen cannula



(2) Environmental control

① Processing and assembling of components and parts are all completed in 100,000 class cleaned room.

② Environmental requests and monitoring parameters

Monitoring items		Technical guideline	Monitorig method	Monitoring frequency
		100000 class		
Temperature(℃)		(If there is no special requests) 18-28	JGJ-1990	1time per shift
Relative humidity(%)		45-65		1time per shift
Wind speed (m/s)		-		1time per month
Times of airation (per hour)		≥15		1time per month
Stillness pressure difference (Pa)		≥5 between cleansed room (area) of different classes or between cleansed room (area) and non-cleansed room (area)		1time per month
		≥10 between cleansed room (area) and out-room air		
Dust number (per m3)	≥0.5 micro meter	≤3 500 000	GB/T16292-1992	1time per season
	≥5 micro meter	≤20 000		
Number of float bacterium (per m3)			GB/T16293-1992	1time per season
Number of sedimentation bacterium (per plate)		≤10	GB/T16294-1992	1time per week

(3) Stock inspection and test

① Object：raw and assistant materials, outsourcing and concerted pieces

Medical-use PVC, Alulium strip, elastic strap.

② Inspection frequency:

Inspect each batch of material.

(4) Delivery test(Final inspection)

① Object: Disposable Suction Tube

② When to test

For each production lot

③ Inspection items:see “delivery test report”

(5) Type test

① Object: Disposable Suction Tube

② when to test

a) Every year

b) When the production process has a significant change

c) When changing the supplier of medical-use of PVC

d) When the customer asks

③ Inspection items:see “Type test report”

1 Packaging of Disposable Suction Tube is descriped as follows:

Packing Methods	Packing materials
Primary package	① HDPE thin membrane ② layer thickness 0.115±0.005(mm)
Outer package	① Double tile paper plate (type B tile) 280g/cm^2 ② Durable strength ≥980kPa (10kgF/ cm^2) ③ Flank pressure strength≥735N/ cm^2 ④ Water content rate ≤14±4%

2 Package validation

Select qualified package materials and validate packing process in accordance with EN 868-1 standard requests

(1) Selection of package materials

When select package materials, the company should evaluate these performances:

① Physical performance :

Includes plastic seal performance, effect of temperature, HDPE can meet requests in accordance with inspection and test.

② Chemical performances:

Contact stability of products

③ Biological performance

Biological compatibility and non-stimulate.

(2) Package validation plan

① Validation contents

Validate Disposable Suction Tube single-packing process.

② Design conformation and products standard

a. Single-packing: no breakage

b. Bursting force test: keep pressure on ≥0.01MPa for 5-6 second and the jointing area does not separate.

③ Equipment identification: identification of equipment frock and approving of measure apparatus

④ Validation process: study out upper limit, lower limit and medium value transferring speed, sealing pressure force of sealing temperature. Carry out packing flow of products in each limit condition respectively.

⑤ Sampling plan of inspection:

Sampling at the beginning and end of the work time.each time 10 samples.

1 label of **Nasal oxygen cannula** is descriped as follows:

Product 1: Nasal oxygen cannula

Model 1： adult/ pediatric/ infant

Note: Single-patient use

Please see instruction for use before using


（出厂日期）：××年××月××日

Batch NO:(Batch NO)　　period of validity：5years

Note:it used for one sigle use

CE 0120


Manufacturer： Ningbo Shengyurui Medical Appliance Co.,Ltd

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Nasal oxygen cannula

【specification】

Product 1: Nasal oxygen cannula

Model 1： adult/ pediatric/ infant

【main configuration and function】 **Nasal oxygen cannula** is made of PVC material, which is used by a special process to produce a special medical material

【apply scope】Nasal oxygen cannula mainly used to supply t oxygen in clinical using.

【Usage method】

1)Uses in front of this product to inspect the packing antiseptic date, the life.

2) the direction opens the small packing according to Sikou, takes out the product.

3) and aspirator connecting pipe coordination use.

【attention proceeding】

1)the goods only for one single use.

2) prohibited to use if packaging be damaged and the sterilization valid date is over, destruct after be used .

3) the date of production refer to the packing seal and the outside packaging boxes.

【Valid】 after ethylene oxide sterilization, five years is valid

【Storage and transportation】

1) when transporting storage Picture shows signs shall be provided for storage outside the box.

2) should be kept in relative humidity less than 80%, non-corrosive gases and good indoor ventilation

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Contactor： Haili Jin

EC REP **Name:** Shanghai International Holding Corp GmbH

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E-mail: shholding@hotmail.com

Checklist according to annex I of the Medical Device Directive (MDD) **QF/GK-CE-01/0-10**		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
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**	**EN14971:2009** **ISO13485:2003**	**Risk Management report** QF/GK-7.1-01 **Quality system Files** QM/GK-01-2012 (B/0) QP/GK-01-2012 (B/0) QF/GK-01-2012 (B/0)		
2.	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: • eliminate or reduce risks as far as possible (inherently safe design and construction), • where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,	**A**	**EN 1041:2008** **EN14971:2009**	**Risk Management Report** QF/GK-CE-01/0-11 **Instruction for use**		

Checklist according to annex I of the Medical Device Directive (MDD) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
	• Inform users of the residual risks due to any shortcomings of the protection measures adopted.			QF/GK-CE-01/0-09		
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**		**Test report** QR-8.2.4-03.1/0 **Instruction for use** QF/GK-CE-01/0-09		
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**		**Test report** QR-8.2.4-03.1/0 **Instruction for use** QF/GK-CE-01/0-09		
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 980:2008**	**Test report** QR-8.2.4-03.1/0 **Instruction for use** QF/GK-CE-01/0-09		
6.	Any undesirable side effects must constitute an acceptable risk when weighed against the performances intended.	**A**	**EN 14971**	**Test report** QR-8.2.4-03.1/0 **Instruction for use**		

Checklist according to annex I of the Medical Device Directive (MDD) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
				QF/GK-CE-01/0-09		
6a.	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	**A**	**ISO10993-1:2003** **ISO10993-5:2009** **ISO10993-10:2010**	**Test report** QR-8.2.4-03.1/0 **Instruction for use** QF/GK-CE-01/0-09		
II.	**REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION**					
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**		**Test report** QR-8.2.4-03.1/0 **Instruction for use** QF/GK-CE-01/0-09		
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**		**Test report** QR-8.2.4-03.1/0 **Instruction for use** QF/GK-CE-01/0-09		
7.3	The devices must be designed and manufactured in such a way	**A**	**ISO 10993-1:2003**	**Test report**		

Checklist according to annex I of the Medical Device Directive (MDD) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
	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.		**EN 1041:2008**	QR-8.2.4-03.1/0 **Instruction for use** QF/GK-CE-01/0-09		
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**				

[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) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
	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. 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.	**NA**				

Checklist according to annex I of the Medical Device Directive (MDD) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
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]. If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC[2], these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.	**A** **A**	**ISO 10993-1:2003**	**Test report** QR-8.2.4-03.1/0 **Instruction for use** QF/GK-CE-01/0-09 **Test report** QR-8.2.4-03.1/0 **Instruction for use** QF/GK-CE-01/0-09		

[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) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
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.	**A**	**ISO 10993-1:2003** **ISO 14971:2009**	**Risk Management Report** QF/GK-CE-01/0-11 **Test report** QR-8.2.4-03.1/0 **Instruction for use** QF/GK-CE-01/0-09		
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**	**ISO 10993-1:2003** **ISO 14971:2009**	**Risk Management Report** QF/GK-CE-01/0-11 **Test report** QR-8.2.4-03.1/0		
8.2	Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Notified Bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	**NA**				
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.	**A**	**EN980:2008** **ISO 14971:2009**	**Risk Management Report** QF/GK-CE-01/0-11 **Test report** QR-8.2.4-03.1/0 **Instruction for use** QF/GK-CE-01/0-09		

Checklist according to annex I of the Medical Device Directive (MDD) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
8.4	Devices delivered in a sterile state must have been manufactured and sterilised by an appropriate, validated method.	**A**	**ISO 11135.1:2007** **ISO10993-7:2008**	**Test report** QR-8.2.4-03.1/0		
8.5	Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions.	**A**	**ISO 11135.1:2007**	**Test report** QR-8.2.4-03.1/0 **Environment control record** QR-6.4-03.2/0		
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.	**A**		**Test report** QR-8.2.4-03.1/0 **Instruction for use** QF/GK-CE-01/0-09 **Package Validation** QF/GK-7.5.5-10.1		
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	**A**		**Instruction for use** QF/GK-CE-01/0-09		
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	**A**	**EN980:2008** **ISO14971:2009**	**Labelling** **Instruction for use** QF/GK-CE-01/0-09		

Checklist according to annex I of the Medical Device Directive (MDD) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
	connection system must be safe and must not impair the specified performance of the devices. Any restrictions on use must be indicated on the label or in the instruction for use.					
9.3	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.	**A**	**ISO14971:2009**	**Risk Management Report** QF/GK-CE-01/0-11 **Test report** QR-8.2.4-03.1/0		
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 manufacturer.	**NA**				

Checklist according to annex I of the Medical Device Directive (MDD) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
10.3	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**				
11.3 11.3.1	*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**				
11.3.3	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) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
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**				
11.5.3	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					

Checklist according to annex I of the Medical Device Directive (MDD) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
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 eliminate or reduce as far as possible consequent risks	**NA**				
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**				
12.3	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**				

Checklist according to annex I of the Medical Device Directive (MDD) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
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**				
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 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**				
12.8.3	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a	**NA**				

Checklist according to annex I of the Medical Device Directive (MDD) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
	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.					
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**	**EN980:2008** **ISO 14971:2009**	**Labelling** **Instruction for use** QF/GK-CE-01/0-09 **CE technical file** QF/GK-CE.01/0		
13.3	Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must	**A**	**EN980:2008**	**Labelling** **Instruction for use** QF/GK-CE-01/0-09		

Checklist according to annex I of the Medical Device Directive (MDD) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
	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.			**CE technical file** QF/GK-CE-01/0		
13.3	The label must bear the following particulars: a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community; b) the details strictly necessary to identify the device and the contents of the packaging especially for the users; c) where appropriate, the word "STERILE"; d) where appropriate, the batch code, preceded by the word "LOT", or the serial number; e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month; f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community; g) if the device is custom made, the words "custom made device"; h) if the device is intended for clinical investigations, the words "exclusively for clinical investigations"; i) any special storage and/or handling conditions; j) any special operating instructions;	**A** **A**	**EN980:2008** **EN980:2008**	**Labelling** **Instruction for use** QF/GK-CE-01/0-09 **Labelling** **Instruction for use** QF/GK-CE-01/0-09		

Checklist according to annex I of the Medical Device Directive (MDD) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
	k) any warnings and/or precautions to take; l) year of manufacture of active devices other than those covered by e). This indication may be included in the batch or serial number; 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."					
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**		**Instruction for use** QF/GK-CE-01/0-09/0		
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	**A**		**Instruction for use** QF/GK-CE-01/0-09/0 **Risk Management Report** QF/GK-CE-01/0-11 **Labelling**		
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; 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	**NA**				

Checklist according to annex I of the Medical Device Directive (MDD) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
	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 event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilisation 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; i) details of any further treatment or handling needed before the device can be used (for example, sterilisation, final	**A**	**EN980:2008**	**Labelling**		

Checklist according to annex I of the Medical Device Directive (MDD) QF/GK-CE-01/0-10		A/ NA	Standards, other directives and other rules applied by manufacturer	Documentation (test reports, protocols, literature or reason for no applicability)	Requirements fulfilled (to be filled in by Notified Body)	Ok / Fail
	assembly, etc.) 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: k) precautions to be taken in the event of changes in the performance of the device; l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources etc.; m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered; n) precautions to be taken against any special, unusual risks related to the disposal of the device; o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4; p) degree of accuracy claimed for devices with a measuring function. q) date of issue or the latest revision of the instructions for use.			**Instruction for use** QF/GK-CE-01/0-09		

1 Products name: Nasal oxygen cannula

2 Prepared on the basis of : ISO14971:2007 idt YY/T0316-2007.

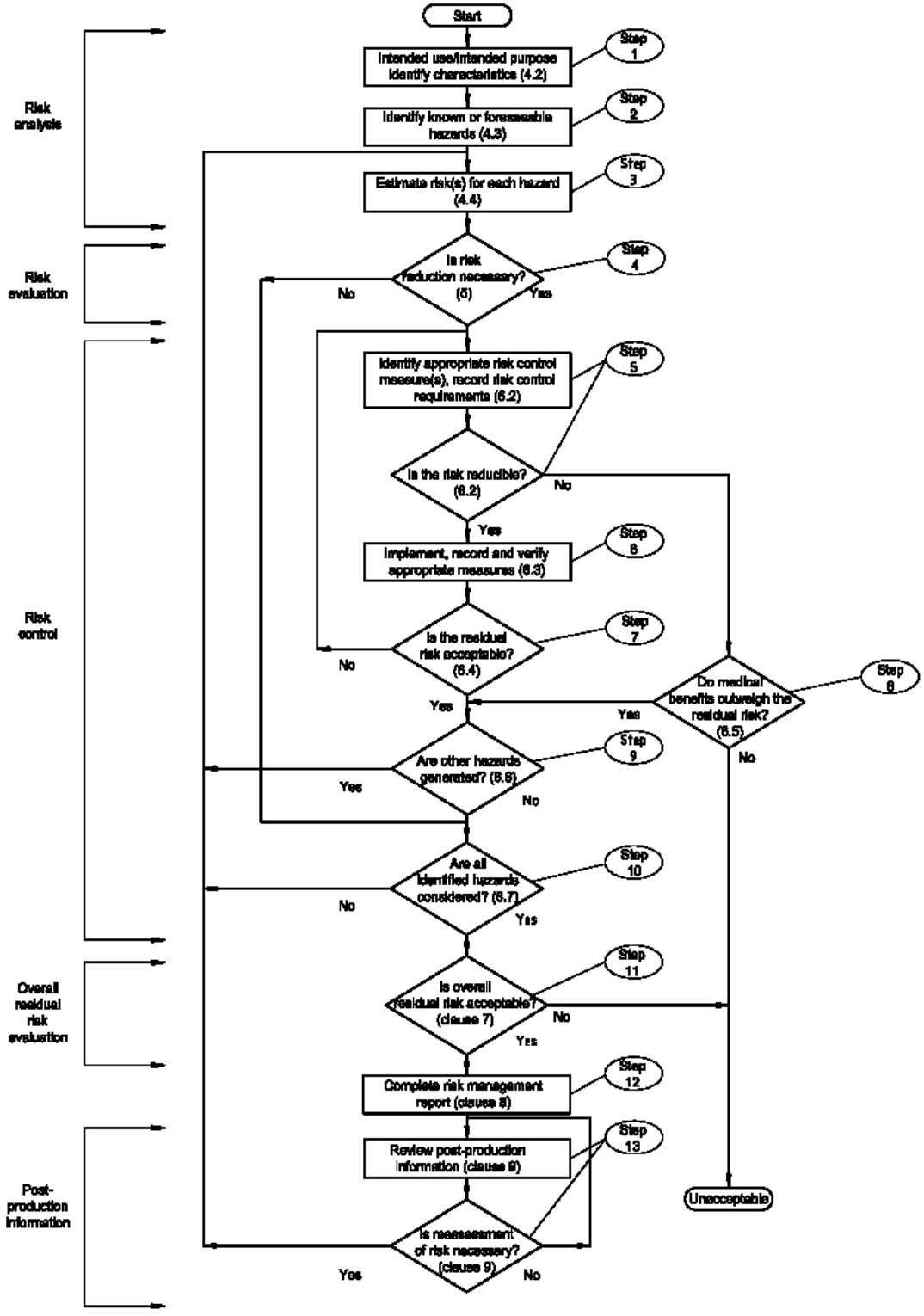


Figure 1 — Overview of risk management activities as applied to medical devices

二、test :

The products are used for one-time use separate patients. Each product must be tested before use in the delivery. Only those products through the identification testing procedures can be used.

三、summarize

According to IS014971-2007 idt YY / T0316-2007《medical device management the first part risk management》to manage risk, The Nasal oxygen cannula the use certainly not to increase any direct risk to the patient, because does not use in the human body, however in certain situation, because the instrument related harm causes not to be able normally to use, constitution indirect risk. Moreover, because operates and so on the use is not standard also can have the harm, therefore risk also within consideration.

四、the procedure of risk management

According to IS014971-2007 idt YY / T0316-2007《 medical device management the first part risk management》to manage risk, Below carries on the risk management to the medical instrument, should consider the procedure.

(1) secure related characteristic determination

(2) determines the harm with the secure related characteristic

(3) to estimate each kind of harm or many risks

(4) the risk assessment

{5) reduces the risk

(6)the surplus risk appraisal

(7) Determines harm which newly produces

{8) Makes the acceptant judgement.

1、With secure related characteristic determination

The medical devicet and the secure related characteristic determination, is the determination is possible to affect the medical instrument secure qualitative and the quota characteristic.

Shows l is the Nasal oxygen cannula and the secure related characteristic.

Shows l

Serial NO	characteristic	determinant
1	Anticipate use	Nasal oxygen cannula mainly used to supply t oxygen in clinical using.
2	using	Operates the use by the medical care personnel
3	Whether contacts with the patient	contact
4	Whether has the material output which did not hope	Only have inception
5	whether is sensitive to the environmental effect	None infection
6	Whether has the storage life limit	Marks on the instruction for use and the packing
7	Whether has the long-term use effect	But the identical patient uses many times
8	Withstands what kind of mechanical power	withstanding certain pulling force
9	The operation uses whether requests special training	The operation medical care personnel must pass through corresponding special-purpose instrument training
10	Product material to human body harm	The biological compatibility is qualified

2、Determines harm which known or may foresee

Based on the medical instrument characteristic quantity judgement, from the energy, the biology, the environment, the use and not the correct material output and so on several principal aspects considered below that, it is possible that the Nasal oxygen cannula be harm to the user to carry on determines the following:

(1) the energy harm

only connects the transmission carrier, does not have the participation the energy, therefore does not have the energy harm.

(2) The biology harm

the product directly contacts the patient skin, therefore possibly causes the biological compatibility harm to the patient, like produces skin stimulat, sends and so on sensitively.

(3) Environment harm

because the storage temperature or the application temperature change can cause the Nasal oxygen cannula to appear the certain degree the life to reduce.

(4) uses the operation harm

a) not or not the suitable operating manual,

b) the operator has not passed through special training.

(4) Not the correct material output produces the harm

the Nasal oxygen cannula not not correct matter output, therefore cannot not good affect to the human body product..

3、Estimates each kind of harm or many risks

Possible to harm to on way judgement each item, the basis objective material, the data, analyze all risks. Among them, the objective material, the data originate following four aspects：

(1) Related standard: Including related international standard, national profession standard, instruction document。

(2) Clinical evidence: Product conclusion or clinical long-term accumulation experience which obtains after the clinical confirmation.

(3) Investigation and study result：

a、Domestic and foreign literature material retrieval；

b、Similar situation investigation and so on product design, manufacture, expiration。

(4) Technical material：

a、Uses the analogy law to carry on the forecast；

b、Using reliability test data.

According to risk definition: "Causes the harm the harm occurrence probability and the harm serious degree", obviously, the risk involves two big essential factors: Has the probability and the serious degree.

Has the probability：

The probability is expressed the event occurs possibility. The medical service holds the weapon harm to have the probability to be possible to divide into six ranks, see Table 2

Table 2

Probability type	grade	define	probability
Frequently occurs	A	Very possible to occur	>10
Sometimes occurs	B	occurs several time during the period of validity	$1\text{-}10^{-1}$
Heterogenesis	C	occurs one time at least during the period of validity	$10^{-1}\text{-}10^{-2}$
Very little occurs	D	May not occur during the period of validity	$10^{-2}\text{-}10^{-4}$
Extremely little occurs	E	Not necessarily can occur, but still had the possibility	$10^{-4}\text{-}10^{-6}$
Extremely little occurs	F	Almost not occur	$<10^{-6}$

Serious degree: Refers to worst consequence measure which the harm creates. According to the medical instrument special details, affects the human body health and the safety injury to the possibility divides into three ranks, see Table 3

Pastes the piece with the above method to the electrode to carry on the risk to estimate that, takes the corresponding measure in view of the risk, causes the original risk to fall to is the surplus risk, and makes the risk estimate table. See Table 4

Table 3

Harm type	grade	Harm degree
Low-grade	1	Mildly is injured or is not injured
serious	2	Causes to be injured
deadly	3	Causes to be GBH or death

Table 4

Serial number	Possible harm	cause	Risk estimate			Prevent measure	Remain risk		
			Harm grade	probability	Risk area		Harm grade	probability	Risk area
1	Raw material since biological compatibility harm;	Material is not qualification	1	B	III	The material must pass through biological compatibility experiment qualification, carries on the qualified appraisal to the supplier, the supplier material quality changes to need promptly to inform the enterprise.	1	F	I
2	Machining production is not qualification	lose control of procedure	1	B	II	Must defer to the product in the product processing process the processing technology document operation	1	F	I
3	The production condign to client is not qualification	delivery examination not to control	2	C	III	After the product goes into storage must carry on delivery examination	2	F	I
4	Not suitable operating manual;	Operate display	2	B	III	The company formulates also conforms to the standard use, maintains the operating manual	2	F	I
5	The operating manual or the instruction booklet are taken away;	Can't be operated	2	B	III	The scene preparation product operation instruction for use, the implementation borrows the registration system	1	F	I
6	Is not skilled or without the training personnel;	Operate improper	3	C	III	Is qualified after the approval, calls the courtyard only then concerned personnel to carry on theory training and practice training.	1	F	I
7	Has the composition part to fall down affects the use	Between each composition part connects not firmly.	3	C	III	Extremity and the wire union spot ought to be able to withstand 15N the radial direction pulling force.	1	F	I
8	The viscose goes to extremes sticks thickly down to uses time feels not comfortably.	The raw material has not examined, belongs to the unqualified raw material	3	C	III	Stocks with goods the examination standard according to the raw material to carry on the examination to each A kind of commodity material, and when the payment use carries on feel to each product the test, the necessity uses the instrumentation equipment to carry on the viscosity test.	1	F	I
9	The production can't be used naturally	Not good memory environment and barbaric means of transportation	3	C	III	The product exterior label must conform to EN 980. And in India "like`the discovery has the obvious quality question on the packing the product please not to use."	2	F	I
10	Across infecting。	The product uses in between the different patient	3	C	III	Is clear about in India on the packing to warn "this product only limits a patient independent employment".	2	F	I

11	Production be Polluted	The packing eak-proof quality s not good or has ittle damages	3	C	III	(1) Examination packing leak-proof quality. (2) Increases an examination procedure to the packing to cause it to conform to the standard requirement; The warning sentence "like the packing damages on the packing, pastes the piece pollution please not to use!"	1	F	I
12	Is unable correctly to derive the signal	The product use surpasses the guarantee time scope	3	B	III	All must have explicitly on each batch of products guarantees the nature time, and warned "ultra posts bond the nature time please not to use!" .	1	F	I

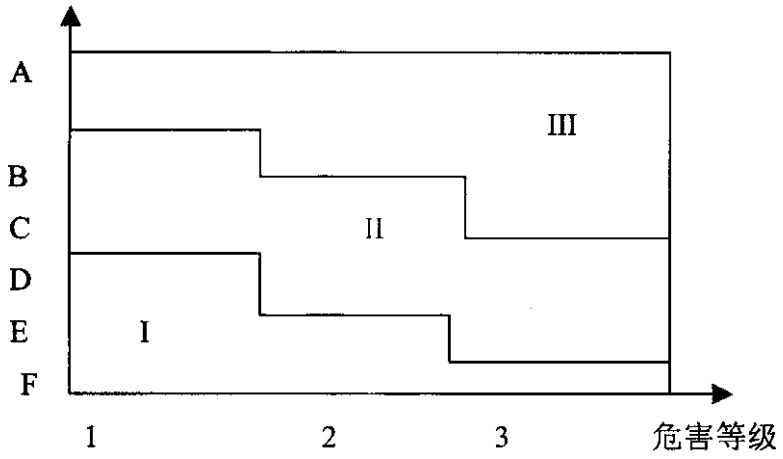
4、risk appraisa

Risk l: According to the possible harm, to carry on the risk probability and the harm degree estimate to it, makes the risk appraisal, namely determination risk acceptability.

Above according to the Farmer curve principle, unifies pastes the piece to the electrode the concrete analysis, generally accepts its risk probability and the harm degree composition the area, reasonable feasible is low level area and cannot accept the area three regions，Enables the risk appraisal to have may be operational (like chart 2) if estimated the risk generally is accepting the area, generally does not need to take the preventive measure: The risk in reasonable feasible is low level area, may consider accepts

the risk benefitor with further to reduce the risk the price, and enable to approach cannot accept nearby the region the risk to reduce as far as possible: The risk in cannot accept,

then must take the preventive measure. After takes the preventive measure, the original risk falls to is the surplus risk, again carries on the appraisal to the surplus risk according to the above method, makes the risk to be possible to accept the judgement. After the appraisal thought the complete surplus risk oneself falls to generally accepts the area and reasonable feasible is low level area, and adopts the preventive measure has not caused the new risk, then may think the risk management basic conclusion; Otherwise, after the appraisal thought surplus risk still might not accept, then should reconsider the product anticipated goal to be suitable the nature.



I generally accepts the area, II reasonable feasible is low level area , III cannot accept the area

Table 2

Risks estimates table is worthy of looking at by the above table in 4, the Nasal oxygen cannula original risk majority of in III level of regions, after uses the preventive measure the surplus risk, all the oneself falls to I level of regions, Also after the appraisal thought above uses the preventive measure cannot have the new risk. Through risk analysis, not only in design, craft, quality system, product packing marking, Aspect and so on instruction for use takes the effective action to reduce the risk, but is high or the harm degree big event to the risk probability, but also must use the security target to give in the product standard to stipulate guarantees the product the security.

Ningbo Shengyurui Medical Appliance Co.,Ltd

2012.04.08

1. Introduction

This report is performed on Nasal oxygen cannula for the purpose of evaluating

1) Performance ; if Nasal oxygen cannula achieve the performances intended by Hangzhou Guankang Medical Device Co.,Ltd
2) Safety ; if undesirable side-effects, under normal conditions of use, are acceptable when weighed against the benefits to the patient

Referenced publications are;

MDD 93/42/EEC Annex X

. ISO 14155-1 Clinical investigation of medical devices for human subjects

2. Device description

1) Overview

Nasal oxygen cannula is mainly made of PVC.

3) Device Name

. Common name : Nasal oxygen cannula

. Trade name : none

4) Indication for use :

Nasal oxygen cannula mainly used to supply t oxygen in clinical using..

5) Information for use

QF/GK-CE-01/0-09. – Instructions for use

3. Clinical information

1) Market history of predicate device

Nasal oxygen cannula is mainly used by PVC, which be safe and easy use.

2) clinical information collecting

Every year, our sales dept will collect the clinical information from our customers(maybe hospital, directly customer, channel intermediaries and so on), and our sales dept will take these information to AD.

AD arrange sales dept, manufacture dept and inspecting dept talking, analysis, and get the according solving results. The according record will be Archived.

All materials of Nasal oxygen cannula have been used as much success for more over 10 years in worldwide. Various modifications of the materials has developed over years. Main manufacturers are 3M, Guangzhou weili and Ningbo shengyurui company..

As the Nasal oxygen cannula, sizes and intended use are similar to the devices marketed, the safety and effectiveness of Nasal oxygen cannula from our company are acceptable.

3.1) Market experience of Nasal oxygen cannula

The Nasal oxygen cannula record is about 100,000 pcs in Dec, 2010 in our company.

3.2) Comparison to Predicate Device

Nasal oxygen cannula series are substantially equivalent in design, function and intended use to currently marketed ones;

Devices Nasal oxygen cannula

Indication

Application of all build-up

Nasal oxygen cannula build-ups of all kinds,

Remark - CE 0120

In addition, the other models have the following points;

Use of the raw material proved of its safety

Same indications

3.3) Performance and safety data

3.4)Clinical status

Nasal oxygen cannula is an “old” device. it has been used as much success for more 20 years in worldwide. It belongs to the medical device which can be used independently. It has many years production in our industry. They were put into clinical use in many hospitals in China and recognized conformably.

Biocompatibility and Physical Test Report

Biocompatibility Assessment Report

4. Conclusion

From the above clinical data, we can conclude that

- Nasal oxygen cannula is not a new device in that;

. The component, raw material, features, method of action is similar to predicate devices.

They have the same indication.

. New material is not applied.

2) Biocompatibility evidence is demonstrated by way

. Experience from previous use

. Testing reports And the biocompatibility evaluation of Nasal oxygen cannula are verified.

The main raw material of PVC. It makes sure the good biocompatibility. Our products also had been tested in the united states, and has been proved to be good quality. We also have exported the products to U.S.A and south-east Asian and so on. The products are accepted by people because their benefit is higher than lateral risk. The quality of products is safe, effective, and being elevated

steadily. The products gained users’ recognition and good comments in long-term clinical uses.