CE Technical File of Oropharyngeal Airways

Control status	
Hold No.	
Release date	

Prepared by	Reviewed by	Approved by

Contents

Note: In accordance with requirements of medical device directive, the CE technical documents of our company include the above 6 parts. The other parts of CE technical document include product description, pre-clinical study report, biological evaluation report, packing qualification report, manufacture flow chart and sterilization qualification report, which are retained by OEM-supplier. The supplier will offer the above documents in accordance with Quality Assurance Agreement if necessary.

01 Declaration of Conformity

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Product Name: Oropharyngeal Airways
Classification: I sterile
Classification and relevant Rule of MDD 93/42/EEC: Annex IX, Rule 5
UMDNS code: 10059
CE conformity assessment route: Annex V.3 of MDD 93/42/EEC

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the promises of the manufacturer.

DIRECTIVES
General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 JUNE 1993 concerning medical devices (93/42/EEC).

Notified Body: TUV SUD Product Service GmbH Ridlerstr.65, 80339 München, Germany
Identification Number: 0123
CE Certificate No.: G2S.15.12.86250.008
Expiry date of CE Certificate: 2021-01-03
Date of CE mark beginning to mark: Not mark till now

Signature of issuing person: _____
Name: Yehui Gu
Position: General Manager
Date: 2016-04-08
Place: Yuyao City, Zhejiang Province, China

02 Product Introduction

1 Introduction of the company

Ningbo Luke Medical Devices Co., Ltd. is a professional medical devices manufacturer. The main products cover Anesthesiology, Respiratory, Urology, Wound Drainage and Gastroenterology.

Luke focused on providing high quality and low price medical devices purchased from China mainland. In order to develop solidly and rapidly, we invested and established our own medical devices factory in Hangzhou, China, in 2005.

Today, our main products consist of laryngeal mask, foley catheter, drainage tubes, stomach tube and manual resuscitator etc. Most of them have passed ISO: 13485, CE and FDA certification or registration. And the Luke's products have been expressed worldwide with a good reputation.

With our own medical device factory, experienced team, innovative products and China branch office, Luke will dedicate itself to human's health further in future. Luke, on the way.

2 Product introduction

The Oropharyngeal Airways is made from the raw material of PE for medical use, used for forming an airway between oral cavity and pharynx and assist for cavity and pharynx operation.

3 Intended uses of product

This product is intended for forming an airway between oral cavity and pharynx and assist for cavity and pharynx operation.

4 Contraindications

- Do not use if the package is damaged;
- For single use only;
- Use immediately after packaging is openned;
- Destroy after use according to local regulations.

5 Classification of product

According to the intended use and purpose of the product, we define and classify the product as Class I sterile in accordance with 93/42/EEC, Annex IX, rule 5.

6 CE conformity assessment route:

Annex V.3 of MDD 93/42/EEC

03 Essential Requirements Checklist

1 List of applicable standards:

S/N	Document number	Edition	Title
1	EN ISO 13485	2012	Quality system——Medical devices-Particular requirements
2	93/42/EEC	Amended in 2007	Medical Device Directive
3	EN ISO 14971	2012	Medical devices - Application of risk management to medical devices
4	EN ISO 10993-1	2009	Biological Evaluation of Medical Device——Part 1: Evaluation and testing within a risk management process
5	EN ISO 10993-5	2009	Biological Evaluation of Medical Device——Part 5: Test for in vitro cytotoxicity
6	EN ISO 10993-7	2008	Biological evaluation of medical devices ——Part 7: Ethylene oxide sterilization residuals
7	EN ISO 10993-10	2010	Biological Evaluation of Medical Device——Part 10: Test for Irritation and delayed -type hypersensitivity
8	EN ISO 15223-1	2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9	EN 1041	2008	Terminology, Symbols and Information with Medical Devices; Information supplied by the manufacturer with medical devices
10	EN ISO 14155	2011	Clinical investigation of medical device for human subjects
11	EN ISO 11607-1	2009	Packaging for terminally sterilized Medical Device Part 1: Requirement for materials, sterile barrier systems and packaging systems
12	EN ISO 11607-2	2006	Packaging for terminally sterilized Medical Device——Part 2: Validation Requirement for forming, sealing and assembly process
13	EN ISO 11737-1	2006	Sterilization of Medical Device-Microbiological methods ——part 1: Determination of population of microorganisms on products
14	EN ISO 11737-2	2009	Sterilization of Medical Device-Microbiological methods ——part 2: Tests of sterility performed in the validation of a sterilization process
15	EN ISO 11135-1	2007	Sterilization of health care products - Ethylene Oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
16	EN ISO 11138-2	2009	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes

2 List of essential requirements:

Essential Requirements	A-N/A	Standards	Manufacturers Compliance	Reserved Sector
1 The devices must be designed and manufactured in such a way that when used under the conditions and for the purposes intended they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include: --Reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used(design for patient safety),and --consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	A	EN ISO 14971	LK-TF-16-04 Risk Management Report LK-TF-16-05 Clinical Evaluation	Quality Department
2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order. -eliminate or reduce risks as far as possible (inherently safe design and construction). -where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated. -inform users of the residual risks due to any shortcomings of the protection measures adopted.	A	EN ISO 14971	LK-TF-16-04 Risk Management Report	Quality Department
3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1(a), as specified by the manufacturer.	A	EN ISO 11607-1/2	Performance Test Report Validation of Packaging	OEM-supplier
4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and. where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	A	EN ISO 11607-1/2	Performance Test Report Validation of Packaging	OEM-supplier
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 11607-1/2	Performance Test Report Validation of Packaging	OEM-supplier
6. Any undesirable side effect must constitute an	A	EN ISO	LK-TF-16-04	Quality

acceptable risk when weighed against the performances intended.		14971	Risk Management Report	Department
6a.Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	A	MDD Annex X	LK-TF-16-05 Clinical Evaluation	Quality Department
7.chemical, physical and biological properties 7.1 The devices must be designed and manufactured in such away as to guarantee the characteristics and performances referred to in section o 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.	A	EN ISO 10993-1 EN ISO 10993-5 EN ISO 10993-10	Total Performance Test Report	OEM-supplier
-Where appropriate, the results of biophysical or modeling research whose validity has been demonstrated beforehand.	N/A			
7.2The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.	A	EN ISO 14971	Single use product LK-TF-16-04 Risk Management Report	Quality Department
7.3 The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	A	Product standard EN ISO 11607-1/2	Performance Test Report Validation of Packaging	OEM-supplier
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 competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation(EC) No 726/2004 on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA	N/A			

shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the devices as determined by the notified body. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.				
Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that 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 device, 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.	N/A			
7.5The 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	A	Product standard	Total Performance Test Report	OEM-supplier
Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relation to the classification, packaging and labeling of dangerous substances. If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body. or devices intended for transport and storage of such body fluids or substances,	N/A			

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 labeling 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 p0articular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.				
7.6 Devices must be designed and manufactured in such a way as to reduce as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	A	EN ISO 11607-1/2	Total Performance Test Report Validation of Packaging	OEM-supplier
8.Infection and microbial contamination 8.1 The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.	A		Single use product	
8.2 Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance accepted to the intended use of the tissues. Notified bodies shall retain information on the geographical origin of the animals. Processing, preservation testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transferable agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	N/A			
8.3 Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down until the protective packaging is damaged or opened, 8.4Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	A	EN ISO 11135-1 EN ISO 11607-1/2	Validation of Sterilization Validation of Packaging	OEM-supplier
8.5 Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	A	EN ISO 14644	Procedure for Environment Control	OEM-supplier
8.6 Packaging systems for non-sterile devices must keep the	N/A			

product without deterioration at the level of cleanliness stipulated and if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.				
8.7 The packaging and /or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	N/A			
9 Construction and environmental properties 9.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the correction system must be safe and must not impair the specified performances of the devices the restrictions on use must be indicated on the label or in the instructions for use (Product Labeling).	A	EN ISO 14971	Single use product LK-TF-16-04 Risk Management Report	Quality Department
9.2 Devices must be designed and manufactured in such a way as to remove or minimize is far as is possible: the risk of injury in connection with their physical features including the volume/pressure ratio, dimensional and where appropriate ergonomic features, risk connected with reasonably reasonable environmental conditions, such as magnetic fields external electrical influences, ecstatic 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 aging of materials used or loss of accuracy of any measuring or control any measuring or control mechanism.	N/A			
9.3 Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and a single fault condition,. particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	N/A			
10.Devices with a measuring function 10.1 Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device The limits of accuracy must be indicated by the manufacturer.	N/A			
10.2 The measurement monitoring and display scale must designed N/A in line with ergonomic principles, taking account of the intended purpose of the device.	N/A			
10.3 The measurements made by with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC.	N/A			
11. Protection against radiation 11.1 General 11.1.1. Devices stall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose whilst not restricting the	N/A			

application of appropriate specified levels for therapeutic and diagnostic purposes.				
11.2. Intended recitation 11.2.1 Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibly and tolerance of relevant variable parameters. 11.2.2. Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	N/A			
11.3 Unintended radiation Devices shall be designed and manufactured in such a way that exposure of patients, users are other persons to the emission of unintended, stray or scattered radiation is reduced as fares possible.	N/A			
11.4. 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 tissues and of eliminating the risks inherent in installation.	N/A			
11.5 Ionizing radiation 11.5.1 Devices intended to emit ionizing radiation must be designed and manufactured In such a way as in ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended. 11.5.2. Devices enrolling ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user. 11.5.3. Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose. The bean type and energy and where appropriate the quality of radiation.	N/A			
12. Requirements for medical devices connected to or equipped with an energy source 12.1 Devices incorporating electronic programmable systems must he designed to ensure the repeatability reliability and performance of these systems according to the intended use in the event of a single fault condition(in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks. 12.1a For device 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	N/A			

management, validation and verification.				
12.2 Devices where the safety of use patients depends on an internal power supply must be equipped with a means of determining the state of the power supply	N/A			
12.3 Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure	N/A			
12.4 Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patients state of health	N/A			
12.5. Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment	N/A			
12.6 protection against electrical risks Devices must be designed and manufactured in such a way as to avoid as far as possible the risk of accidental electric shocks during normal use and in single fault condition provided the devices are installed correctly	N/A			
12.7 protection against mechanical and thermal risks 12.7.1 Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, resistance, stability and moving parts 12.7. 2 Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source unless the vibrations are part of the specified performance 12.7.3 Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance 12.7.4Terminals and connectors to the electricity gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks 12.7.5 Accessible parts of the devices (excluding the parts or areas intended to supply beat or reach given temperatures) and their surroundings must mot attain potentially dangerous temperatures under normal use.	N/A			
12.8. Protection against the risks posed to the patient by energy supplies or substances 12.8.1 Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	N/A			

12.8.2 Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance scarce.				
12.9. The function of the controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and. as appropriate the patient.	N/A			
13Information supplied by the manufacturer 13.1. Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the poetical users. This information comprises the details on the label and the data In the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sizes packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.	A	EN ISO 15223-1 EN 1041	LK-TF-16-06 Label and language	Quality Department
13.2. Where appropriate, this information should take the form of symbols. Any symbol or identification color used must conform to the harmonized standards. In areas for which no standards exist, the symbols and collars must be described in the documentation supplied with the device.	A	EN ISO 15223-1 EN 1041	LK-TF-16-06 Label and language	Quality Department
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 authorized 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 contorts 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 devices is	A	EN ISO 15223-1 EN 1041	LK-TF-16-06 Label and language	Quality Department

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';	N/A			
(i) any special storage and/or handing conditions; (j) any special operating instructions; (k) any warnings and/or precautions to take;	A	EN ISO 15223-1 EN 1041	LK-TF-16-06 Label and language	Quality Department
(l) year of manufacture for active devices other than those covered by(e). This indication may be included in the batch or serial number.	N/A			
(m) Where applicable, method of sterilization.	A	EN ISO 15223-1 EN 1041	LK-TF-16-06 Label and language	Quality Department
13.4 If the intended purpose of the device is not obvious to the user, the manufacturer must clearly stare it on the label and in the instructions for use.	A	EN ISO 15223-1 EN 1041	LK-TF-16-06 Label and language	Quality Department
13.5 wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	N/A			
13.6 where appropriate, the instructions for use must contain the following particulars: (a) the details referred to in Section 13.3, with the exception of (d) and (e); (b) the performances referred to in Section 3 and any undesirable side-effects; (c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;	N/A			
(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 property 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 of treatment;	N/A			
(g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate details of appropriate methods of sterilization; if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfecting, packaging and, where appropriate,	A	EN ISO 15223-1 EN 1041	LK-TF-16-06 Label and language	Quality Department

	detail of appropriate method of sterilization;				
(h)	if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section1;	N/A			
	If the device bears an indication that the device is for single use, information on known characteristics and technical factors 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.	A	EN ISO 15223-1 EN 1041	LK-TF-16-06 Label and language	Quality Department
(i)	details of any further treatment or handing needed before the device can be used (for example, sterilization, final assembly, etc.);	N/A			
(j)	In the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation. The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details shout 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/A			
(n)	precaution to be taken against any special unusual risks related to the disposal of the device;				
(o)	medicinal substances incorporated into the device as an integral part in accordance with Section 7.4. Not only medicinal substances(as up to now), also human blood derivates contained in a device must be indicated in the IFU.				
(p)	degree of accuracy claimed for devices with a measuring function.				
(q)	The date of issue or the latest revision of the IFU must be indicated.				

04 Risk Management Report

Contents

1 Foreword

This document is about the risk management to Oropharyngeal Airways, overall potential harms and the potential reasons of each hazard are identified in the article. The likely degree caused by every hazard and the probability are evaluated. The necessary measures must be adopted to the risks which are not acceptable, and the residual risk level must evaluated.

Result: The risks which cause potential hazard reduce to the acceptable level by the proper measures. And the all risks accumulated from every kind of risk reduce to the acceptable level too.

2 Purposes

The purpose of this risk management is identification to Oropharyngeal Airways which has sell production. Elaborate the necessary related measures, so that the risk is controlled to the acceptable levels. The company can adopt the appropriate measures to improve the product by the risk management and advance the quality of product, so it can meet the regulated and potential demand of clients.

3 Applicable scope

The product which this risk analysis is applicable to: Oropharyngeal Airways

4 References

1)93/42/EEC

2)EN ISO 14971: 2012 <Medical device—Application of risk management to medical device>

5 Object of risk management

5.1 Intended use

Oropharyngeal Airways is intended for forming an airway between oral cavity and pharynx and assist for cavity and pharynx operation.

5.2 Picture:

5.3 Applicable environment

- Strictly prohibit using it if the package is broken;
- It is used only once;
- It must be destroyed immediately after using;
- It must be used after opening the package.

6 Implementation of risk control process

6.1 Step 1: Intended use and identification of characteristics related to the safety of the medical device.

6.1.1 Risk management of life cycle

Risk management is accompanying the overall life cycle process of product, from the input of order form, production, to the output of service, and the evaluation to feedback information system after selling.

The primary risk management is carried out in the design stage. It will put forward requirement to reduce and risk control. In the special stage of developing stage it should validate whether there is new hazard, whether the existent hazard level valuation and valuation of hazard probability is effective, make necessary modification.

Risk management should be commented, the completeness and accuracy should be identified after developing work is finished formal.

Feedback information is not gained from practice in the developing stage. Risk management should be validated again if the feedback of safety problem in the production and using process is gained, and make necessary modification.

6.1.2 Risk management group

Risk management is carried out by special personnel from many departments. It includes the following members:

Name	Position	Responsibility scope
Yehui Gu	Manager of Sales department	Analysis the risk of product about feedback and complaint of clients
Wencheng Shen	Management Representative	Monitor of item is responsible for the implement of risk management
Yehua Zhang	Quality Manager	Evaluate the potential risk and propose the preventive actions to reduce the risk.
OEM-supplier	Supplier	Evaluate the pollution and production defect in production process
		Evaluate the probability of hardware trouble about techniques.
		Estimate the degree of hazard about biology, physics and practical inspection

6.1.3 Intended use and identification of characteristics related to the safety of the medical device(See Risk Management Report kept in the supplier.).

6.2 Step 2: Identification of known or foreseeable hazards

The hazard “H_…” sign is used to designate in the risk management sheet.

Source of information:

The following information can be used in the list of potential hazard:

- Risk analysis report similar product
- Investigation to developer of product

- Expert judgment
- Analysis the report of the foreign department of medical device
- Study the related measures to reduce risk in the similar product, it often suppose the hazard at first.
- The scene information is gained from the similar product which has been used, service report, complaint and accident record.

Related potential hazard

Identification of related potential hazard from group is followed:

1) Determine related potential hazard and List of risk management according to selecting supplier, confirming the special clauses in the contract and after selling see Attachment A.

2) Determine related potential hazard and List of risk management about patient, users(E.g.: doctor,nurse) and cause the trouble of other technical equipment according to design development, production and inspection, See Risk Management Report kept in the supplier.

6.3 Severity valuation of each hazard

Severity valuation of each hazard is judged by the medical expert and the quantitative identification is given(in the form of severity).

Rate	Severity levels	Possible description
1	Negligible	Inconvenience or temporary discomfort
2	Minor	Results in temporary injury or impairment not requiring professional medical intervention
3	Serious	Results in injury or impairment requiring professional medical intervention
4	Critical	Results in permanent impairment or life-threatening injury
5	Catastrophic	Results in patient death

6.4 Identification to the potential reason of each hazard

All members of group firstly search for the potential reason straight through the special knowledge of every person.

Search for the reason of hazard and take record in the “reason” column of risk management, mark it with the sign “C…”

6.5Evaluation to the probability of every reason

The probability of potential reason of hazard should be evaluated. Besides the related information source is:

a) Similar product using experience(such as: service statistics data)
b) Approved technical regulation(such as: intensity calculation)
c) Self life cycle investigation

d) Expert judgment

These estimations are classed to six kinds by engineering expert.

Rate	Classification	Description
1	Impossible	$<10^{-6}$
2	Remote	$<10^{-5}$ and $\geqslant 10^{-6}$
3	Occasional	$<10^{-4}$ and $\geqslant 10^{-5}$
4	Probable	$<10^{-3}$ and $\geqslant 10^{-4}$
5	Frequent	$\geqslant 10^{-3}$

6.6 Step 3: Risk evaluation(before adopting control measures)

Two risk factors are summed in the first hazard/ reason: severity of hazard and occurring probability, and the related risk. Three "risk areas" can be defined in accordance with the suggestion of EN ISO 14971:

1 unacceptable area 2 acceptable area

3 ALARP(As Low As Reasonably Practicable) reasonable reducing area

6.7 Step4: risk evaluation

Refer to the following list

Rate		1	2	3	4	5
	Severity / Probability	Negligible	Minor	Serious	Critical	Catastrophic
5	Frequent	ALARP	NAC	NAC	NAC	NAC
4	Possible	ALARP	ALARP	NAC	NAC	NAC
3	Occasional	ALARP	ALARP	ALARP	ALARP	NAC
2	Remote	AC	ALARP	ALARP	ALARP	ALARP
1	Impossible	AC	AC	ALARP	ALARP	ALARP

NAC=unacceptable AC= Acceptable ALARP=Reasonable reducing area

The estimated risk to each hazard/ reason is written in the "R" column of risk management list with the form of classification (NAC/AC/ALARP), give clear indication if it has control measures.

6.8 Step5 and 6: Adopt risk control measures

If the estimated risk is not acceptable when control measure is not adopted, the control measures of each hazard/ reason must be adopted. If several control measures are drawn out, the effectiveness is the result adopting related measures.

Measures are written in "related measure" column in the risk management list, mark it with the sign "M…".

6.9 Step 7: Residual risk analysis

Adopting control measure will reduce hazard degree or occurring probability, or these two will reduce. One kind of related measure will reduce the risk factor(hazard degree or occurring probability) to some degree which can not be identified quantitatively. Residual risk evaluation is analyzed and summarized by the members

of group with the special knowledge.
Change of each classification is written in “residual risk” column in the risk management list.
Residual risk of each hazard/reason can be identified in the area in accordance with the list of the former chapter (NAC/AC/ALARP)

6.10 Step 8: Risk /benefit analysis

ALARP does not show to reach the purpose, only further risk reducing measure will cause the expense larger than the benefit it is not be practical in techniques, it is can be acceptable when the benefit is larger than risk. If the result is ALARP after reducing risk, explanation must be given why the further reducing risk is not practical.

6.11 Step 9, 10, 11

7 Step 12: Result of risk management

As indicated in Attachment A and Risk Management Report kept in the supplier for the risk management list, residual risk of each hazard/ reason is reduced the accept table scope or ALARP, in the meantime each ALARP situation is not practical, why the further reducing risk is not practical. The following list indicates that adopting or not adopting measure will have hazard/reason. Therefore after taking related actions, there is no unacceptable risk.
Because Oropharyngeal Airwaysis extensively used all over the world, its medical use is obviously, its strong points are not said too much. Because its residual risk is little, its benefit is larger its risk.

8 Attachment A: List of risk management

Possible harm	ID reason	Before adopting measure			ID control measure	New risk	after adopting measure			Acceptable determinant
		S	P	R			S	P	R	
Confirm the harm of product the requirement of clients	The related requirements in the contract is not clear, communication with clients is not enough.	2	3	ALARP	Make out “Process control procedures related with clients” in the document, know the requirements in the clauses, confirm the clear and connotative requirements of clients, the related statute with product and the enclosed requirements of enterprise, reserve the evidence of enforcement.	N	2	1)	AC	Y
Harm in the selection of suppliers	No or improper document regulation	3)	2)	ALARP	Make out “Control procedures to supplier assess” in the document, enforce the assess of supplier, obtain legal quality information which can ensure the quality of product.	N	3)	1)	ALARP	Y
Harm in the communication with suppliers on the special clauses of product	Do not know special requirements, some necessary clauses are not communicated with supplier.	3)	2)	ALARP	Know special requirements, clarify its importance, put it in the “quality agreement”, the both party sign in it, the supplier is asked to promise to fulfill the contract.	N	3)	1)	ALARP	Y
Supervision about harm related product after selling	1. The regulation is not written in the document about supervision after selling. 2. Don’t carry out according to the document or not carry out completely. 3. Don’t notice the information of product after selling to other company the related data.	2)	3)	ALARP	Set supervision procedure after selling in the document, the personnel engaging selling work must be trained about it, the principal in the department must control the enforcement of it.	N	2)	2)	ALARP	Y

05 Clinical Evaluation

1 Purpose

According to the requirements of the Annex X of 93/42/EEC, we compile this Clinical Evaluation to certify that the products of our company are fulfilled the requirements of the Annex 1. I.e. the CE products, Oropharyngeal Airways, must give a evidence of the clinical performance and safety is qualified, appropriate and adequate to conform with the pertinent essential requirements of the Directive, and risks and side effects is acceptable when weighed against the intended benefits of the device.

2 Product introductions, Intended use, Contraindications

See Chapter 02.

3 Situations of Product Selling and Feedback from Clients

Since the foundation of the company, we always select the suppliers, which have mature technology, good quality, manufacture by machine, and have passed the quality management system and CE certificate according to ISO 13485 and MDD directive requirements. The company has established trade relation with many countries such as America, Middle East, Europe.

Since our company sold Oropharyngeal Airways, according to the result of client, from the production capability, environment and quality system of suppliers, these things mean the products are safe. It has never received any complaint of customers with the product quality such as their physical-chemical specifications, and never lead or has led to death or health deterioration of users or patients.

6 Detailed Clinical Evaluation collection is kept in the supplier.

7 In Part 04 《Risk Management Report》had been made on the possible risk of the products about the confirmation of customers and suppliers, analysis is made about the possible risk of patients and users, and effective actions is adopted for controlling the possible risk, the risk have been taken to reduce it to and acceptable extent. The report shows that the application value of the product is much larger than their risk

It can be concluded from the above that the product of this company can be safely used as Oropharyngeal Airways. The application value of the product is much larger than their risk; it can be used as medical device.

06 Label and Language

1 According to LK-QP-9.0-05《Label and language control procedure》, EN ISO 15223-1 and EN 1041, we have drafted small, middle and outer pack label of Oropharyngeal Airways, more details see Attachment.

2 Related documentations

a) EN ISO 15223-1:2012 《Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements》
b) EN 1041:2008《Terminology, Symbols and Information with Medical Devices; Information supplied by the manufacturer with medical devices》
c) LK-QP-9.0-05《Label and language control procedure》

3 Attachments

Attachment 1: Oropharyngeal Airways primary package labeling sample
Attachment 2: Oropharyngeal Airways middle package labeling sample
Attachment 3: Oropharyngeal Airways outer package labeling sample

Attachment 1: Oropharyngeal Airways primary package labeling sample

Oropharyngeal Airway

CE 0123

REF xxxxxx

STERILE EO

Qty.: ___1___pc

Use immediately after packaging is opened

xxxxxx

Do not use if package is damaged

Ningbo Luke Medical Devices Co., Ltd.
Gujiayan, Yangming Road, 315400 Yuyao City, Zhejiang Province, People's Republic of China
Telephone: 86-574-22661850
Fax: 86-574-22661880

LOT xxxxxx

xxxxxx

EC REP

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Tel: (0031)0631000394

Ver.3 / Issued on 2013-09-15

Attachment 2: Oropharyngeal Airways middle package labeling sample

Oropharyngeal Airways

CE 0123

REF xxxxxx

STERILE EO

Qty.: _____pcs

Use immediately after packaging is opened

xxxxxx

Do not use if package is damaged

Ningbo Luke Medical Devices Co., Ltd.
Gujiayan, Yangming Road, 315400 Yuyao City, Zhejiang Province, People's Republic of China
Telephone: 86-574-22661850
Fax: 86-574-22661880

LOT xxxxxx

xxxxxx

EC REP

Weihua Hu
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Ver.3 / Issued on 2013-09-15

Attachment 3: Oropharyngeal Airways outer package labeling sample

Oropharyngeal Airways

CE 0123

REF xxxxxx

STERILE EO

Qty.: _____pcs

Use immediately after packaging is opened

xxxxxx

Do not use if package is damaged

Ningbo Luke Medical Devices Co., Ltd.
Gujiayan, Yangming Road, 315400 Yuyao City, Zhejiang Province, People's Republic of China
Telephone: 86-574-22661850
Fax: 86-574-22661880

LOT xxxxxx

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