CE Technical Files

Medical Face Mask

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Issued By	Yang Mei	Date	2020.07.20
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Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A/0	Initial Release	Yang Mei	2020.07.20

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Technical File

<Product: Medical Face Mask>
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Date	2020.07.20	**Date**	2020.07.20	**Date**	2020.07.20
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MEDLINK(SONGZI)MEDICAL PRODUCTS CO., LTD
LIYE RD, XINJANGKOU TOWN, SONGZI CITY, JINGZHOU CITY, HUBEI PROVINCE, CHINA

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1 General Description

1.1 Device description and specification

Medical Face Mask is used as barrier for user working in general medical environment to avoid unwanted inhalation or protecting from spray and spill to avoid any unexpected infection of flu or disease.

This device is a disposable product, suitable for the health care of the wearer in the general medical environment and the general care in public health places where there is any risk of bodily fluids and spillage.

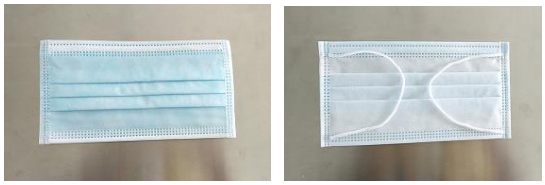
Medical Face Mask is going to contact with the intact skin of the user, and it has been tested according to related compatibility standards including ISO 10993-1:2018, EN ISO10993-5： 2009 and EN ISO 10993-10:2013, please refer to Annex 3 <biocompatibility test report>.

The Medical Face Mask also must meet the requirements of EN 14683:2019 (please refer to: Annex 2 <performance test of EN14683>).

Material for Medical Face Mask as follows:

No.	Component	Material Used
1	Outside Layer	Spunbond Polypropylene 25 g/m^2
2	Middle Layer	Meltblown Polypropylene 25 g/m^2
3	Inside Layer	Spunbond Polypropylene 25 g/m^2
4	Nose Wire	Polyethylene coated steel wire
5	Ear Loops	Terylene and spandex

The product images and specification of Medical Face Mask are shown as below.

Photo	
Specifications	17.5cm*9.5cm（±0.5cm）

Executive Standard: EN 14683:2019+AC:2019
Protection Grade: Type IIR

Intended Use

The Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

Packaging and Storage

The products were generally packed 10 pcs per box, and 2000 pcs per carton. Also we can pack the quantity and pack system style under the customer’s requirements.

Do not store in temperature above 104"F (40'C). Store away from direct sunlight, x-ray devices, and any intense artificial light.

How to use the device

1. Open the packaging pouch and take out the mask.
2. Place the side with nose piece upward. Hang the ear loops on the ears.
3. Press the nose piece to fit the bridge of the nose, then press the nose piece and pull the lower end of the mask to the lower jaw.
4. Adjust the mask so that it covers the bridge of the nose to the lower jaw in order to get the best protection effect.

How to remove the device

When the user wants to remove the Medical Face Mask, he shall first move to the safety environment and then remove the Medical Face Mask.

Shelf Life

3 years

Precaution and Warning

1. Check the package completeness before using. Check the label, manufacturing date and validity time, to make sure the product is in valid date.
2. Do not use if the package damaged.
3. Do not reuse. Reusing may cause cross-contamination.

Disposal

Please dispose the product after use to comply with local regulation.

Harmonized standards

No.	Standard No.	Version	Title
1	(EU) 2017/745	2017	Medical Device Regulation
2	EN ISO 14971	2019	Medical Device -Application of Risk Management to Medical Devices
3	EN ISO 15223-1	2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements.
4	ISO 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
6	EN ISO 10993-10	2013	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
7	EN 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices
8	EN 1041	2008+A 1:2013	Terminology, Symbols and Information Related to Medical Devices –Information supplied by the manufacturer of medical devices
9	EN 14683	2019	Medical Face Masks — Requirements and test methods

Classification

According to Rule1, Annex VIII (Rule1: All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies) of Medical Device Regulation (EU)2017/745, based on the intended use of Medical Face Mask, it shall be Class I.

UDI

We will apply the UDI and have the UDI-DI placed on the label of devices before May 26, 2025 as per the requirement of Article 123, 3f) of Medical Device Regulation (EU)2017/745.

SRN

We plan to get SRN by registering in EUDAMED once it's fully functional as soon as

the product is evaluated to conform to Medical Device Regulation (EU)2017/745.

1.2 Reference to previous and similar generations of the device

The masks are pleated 3 plys single use, disposable masks. Inner layers and outer layers are made of spun-bond polypropylene nonwoven fabric. Middle layer is made of melt blown polypropylene filter. Earloops are Knitted Elastic loops.

Medical Face Masks are suitable for medical workers and family workers working in general medical environment.

The raw materials of Medical Face Mask are non-woven, melt-blown nonwoven. We develop the Medical Face Mask base on the similar product which has been sold and wildly use in the market, no previous and similar generations of the device was exist.

2 Information to be supplied by the manufacturer

2.1 Label and Language

The label was designed according to the standard of EN ISO 15223-1：2016 and requirement of Clause 23.2, Annex I <General Safety and Performance Requirements> of Regulation (EU) 2017/745.

2.1.1 General

This Clause contains symbols that are already in use, and are deemed to be suitable without need for further explanation.

NOTE Symbols used with medical devices for use by other than healthcare professionals can require additional explanations.

2.1.2 Symbol for "DO NOT REUSE"

NOTE 1 Synonyms for "Do not reuse" are "single use, "Use only once"

2.1.3 Symbol for “BATCH CODE”

This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol.

NOTE 1 The relative size of the symbol and the size of the batch code are not specified.

NOTE 2 Synonyms for "batch code" are "lot number", "batch number".

2.1.4 Symbol for "DATE OF MANUFACTURE"

This symbol shall be accompanied by a date to indicate the date of manufacture, expressed as given in ISO 8601, as four digits for the year, and where appropriate, two digits for the month and two digits for the day. The date could be a year, year and month, or year, month, and day, as required by the relevant Directive. The date shall be located adjacent to the symbol.
NOTE 1 The relative sizes of the symbol and the date are not specified.

2.1.5 Symbol for "CATALOGUE NUMBER"

The manufacturer's catalogue number shall be after or below the symbol adjacent to it .
NOTE 1 The relative size of the symbol and the size of the catalogue number are not specified.
NOTE 2 Synonyms for "catalogue number" are "reference number", "re-order number".

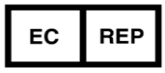
2.1.6 Symbol for "CAUTION"

NOTE 1 This symbol is essentially a safety symbol and should be used to highlight the fact that there are specific warnings or precautions associated with the device, which are not otherwise found on the label. The symbol “Caution” is still sometimes used to have the meaning of “Attention, see instructions for use”.

2.1.7 Symbol for "MANUFACTURER"

This symbol shall be accompanied by the name and the address of the manufacturer (the person placing the device on the market), adjacent to the symbol.

2.1.8 Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"



This symbol shall be accompanied by the name and the address of the authorised representative in the European Community, adjacent to the symbol (see A.8).

NOTE The relative size of the symbol and the size of the name and address are not specified.

b) Diameter of the pattern shall not be less than 5mm.

c) CE marking shall be distinct, visible, durable and in clear writing.

2.1.9 After passing CE certification, mark of CE needs to be printed on labels;

a) Pattern CE

b) Diameter of the pattern shall not be less than 5mm.

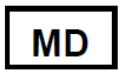
c) CE marking shall be distinct, visible durable and in clear writing.

2.1.10 Symbol for "NON-STERILE"

NOTE 1 This symbol should only be used to distinguish between identical or similar devices sold in both sterile and non-sterile conditions.

NOTE 2 This symbol corresponds to that given in ISO 7000-2609 and to symbol number 5.26 in EN ISO 15223-1:2016.

2.1.11 Symbol for "Medical Device"



This symbol indicated that the device is a medical device.

2.1.12 Symbol for "Keep dry"

NOTE This symbol can also mean "Keep away from rain" as referenced in ISO 7000.

2.1.13 Symbol for "Keep away from sunlight"

NOTE This symbol can also mean "Keep away from heat", as referenced in ISO 7000.

2.1.14 Examples of use of symbol for "DATE OF MANUFACTURE"

2004-06

2005 

2.1.15 Examples of use of symbol for "CATALOGUE NUMBER"

REF ABC123

2.1.16 Example of use of symbol for "MANUFACTURER"

Company Name:
Company Address:

2.1.17 Example of use of symbol for “MANUFACTURER” combined with “DATE OFMANUFACTURE”

Company Name:
Company Address:
Manufacture Date:

2.1.18 Example of use of symbol for " AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"

Company：
Address：

2.1.19 Language Requirements for Labeling in the EU Member States

Language / Country	Bulgarian	Croatian	English	Czech	Dutch	Danish	Estonian	Finnish	French	German	Greek	Hungarian	Irish	Italian	Latvian	Lithuanian	Maltese	Polish	Portuguese	Romanian	Slovak	Slovenian	Spanish	Swedish	Norwegian
Austria										★															
Belgium					★				★																
Bulgaria	★																								
Cyprus											★														
Croatia		★																							
Czechia				★																					
Denmark						★																			
Estonia							★																		
Finland								★																	
France									★																
Germany										★															
Greece											★														
Hungary												★													

Ireland			★										★												
Italy														★											
Latvia															★										
Lithuania																★									
Luxembourg									★	★															
Malta			★														★								
Netherlands					★																				
Poland																		★							
Portugal																			★						
Romania																				★					
Slovakia																					★				
Slovenia																						★			
Spain																							★		
Sweden																								★	
Norway																									★
Switzerland									★	★															
Iceland			★																						

2.2 label

Please refer to <Labelling> (CE/MDR-MDK-01-08)

2.3 Instruction for use

Please refer to <Instruction For Use> (CE/MDR-MDK-01-09)

3 Design and Manufacturing Information

Introduction of Manufacture

Name: MEDLINK(SONGZI)MEDICAL PRODUCTS CO., LTD

Address: LIYE RD, XINJANGKOU TOWN, SONGZI CITY, JINGZHOU CITY, HUBEI PROVINCE, CHINA

Figure1 MEDLINK(SONGZI)MEDICAL PRODUCTS CO., LTD

Medlink is a world-class producer of high quality Medical & PPE non-woven products. We're one of the leading companies in China manufacturing disposable Non-Woven products comply to US QSR820 and ISO system. We focused on the production of coveralls, gowns, masks, caps, shoe covers, and so on.

Our company occupies 80,000 square meters, over 15,000 square meters of building area; own more than 20 large-advanced production equipments, more than 50 small process equipments.

Figure2 Manufacturing process

4 General Safety and Performance Requirements

Please refer to file CE/MDR-MDK-01-03 < General Safety and Performance Requirements >

5 Benefit-Risk Analysis and Risk Management

Risk Management was conducted according to standard EN ISO 14971:2019 Medical devices – Application of risk management to medical devices. The below table is the risk management team and its responsibilities.

Name	Assignment of responsibility
Chen Fang	Responsible for the risk management implementation After production and production various stages collection of information and appraisal
Yang Mei	Responsible for the risk management plan, the implementation, the risk appraisal and the confirmation and the establishment documents
Yang Mei	From product examination and confirmation angle appraisal risk
Cheng Yuan	From customer and service angle appraisal risk

Please refer to file CE/MDR-MDK-01-04 <Risk Management Report>

6 Product Verification and Validation

- The material used to manufacture Face Masks has passed the Biocompatibility test, the test reports are attached as Annex 3 <Biocompatibility Test Report>.
  The final products was tested and the test result shows it meet the requirement of EN 14683:2019, for test report please refer to Annex 2 <Performance Test-EN14683>.

6.1 Pre-Clinical and clinical data

Please refer to file CE/MDR-MDK-01- 05 <Clinical Evaluation Report>

6.2 Additional information required in specific cases

Medical Face Mask is wildly used in the surgery operation department, laboratory, food industries and other environment which need a breath protection, and it's main purpose is prevent unwanted inhalations. No additional information in specific cases is required.

7 Post Marketing

7.1 Post-market Surveillance Plan

This Post-Market Surveillance Plan (PMS) plan is to address the residual risks identified related to clinical safety and clinical performance of the device.

PMS methodologies

a) The PMS methodologies are carried out through reviewing relevant retrospective data from patients previous exposed to Medical Face Mask. Quality and Customer Service gather the customer feedbacks, and reviewing on a monthly basis.

b)Post-market clinical surveillance studies are performed on the devices within their intended use according to the instructions for use.

c) Device intended use:

The Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

d)The clinical investigation plan /study plan:

1)Study population and group of patients shall include the following population. The study population is selected based on the product intended use.

2)Quality department and customer service are responsible for analyzing the customer feedback and submit management team to review.

3)Study objectives are to gather customer feedbacks for 1,000 units or one year patients follow-up for each type of production. After analysis, Sales and quality team will determine the endpoint of the study.

4)PMS studies shall be conducted by product type.

5) Where appropriate, such as a new risk identified through the PMS, the interim report need to be generated to ensure continuous risk management based on clinical data.

6) In case of natural disaster, it might terminate the early study in the PMS site.

7) After gathering the clinical data, follow the following procedure to control data and update the risk analysis when appropriate.

Table 1: PMS Study population selection, methodologies and timing design

PMS Method	Department	Time and requency
1 Investigate people who are seriously ill	Sale Department	When serious illness occurs to persons using the product
2 Visit long - term service personnel	Sale Department	When there are people who use the product for a long time
3 Survey sensitive people	Sale Department	When a sensitive person uses the product
4 Continue to study the relevant literature	Production Department	The relevant clinical literature should be updated once a year
5 Continuing research on similar medical devices aftermarket release	Production Department	Long-term continuous study
6 Continuing research on the materials, operating principles and techniques of medical devices	Production Department	Long-term continuous study
7 Continuous research into new technologies	Production Department	When there were new technology
8 Continuous research on product life	Quality Department	Long-term continuous study
9 Study adverse events and establish and implement the medical device notification and withdrawal control procedures	Quality Department	When adverse event occurs
10 Solicit relevant improvement opinions from customers, measure customer satisfaction, and establish and implement customer related process control procedures	Sale Department	Once a year

11 Solicit relevant improvement opinions from customers, measure customer satisfaction, establish and implement customer satisfaction survey control procedure	Sale Department	When there was customer complain happened
12 Pay close attention to the recalled products and establish and implement the medical device notification and withdrawal control procedures.	Sale Department	When there were product recall
13 Research on new product related standards	Production Department	When product related standards are updated
14 Study of new product-related regulations	Production Department	When product related standards are updated

Risk Analysis of Post marketing Surveillance

Risk analysis indicates all risks associated with the identified hazards have been evaluated. After appropriate retirement actions of reducing these risks have been taken, the overall level of risks of the product is acceptable with regard to the intended application and use of the products. Therefore, the post-marketing follow-up plan is designed to follow up the clinical performance of the device through Medical Face Mask customers and analysis on monthly basis.

7.2 Post-market Surveillance Report

7.2.1 Post-market Surveillance data

Base on the post-market surveillance plan we made in section 7.1, the corresponding data collected are shown as follow,

Sales list

We did not receive customer complains. the customer feedback of the propose device and similar device are shown in the table below.

Table2 Customer feedback list of the propose device

NO.	Description	Root Cause	Corrective actions	state
0	/	/	/	/

Table3 Post Market experience of similar device

Area	Time	Quantity	Complaints	Adverse events
EU	2017	0	/	/
	2018	0	/	/
	2019	0	/	/
USA	2017	0	/	/
	2018	0	/	/
	2019	0	/	/
Total	0			

Table 4: PMS Study Result

PMS Method	Department	Collecting Data
1 Investigate people who are seriously ill	Sale Department	None, this product is not intended for persons with serious illness
2 Has an interview on long term use people	Sale Department	None, this product has no long-term use of personnel
3 Survey sensitive people	Sale Department	None, no sensitive person USES this product
4 Continue to study the relevant literature	Production Department	Refer to file CE/MDR-MDK-01-05 Clinical Evaluation Report
5 Continuing research on similar medical devices aftermarket release	Production Department	Refer to file CE/MDR-MDK-01-05 Clinical Evaluation Report
6 Continuing research on the materials, operating principles and techniques of medical devices	Production Department	The material, operating principle and technology of this product are not updated
7 Continuous research into new	Production	No new technology

technologies	Department	
8 Continuous research on product life	Quality Department	No change in life period
9 Study adverse events and establish and implement the medical device notification and withdrawal control procedures	Quality Department	None, no adverse event
10 Solicit relevant improvement opinions from customers, measure customer satisfaction, and establish and implement customer related process control procedures	Sale Department	None, no customer feedback.
11 Solicit relevant improvement opinions from customers, measure customer satisfaction, establish and implement customer satisfaction survey control procedure	Sale Department	None, no customer complains
12 Pay close attention to the recalled products and establish and implement the medical device notification and withdrawal control procedures.	Sale Department	None, no product recall
13 Research on new product related standards	Production Department	Refer to section 7.2
14 Study of new product-related regulations	Production Department	Refer to section 7.2

Product Standard, regulation Updated

A) Product standard

Bio-compatibility standard ISO 10993-1 has been updated to ISO 10993-1:2018, we will updated the bio-compatibility report based on the new standard.

B) Product regulation

The Europe Regulation about medical device (EU) 2017/745 has been released on 26th, May, 2017. We update this CE document based on the new Medical Device Regulation (2017/745). And implement quality management base on the new Medical Device Regulation (EU) 2017/745.

7.2.2 Safety and Effectiveness Conclusion

By collecting and analyzing PMS data of the propose device and similar device, the technology of Medical Face Mask is mature. Risk management, bench test, literature analysis and post- market data has proven the safety and effectiveness of the propose device.

The risk identified in the device risk management documentation and literature has been controlled. All the hazards and other clinically relevant information have been identified appropriately. The literature results are enough to address the points we aim to clarify and there is no need to get the new clinical information.

From the PMS data of the similar device, there is no significant risk were identified and at the same time, the therapy was proved to be effective. So the benefit is higher than the risk.

8 Declaration of Conformity

Please refer to file CE/MDR-MDK-01-02 < Declaration of conformity >.

DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745

Manufacturer:	MEDLINK(SONGZI)MEDICAL PRODUCTS CO., LTD
Address:	LIYE RD, XINJANGKOU TOWN, SONGZI CITY, JINGZHOU CITY, HUBEI PROVINCE, CHINA
EC Representative:	SUNGO Europe B.V.
Address:	Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name:	Medical Face Mask
Model:	/

SRN: / **Basic UDI-DI:** /

Classification:	Class I
Rule:	Rule 1, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment Procedure:	Annex II+III of Regulation (EU) 2017/745

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 14683:2019+AC:2019 Type IIR

Signature: Bill Liao

Name / Position: Liao Chan / GM

Date: 2020.7.4

Place: Hubei / China

General Safety and Performance Requirements

File No.: CE/MDR-MDK-01-03

Version: A/0

Product: Medical Face Mask

Issued By	Reviewed By	Approved By	Effective Date
Yang Mei	Lei Zhenghong	Liao Chan	2020.07.20

MEDLINK(SONGZI)MEDICAL PRODUCTS CO., LTD

LIYE RD, XINJANGKOU TOWN, SONGZI CITY, JINGZHOU CITY, HUBEI PROVINCE, CHINA

Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A/0	Initial	Yang Mei	2020.07.20

4 General Safety and Performance Requirements

Item	The requirement of Medical Device Regulation 2017/745	Applicable	Standard	Evidence of Conformity
GENERAL REQUIREMENTS				
1	1.Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall 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, taking into account the generally acknowledged state of the art.	A	ENISO15223-1：2016 ENISO14971：2019 ISO10993-1：2018 ENISO10993-5：2009 ENISO10993-10：2013 EN 14683:2019 EN 62366-1:2015	Label & IFU Risk Management Report CE/MDR-MDK-01-04 Biocompatibility compliance evidence: Refer to Annex3 <Biocompatibility Test Report> Product Verification Report Usability Evaluation Report
2	2.The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.	A	ENISO14971：2019	Risk Management Report CE/MDR-MDK-01-04
3	3.Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:	A	ENISO14971：2019	Risk Management Report CE/MDR-MDK-01-04

	(a) establish and document a risk management plan for each device; (b) identify and analyse the known and foreseeable hazards associated with each device; (c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse; (d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4; (e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and (f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.			
4	4.Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority: (a) eliminate or reduce risks as far as possible through safe design and manufacture; (b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and (c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users. Manufacturers shall inform users of any residual risks.	A	ENISO14971：2019	Risk Management Report CE/MDR-MDK-01-04
5	5.In eliminating or reducing risks related to use error, the manufacturer shall: (a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and	A	ENISO14971：2019	Risk Management Report CE/MDR-MDK-01-04

	(b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).			
6	6.The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user 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 and has been properly maintained in accordance with the manufacturer's instructions.	A	ENISO15223-1：2016 ENISO14971：2019 ISO10993-1：2018 ENISO10993-5：2009 ENISO10993-10：2013 EN62366-1:2015	Label & IFU Risk Management Report CE/MDR-MDK-01-04 Biocompatibility compliance evidence: Refer to Annex3 <Biocompatibility Test Report> Product Verification Report Usability Evaluation Report CE/MDR-MDK-01-07
7	7.Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.	A	ENISO14971：2019	Risk Management Report CE/MDR-MDK-01-04
8	8.All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.	A	ENISO14971：2019	Risk Management Report CE/MDR-MDK-01-04

9	9.For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.	NA	-	It's not an device referred to in Annex XVI that device without an intended medical purpose.
REQUIREMENTS REGARDING DESIGN AND MANUFACTURE				
10	Chemical, physical and biological properties			
	10.1. Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to: (a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability; (b) the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution,metabolism and excretion; (c) the compatibility between the different parts of a device which consists of more than one implantable part; (d) the impact of processes on material properties; (e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand; (f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance; (g) surface properties; and (h) the confirmation that the device meets any defined chemical and/or physical specifications.	A	ENISO15223-1:2016 EN1041:2008+A1:2013 ISO10993-1：2018 ENISO10993-5:2009 ENISO10993-10:2013	Label & IFU Biocompatibility compliance evidence: Refer to Annex3 <Biocompatibility Test Report>
	10.2. Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of	A	ENISO15223-1:2016 EN1041:2008+A1:20	Label & IFU

	the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.		13	
	10.3. Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use.	NA	-	The device would not be used with materials and substances like gas and so on.
	10.4. Substances			
	10.4.1. Design and manufacture of devices Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Devices, or those parts thereof or those materials used therein that: — are invasive and come into direct contact with the human body, — (re)administer medicines, body liquids or other substances, including gases, to/from the body, or — transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body, shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2: (a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1), or	A	ENISO14971：2019	Risk Management Report CE/MDR-MDK-01-04

	(b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (2) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council (3), in accordance with the criteria that are relevant to human health amongst the criteria established therein.			
	10.4.2. Justification regarding the presence of CMR and/or endocrine-disrupting substances The justification for the presence of such substances shall be based upon: (a) an analysis and estimation of potential patient or user exposure to the substance; (b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives; (c) argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and (d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4.	NA	-	The device does not contain CMR or endocrine-disrupting substances
	10.4.3. Guidelines on phthalates For the purposes of Section 10.4., the Commission shall, as soon as possible and by 26 May 2018, provide the relevant scientific committee with a mandate to prepare guidelines that shall be ready before 26 May 2020. The mandate for the committee shall encompass at least a	NA	-	The device does not include phthalates.

	benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1. The benefit-risk assessment shall take into account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every five years, the guidelines shall be updated.			
	10.4.4. Guidelines on other CMR and endocrine-disrupting substances Subsequently, the Commission shall mandate the relevant scientific committee to prepare guidelines as referred to in Section 10.4.3. also for other substances referred to in points (a) and (b) of Section 10.4.1., where appropriate.	NA	-	The device does not contain other CMR or endocrine-disrupting substances
	10.4.5. Labelling Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use.	A	ENISO15223-1:2016 EN1041:2008+A1:2013	Label & IFU
	10.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible the 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	ENISO14971：2019	Risk Management Report CE/MDR-MDK-01-04
	10.6. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the	A	ENISO14971：2019	Risk Management Report CE/MDR-MDK-01-04

	patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials.			
11	11. Infection and microbial contamination			
	11.1. Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall: (a) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries, (b) allow easy and safe handling, (c) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and (d) prevent microbial contamination of the device or its content such as specimens or fluids.	A	ENISO14971：2019	Risk Management Report CE/MDR-MDK-01-04
	11.2. Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.	A	ENISO15223-1:2016 EN1041:2008+A1:2013	Label & IFU
	11.3. Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.	NA	-	The device is not labelled as having a specific microbial state
	11.4. Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.	NA	-	The device is not delivered in a sterile state.
	11.5. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	NA	-	The device is not sterile.

	11.6. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	NA	-	The device is not intended to be sterile.
	11.7. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.	NA	-	The device is not needed to be sterilized before use.
	11.8. The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.	NA	-	The device is not sterile.
12	12. Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.			
	12.1. In the case of devices referred to in the first subparagraph of Article 1(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of point (2) of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as required by the applicable conformity assessment procedure under this Regulation.	NA	-	The device is not medicinal device.
	12.2. Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under this Regulation.	NA	-	The device is not medicinal device.
	13. Devices incorporating materials of biological origin			
	13.1. For devices manufactured utilising derivatives of tissues or cells of human origin which are	NA	-	The device does not

	non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply: (a) donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC; (b) processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process; (c) the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC.			contain materials of biological origin
	13.2. For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply: (a) where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers; (b) sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device; (c) in the case of devices manufactured utilising tissues or cells of animal origin, or their	NA	-	The device does not contain materials of biological origin

	derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply			
	13.3. For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	NA	-	The device does not contain materials of biological origin
14	14. Construction of devices and interaction with their environment			
	14.1. If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.	NA	-	The device is not intended for use in combination with other devices or equipment
	14.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible: (a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; (b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences; (c) the risks associated with the use of the device when it comes into contact with materials,	NA	-	The design and manufacture of device would not produce these risks.

	liquids, and substances, including gases, to which it is exposed during normal conditions of use; (d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts; (e) the risks of accidental ingress of substances into the device; (f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; and (g) risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.			
	14.3. Devices shall 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 shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.	NA	-	There is no risk of fire or explosion during normal use of the device.
	14.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.	NA	-	The device does not need adjustment, calibration or maintenance.
	14.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.	NA	-	The device is not intended to be operated together with other devices or products.
	14.6 Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.	NA	--	It's not measurement, monitoring or display scale device.
	14.7. Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use.	NA	-	The device is manufactured with normal safety material that can be safely disposed.

	Such procedures shall be described in the instructions for use.			
15	15. Devices with a diagnostic or measuring function			
	15.1. Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.	NA	-	The device does not have diagnostic function.
	15.2. The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC	NA	-	The device does not have measuring function.
16	16. Protection against radiation			
	16.1. General (a) Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes. (b) The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.	NA	-	The device would not exposure of patients, users and other persons to radiation
	16.2. Intended radiation (a) Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or nonionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.	NA	-	The device would not exposure of patients, users and other persons to radiation

	(b) Where devices are intended to emit hazardous, or potentially hazardous, ionizing and/or non-ionizing radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.			
	16.3. Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.	NA	-	The device would not exposure of patients, users and other persons to radiation
	16.4. Ionising radiation (a) Devices intended to emit ionizing radiation shall be designed and manufactured taking into account the requirements of the Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. (b) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during treatment. (c) Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user. (d) Devices that emit ionising radiation and are 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, energy and, where appropriate, the quality of radiation.	NA	-	The device would not exposure of patients, users and other persons to radiation
17	17. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves			
	17.1. Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment	NA	-	This device does not incorporate electronic programmable systems

	of performance.			
	17.2. For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.	NA	-	This device does not incorporate electronic programmable systems
	17.3. Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).	NA	-	This device does not incorporate electronic programmable systems
	17.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.	NA	-	This device does not incorporate electronic programmable systems
18	18. Active devices and devices connected to them			
	18.1. For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks.	NA	-	The device is not active devices
	18.2. Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.	NA	-	The device is not active devices
	18.3. Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure.	NA	-	The device is not active devices
	18.4. Devices intended to monitor one or more clinical parameters of a patient shall 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	-	The device is not active devices
	18.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the	NA	-	The device is not active devices

	device in question or other devices or equipment in the intended environment.			
	18.6. Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.	NA	-	The device is not active devices
	18.7. Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.	NA	-	The device is not active devices
	18.8. Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended.	NA	-	The device is not active devices
19	19. Particular requirements for active implantable devices			
	19.1. Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible: (a) risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices, (b) risks connected with medical treatment, in particular those resulting from the use of defibrillators or highfrequency surgical equipment, and (c) risks which may arise where maintenance and calibration are impossible, including: — excessive increase of leakage currents, — ageing of the materials used, — excess heat generated by the device, — decreased accuracy of any measuring or control mechanism.	NA	-	The device is not active implantable devices
	19.2. Active implantable devices shall be designed and manufactured in such a way as to ensure — if applicable, the compatibility of the devices with the substances they are intended to administer, and — the reliability of the source of energy.	NA	-	The device is not active implantable devices

	19.3. Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts.	NA	-	The device is not active implantable devices
	19.4. Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation.	NA	-	The device is not active implantable devices
20	20. Protection against mechanical and thermal risks			
	20.1. Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts.	NA	-	The device will not pose mechanical or thermal risk to patient
	20.2. Devices shall 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	-	The device will not pose mechanical or thermal risk to patient
	20.3. Devices shall 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	-	The device will not pose mechanical or thermal risk to patient
	20.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.	NA	-	The device will not pose mechanical or thermal risk to patient
	20.5. Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information shall be given on moving parts and/or their housings where the direction	NA	-	The device will not pose mechanical or thermal risk to patient

	of movement needs to be known in order to avoid a risk.			
	20.6. Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.	NA	-	The device will not pose mechanical or thermal risk to patient
21	21. Protection against the risks posed to the patient or user by devices supplying energy or substances			
	21.1. Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.	NA	-	The device does not supply energy or substances to patient
	21.2. Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.	NA	-	The device does not supply energy or substances to patient
	21.3. The function of the controls and indicators shall 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 shall be understandable to the user and, as appropriate, the patient.	NA	-	The device does not supply energy or substances to patient
22	22. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons			
	22.1. Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.	NA	-	The device is designed to be used by lay persons.
	22.2. Devices for use by lay persons shall be designed and manufactured in such a way as to: — ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information,	NA	-	The device is designed to be used by lay persons.

	— reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and — reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.			
	22.3. Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person: — can verify that, at the time of use, the device will perform as intended by the manufacturer, and — if applicable, is warned if the device has failed to provide a valid result.	NA	-	The device is designed to be used by lay persons.
	REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE			
23	23. Label and instructions for use	A	ENISO15223-1:2016 EN1041:2008+A1:2013	label & IFU
	23.1. General requirements regarding the information supplied by the manufacturer Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following: (a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.	A	ENISO15223-1:2016 EN1041:2008+A1:2013	label & IFU Printed label and IFU was used. a) Paper printed label is used. b) The information will be displayed on the packaging for each unit. c) Yes, human-readable

	(b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices. (c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification (‘RFID’) or bar codes. (d) Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section. (e) Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge. (f) Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation. (g) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer. (h) Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.			format. d) Instructions for use will be provided together with devices. e) Not applicable. The device is provided in single packaging each piece. f) Electronic format instruction can be received from manufacturer. g) Limitations, contra-indications, precautions or warnings information will be provided by IFU or label if needed. h) Internationally recognized symbols will be used.
	23.2. Information on the label The label shall bear all of the following particulars: (a) the name or trade name of the device; (b) the details strictly necessary for a user to identify the device, the contents of the packaging	A	ENISO15223-1:2016 EN1041:2008+A1:2013	label & IFU a) The device name is indicated. b) See [Intended Use]

	and, where it is not obvious for the user, the intended purpose of the device; (c) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business; (d) if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative; (e) where applicable, an indication that the device contains or incorporates: — a medicinal substance, including a human blood or plasma derivative, or — tissues or cells, or their derivatives, of human origin, or — tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012; (f) where applicable, information labelled in accordance with Section 10.4.5.; (g) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate; (h) the UDI carrier referred to in Article 27(4) and Part C of Annex VII; (i) an unambiguous indication of the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant; (j) where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable; (k) an indication of any special storage and/or handling condition that applies; (l) if the device is supplied sterile, an indication of its sterile state and the sterilisation method; (m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;			c) the manufacturer and the address information are indicated. d) The authorized representative and address of the registered place of business of the authorized representative are indicated; e) N/A f) N/A g) LOT NUMBER h) UDI-DI will be applied. i) The Shelf Life is 3 years. j) Manufacture date was indicated on label. k) N/A. It's single used device. l) N/A m) N/A n) Symbol of single use is indicated.

	(n) if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union; (o) if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles; (p) if the device is custom-made, the words ‘custom-made device’; (q) an indication that the device is a medical device. If the device is intended for clinical investigation only, the words ‘exclusively for clinical investigation’; (r) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action; (s) for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number.			o) N/A p) N/A q) N/A r) N/A s) N/A
	23.3. Information on the packaging which maintains the sterile condition of a device (‘sterile packaging’) The following particulars shall appear on the sterile packaging: (a) an indication permitting the sterile packaging to be recognised as such, (b) a declaration that the device is in a sterile condition, (c) the method of sterilisation, (d) the name and address of the manufacturer, (e) a description of the device, (f) if the device is intended for clinical investigations, the words ‘exclusively for clinical investigations’, (g) if the device is custom-made, the words ‘custom-made device’,	NA	-	It’s not sterile device.

	(h) the month and year of manufacture, (i) an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and (j) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.			
	23.4. Information in the instructions for use The instructions for use shall contain all of the following particulars: (a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2; (b) the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate; (c) where applicable, a specification of the clinical benefits to be expected. (d) where applicable, links to the summary of safety and clinical performance referred to in Article 32; (e) the performance characteristics of the device; (f) where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories; (g) any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard; (h) specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it; (i) details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection;	A	ENISO15223-1:2016 EN1041:2008+A1:2013	label & IFU a) The points (a), (c) , (k),of Section 23.2 was indicated in IFU, the point (e), (f), (l), (n) and (r) of Section 23.2 is not applicable to the device b) Intended use was indicated in IFU. c) N/A d) N/A e) See IFU Description of function f) N/A g) Warning and Caution information was described in

	(j) any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons; (k) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant: — details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection, — identification of any consumable components and how to replace them, — information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and — methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices; (l) if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use; (m) if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation; (n) if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses; (o) an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements; (p) if the device bears an indication that it 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			IFU. h) N/A i) Pre-use check was described in IFU. j) N/A k) Usage method was provided in IFU. l) N/A m) N/A n) N/A o) N/A p) Symbol of single use is indicated.

	re-used. This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. no instructions for use are required, this information shall be made available to the user upon request; (q) for devices intended for use together with other devices and/or general purpose equipment: — information to identify such devices or equipment, in order to obtain a safe combination, and/or — information on any known restrictions to combinations of devices and equipment; (r) if the device emits radiation for medical purposes: — detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation, — the means of protecting the patient, user, or other person from unintended radiation during use of the device; (s) information that allows the user and/or patient to be informed of any warnings, precautions, contraindications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate: — warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety, — warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature, — warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic			q) N/A r) N/A s) See IFU [Contraindication].

	investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment, — if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered, — warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and — precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user; (t) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contraindications, undesirable side-effects and risks relating to overdose; (u) in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed; (v) warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate: — infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and — physical hazards such as from sharps. If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request;			t) N/A u) NA v) NA.

	(w) for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional; (x) for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device; (y) date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use; (z) a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established; (aa) information to be supplied to the patient with an implanted device in accordance with Article 18; (ab) for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.			w) The device is easy to operate. x) N/A y) Date of issue was indicated z) N/A aa) N/A ab) N/A

Risk Management Report

COMPANY NAME:	MEDLINK(SONGZI)MEDICAL PRODUCTS CO., LTD
COMPANY ADDRESS:	LIYE RD, XINJANGKOU TOWN, SONGZI CITY, JINGZHOU CITY, HUBEI PROVINCE, CHINA
PRODUCT:	Medical Face Mask
DOCUMENT NO.:	CE/MDR-MDK-01-04
VERSION:	A/0
ACCESSORIES:	NA
PROCEDURE:	EN ISO14971:2019
CONCLUSION:	All risks associated with the identified hazards have been evaluated considering EN ISO14971:2019. The overall level of risk of the product is acceptable. After appropriate measures to reduce these risks have been taken, the overall risks (all risks together) have been deemed acceptable versus the benefit of the device.

Issued By	Reviewed By	Approved By	Effective Date
Yang Mei	Lei Zhenghong	Liao Chan	2020.07.20

Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A/0	Initial Release	Yang Mei	2020.07.20

Chapter One Review

1. Product Introduction

Please refer to 01 TCF Section 1.1 Device description and specification.

1.1 Product Name

Medical Face Mask

1.2 Product Function

Please refer to 01 TCF Section 1.1 Device description and specification.

1.3 Product Picture, Configuration and Material

Please refer to 01 TCF Section 1.1 Device description and specification.

1.4 Clinical background,current knowledges and state of art

Please refer to 05 Clinical evaluation report Section 3.Clinical background, current knowledge, state of the art.

2. Standard List

Regulations/Directive

- Medical Device Regulation: Regulation (EU) 2017/745

Guidance

- MEDDEV 2.7.1 revision 4 Clinical evaluation: A guide for manufacturers and notified bodies
- MEDDEV 2.12-1 rev 8 guidelines on a medical devices vigilance system
- MEDDEV 2.12-2 guidelines on post market clinical follow-up

Please refer to 01 TCF Section 1.1 Applicable Standard.

3. Risk Management Responsibilities and Authority Allocation

1) The general manager should provide the appropriate resources for the risk management, and take the responsibility for the risk management. Ensure that the allocation of personnel in charge of risk management, implementation and evaluation of the work are trained and qualified, and ensure that they have related knowledge and experience.

2) The technical department（R&D DP） is responsible for the product design and development process of risk management activities, the formation of risk analysis, risk assessment, risk control, comprehensive assessment of residual risk analysis and evaluation of the relevant records, and the preparation of risk management report.

3) The quality control department, sales department, production department and other relevant departments should analyze all the known and predictable hazards from the perspective of product realization, and the production and production of information collection and timely feedback to the technical department for risk assessment, if necessary, a new round of risk management activities.

4) The technical department（R&D DP）and the assessment team member shall review the results of the risk management activities regularly, and shall be responsible for the correctness and validity of the risk management activities.

5) The Document Control Center (DCC) is responsible for the collection of all risk management documents.

4. Risk Management Review Staff and Responsibilities

Note: please make corresponding increase or decrease according to the actual situation

Department	Assignment of responsibility
R&D Department	Responsible for the risk management implementation After production and production various stages collection of information and appraisal
R&D Department	Responsible for the risk management plan, the implementation, the risk appraisal and the confirmation and the establishment documents
Quality Department	From product examination and confirmation angle appraisal risk
Sales Department	From customer and service angle appraisal risk

5. Risk Management Plan(According to ISO/TR 24971:2020 clause 4.4)

1) **Plan the scope of risk management activities**

The risk management plan is mainly for the product in its entire life cycle (including design development, product realization, the final stop and disposal stage) for risk management activities of planning.

2) Formulation of responsibility and power–refer to the fifth section in Chapter one.

3) Assessment requirements for risk management activities I) whether the risk management plan has been properly implemented Review team members are responsible for the implementation of the risk management plan to verify, to view the risk management document to view the risk analysis, risk assessment, risk control and other records, to ensure that the risk management plan of risk management activities have been properly implemented. Verification of the effectiveness of risk management activities for II The evaluation group can be used to verify the effectiveness of the risk management activities by collecting clinical data and information on the production and production of the risk management.

4) The acceptable criteria for risk acceptability are determined by the manufacturer to determine the acceptable risk criteria for determining the risk acceptable to the first section of the second chapter.

5) Verification activities–refer to Chapter three.

6) Activities related to the collection and evaluation of information related to the production and production after production–Refer to the Chapter five.

7) This risk management plan was established in accordance with EN ISO 14971 and considers the recommendations of all informative attachments of this standard.

This risk management plan is in accordance with all requirements listed in appendix F of ISO 14971. Its task is to describe the risk management process for the following product:

Product to identify potential risks, evaluate them and to control them effectively. This risk management plan describes the risk management process of the medical device manufacturer:

MEDLINK(SONGZI)MEDICAL PRODUCTS CO., LTD for the above-mentioned medical device. It covers all phases of the life cycle, starting with the concept (design and development control), production, storage / despatch up to decommissioning or waste disposal in accordance with EN ISO 14971 Appendix F.1and F.2.

In this risk management plan the following areas are covered:

---Description of the medical device and designation of the performance properties

---Designation of personnel, responsibilities and competence within the risk management process

---Evaluation of the risk management process through the management

---Criteria for the acceptability of risks

---Flow chart of the risk management process

8) Personnel and Responsibilities in the Risk Management Process

The personnel and responsibilities in the risk management process was designated in chanpter4

9) Criteria to Analyze and Evaluate the Acceptability of Risk

Risk severity level

Table 1. Severity Level

Grading	Level	Risk System Definition
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

Risk Frequency Level

Risk management team shall analysis the hazard, on the perspective of loss probability and severity, and record.

Table 2. Probability Level

Probability Grading	Level	Scope Definition
1	Improbable	$< 10^{-6}$
2	Remote	$< 10^{-5}$ and $\geq 10^{-6}$
3	Occasional	$< 10^{-4}$ and $\geq 10^{-5}$
4	Probable	$< 10^{-3}$ and $\geq 10^{-4}$
5	Frequent	$\geq 10^{-3}$

Acceptance Criteria

	Qualitative severity levels				
Probability	**1 Negligible**	**2 Minor**	**3 Serious**	**4 Critical**	**5 Catastrophic**
P5. Frequent	NAC	NAC	NAC	NAC	NAC
P4. Probable	NAC	NAC	NAC	NAC	NAC
P3. Occasional	AC	NAC	NAC	NAC	NAC
P2. Remote	AC	AC	NAC	NAC	NAC
P1. Improbable	AC	AC	AC	NAC	NAC

NAC=unacceptable AC= Acceptable

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

Identification of qualitative and quantitative characteristics(According to ISO/TR 24971:2020 Annex A)

Item	**Questions**	**Answer / Comments**
A.2.1	What is the intended use and how is the medical device to be used?	
A.2.2	Is the medical device intended to be implanted?	
A.2.3	Is the medical device intended to be in	

	contact with the patient or other persons?	
A.2.4	What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	
A.2.5	Is energy delivered to or extracted from the patient?	
A.2.6	Are substances delivered to or extracted from the patient?	
A.2.7	Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	
A.2.8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	
A.2.9	Is the medical device intended to be routinely cleaned and disinfected by the user?	
A.2.10	Does the medical device modify the patient environment?	
A.2.11	Are measurements taken?	
A.2.12	Is the medical device interpretative?	
A.2.13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	
A.2.14	Are there unwanted outputs of energy or substances?	
A.2.15	Is the medical device susceptible to environmental influences?	
A.2.16	Does the medical device influence the environment?	
A.2.17	Does the medical device require consumables or accessories?	
A.2.18	Is maintenance or calibration necessary?	
A.2.19	Does the medical device contain software?	
A.2.20	Does the medical device allow access to information?	
A.2.21	Does the medical device store data critical to patient care?	
A.2.22	Does the medical device have a restricted shelf-life?	
A.2.23	Are there any delayed or long-term use effects?	
A.2.24	To what mechanical forces will the medical device be subjected?	
A.2.25	What determines the lifetime of the medical device?	
A.2.26	Is the medical device intended for single use?	
A.2.27	Is safe decommissioning or disposal of the medical device necessary?	
A.2.28	Does installation or use of the medical	

	device require special training or special skills?	
A.2.29	How will information for safety be provided?	
A.2.30	Are new manufacturing processes established or introduced?	
A.2.31	Is successful application of the medical device critically dependent on the usability of the user interface?	
A.2.31.1	Can the user interface design features contribute to use error?	
A.2.31.2	Is the medical device used in an environment where distractions can cause use error?	
A.2.31.3	Does the medical device have connecting parts or accessories?	
A.2.31.4	Does the medical device have a control interface?	
A.2.31.5	Does the medical device display information?	
A.2.31.6	Is the medical device controlled by a menu?	
A.2.31.7	Is the successful use of the medical device dependent on a user's knowledge,skills and abilities?	
A.2.31.8	Will the medical device be used by persons with special needs?	
A.2.31.9	Can the user interface be used to initiate unauthorised actions?	
A.2.32	Does the medical device include an alarm system?	
A.2.33	In what way(s) might the medical device be misused(deliberately or not)?	
A.2.34	Is the medical device intended to be mobile or portable?	
A.2.35	Does the use of the medical device depend on essential performance?	
A.2.36	Does the medical device have a degree of autonomy?	
A.2.37	Does the medical device produce an output that is used as an input in determining clinical action?	

10) Controlling of the Management Process

The risk management will be achieved continuously, to analyze the experience achieved with the product in question, to evaluate the risk situation and to document this appropriately in the risk management worksheet. If necessary, or in case of special incidents, the management or its deputy will initiate an extraordinary meeting with responsible person. The management controls include the evaluation of actions taken as well as the success of these actions. It includes also the evaluation of available information about competitors' products.

11)Controlling of the risk analysis process

The flow chart describes the levels of realization of the management process and designates single steps for the risk analysis, risk evaluation, action management and the risk controlling. The flow chart is seen **<Figure B.1 — Overview of risk management activities as applied to medical devices> of EN ISO14971:2019**.

Step 1: Intended Use and Identification of Characteristics Related to the Safety of the Medical Device(According to ISO/TR 24971:2020 clause 5.2)

The intended use and each reasonably imaginable and foreseeable misuse will be described in the risk management plan together with the product performance properties, which may influence the safety of the medical device. Then, the performance properties will be taken over into the risk management worksheet and the risks will be evaluated which occur if these performance properties are not achieved. For describing the features of the medical device and its environment in which it is used, Annex C of the current standard ISO/TR 24971:2020 is applied.

Step 2: Identification of Hazards(According to ISO/TR 24971:2020 clause 5.4)

All known and foreseeable failures / dysfunctions / hazards, which infringe the function and safety of the medical device, will be identified. For this the medical device will be analysed in its regular mode, failure mode, (also in case of reasonably foreseeable misuse). Moreover already earlier discovered hazards, incidents or situations will be considered.

Step 3: Estimation of the Risk(s) for Each Hazardous Situation(According to ISO/TR 24971:2020 clause 5.4)

For each defined or assumed hazard of Step 2 the implied risk will be assessed. The expected physical damage or severity of harm, and probability of occurrence.

Reasonably foreseeable sequences or combinations of events that can result in a hazardous situation will be considered and the resulting hazardous situation(s) will be recorded.

Step 4: Risk Evaluation(According to ISO/TR 24971:2020 clause 6)

After that each risk will be evaluated, whether it is acceptable or not and whether a risk reduction is required. The criteria to evaluate the acceptability are listed in the risk management plan.

Step 5 and 6: Adopt risk control measures(According to ISO/TR 24971:2020 clause 7.2)

For risks which are within the acceptable area no actions of risk control will be taken. Risks, which are outside this area, will be treated case by case. Any risk control measures have the goal to reach at least the “AC“ (Acceptable).

The effectiveness of the risk control measures taken will be evaluated/verified and recorded in the risk management worksheet.

Step 7: Residual Risk Evaluation(According to ISO/TR 24971:2020 clause 7.2)

The residual risks will be evaluated and documented in the risk management worksheet. In case a residual risk is not acceptable, Step 5 and step6 will be repeated.

Step 8: Risk / Benefit Analysis(According to ISO/TR 24971:2020 clause 7.4)

Not acceptable risks can be accepted in exceptional cases, if a particularly high benefit is to be expected for the patient, and alternative products or treatment measures with minor risks are not available.

Step 9: Risks Arising from Risk Control Measures(According to ISO/TR 24971:2020 clause 7.5)

In this step whether the actions of risk control and/or risk reduction would introduce new hazards or hazardous situations will be evaluated. In this case Step 3 has to be repeated.

Step 10:Completeness of Risk Control(According to ISO/TR 24971:2020 clause 7)

In this step, whether all relevant risks have been considered and whether the risk evaluation process is complete will be checked. In case the risk evaluation is acknowledged as complete.

Step 11: Evaluation of Overall Residual Risk Acceptability(According to ISO/TR 24971:2020 clause 8)

After the completion of all risk control measures, the whole residual risks as well as the acceptability of the residual risks will be evaluated. The evaluation of the residual risks will be performed analogically to the evaluation of the basic risks.

Step 12: Result of risk management(According to ISO/TR 24971: 2020 clause 9)

There will be a summarizing risk management report. It will summarize the risk analysis, risk evaluation and management of preventive respectively risk control measures. This risk management report will be set up and released at least once per year by the management or its deputy

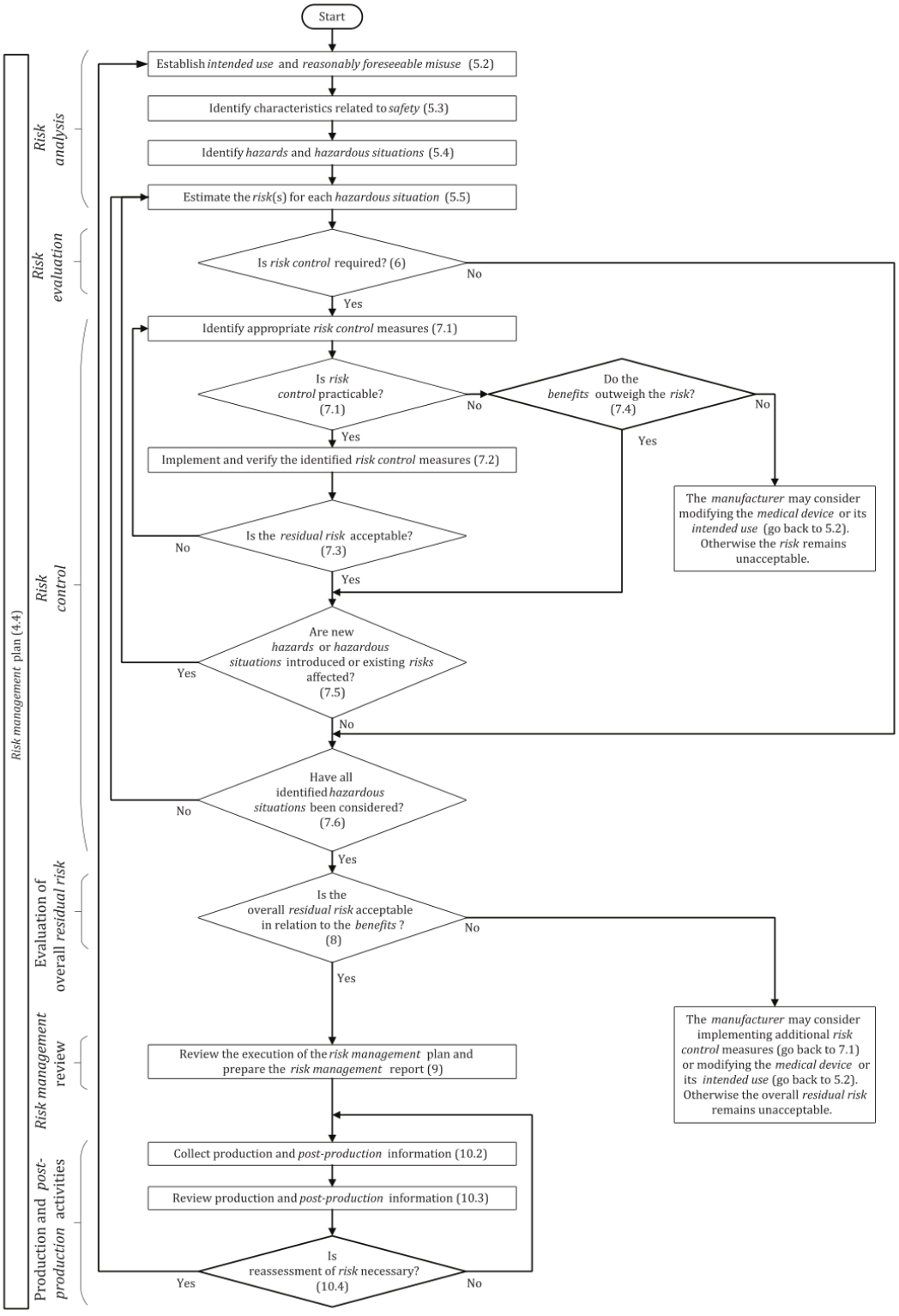
Step13: Production and post-production information(According to ISO/TR 24971: 2020 clause 10)

Production and after production information acquisition method to see the customer information feedback control program, the board of the customer information feedback control program production and after production information access the suitability and effectiveness of the evaluation, think: this method is suitable and effective, the production and after production information access can be according to the requirements of the customer information feedback control program, the project risk management, head to the production and after production information management, when necessary, the risk management team to implement the dynamic risk management activities

This product has been sold for many years. Once the product occurs upgrade or instead by new design, will be collected on various types of risk, and once again to analyze, evaluate, control, update the content of risk management report.
To review all records of above implementing procedures, to evaluate the aroused risk if exist, and start a new round risk analysis and management.
According to the records of the above implementing procedures, no new risks aroused.
Review of risk management experience:
As above, related members reviewed the risk management.
- Market complaints or grievances
Please refer to 01 TCF Section 7.2 Table 5 - Post Market experience of propose device and Table 6 - Customer feedback list of the propose device.

Related records:
a) Customer feedback investigation (included in CER)
b) Sales information (included in CER)
c) Adverse event, recall, complaint, nonconformity (included in CER)

6. Risk Management Process
Risk Management Process The risk management process will be conducted follow the process below and company Risk Management procedure.



Chapter Two Risk Analysis

2.1 Risk evaluation criteria

2.1.1 Risk severity level

Table1 Severity Level

Grading	Level	Risk System Definition
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

2.1.2 Risk Frequency Level

Risk management team shall analysis the hazard, on the perspective of loss probability and severity, and record.

Table2 Probability Level

Probability Grading	Level	Scope Definition
1	Improbable	$< 10^{-6}$
2	Remote	$< 10^{-5}$ and $\geq 10^{-6}$
3	Occasional	$< 10^{-4}$ and $\geq 10^{-5}$
4	Probable	$< 10^{-3}$ and $\geq 10^{-4}$
5	Frequent	$\geq 10^{-3}$

2.1.3 Acceptance Criteria

	Qualitative severity levels				
Probability	**1 Negligible**	**2 Minor**	**3 Serious**	**4 Critical**	**5 Catastrophic**
P5. Frequent	NAC	NAC	NAC	NAC	NAC
P4. Probable	NAC	NAC	NAC	NAC	NAC
P3. Occasional	AC	NAC	NAC	NAC	NAC
P2. Remote	AC	AC	NAC	NAC	NAC
P1. Improbable	AC	AC	AC	NAC	NAC

NAC=unacceptable AC= Acceptable

The estimated risk to each hazard/ reason is written list with the form of classification

(NAC/AC), give clear indication if it has control measures.

Identification of qualitative and quantitative characteristics (According to ISO/TR 24971:2020 Annex A)

Item	Questions	Answer / Comments
A.2.1	What is the intended use and how is the medical device to be used?	Refer to Instruction for Use
A.2.2	Is the medical device intended to be implanted?	NO.
A.2.3	Is the medical device intended to be in contact with the patient or other persons?	Yes, Contact with wearers skin. Biological hazards
A.2.4	What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Main raw materials for the made of Non-woven fabric in testing, product testing materials, meet the health standards. Biological hazards
A.2.5	Is energy delivered to or extracted from the patient?	NO.
A.2.6	Are substances delivered to or extracted from the patient?	NO.
A.2.7	Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	NO.
A.2.8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	NO.
A.2.9	Is the medical device intended to be routinely cleaned and disinfected by the user?	NO. disposable
A.2.10	Does the medical device modify the patient environment?	NO.
A.2.11	Are measurements taken?	NO.
A.2.12	Is the medical device interpretative?	NO.
A.2.13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	NO.
A.2.14	Are there unwanted outputs of energy or substances?	NO.
A.2.15	Is the medical device susceptible to environmental influences?	Do not store in temperature above 104"F (40'C). Store away from direct sunlight, x-ray devices, and any intense artificial light.
A.2.16	Does the medical device influence the environment?	NO.

A.2.17	Does the medical device require consumables or accessories?	NO.
A.2.18	Is maintenance or calibration necessary?	NO.
A.2.19	Does the medical device contain software?	NO.
A.2.20	Does the medical device allow access to information?	NO.
A.2.21	Does the medical device store data critical to patient care?	NO.
A.2.22	Does the medical device have a restricted shelf-life?	Yes. 3 years.
A.2.23	Are there any delayed or long-term use effects?	Material performance, Biological hazards, information hazards, function hazards
A.2.24	To what mechanical forces will the medical device be subjected?	NO.
A.2.25	What determines the lifetime of the medical device?	Determined by the life time of material and storage environment
A.2.26	Is the medical device intended for single use?	Yes, information hazards
A.2.27	Is safe decommissioning or disposal of the medical device necessary?	Yes, biological hazards
A.2.28	Does installation or use of the medical device require special training or special skills?	Yes,information hazards. Hazards operation
A.2.29	How will information for safety be provided?	Yes, Instruction for Use. Information hazards ;operation hazards
A.2.30	Are new manufacturing processes established or introduced?	NO.
A.2.31	Is successful application of the medical device critically dependent on the usability of the user interface?	NO.
A.2.31.1	Can the user interface design features contribute to use error?	NO.
A.2.31.2	Is the medical device used in an environment where distractions can cause use error?	NO.
A.2.31.3	Does the medical device have connecting parts or accessories?	NO.
A.2.31.4	Does the medical device have a control interface?	NO.
A.2.31.5	Does the medical device display information?	NO.
A.2.31.6	Is the medical device controlled by a menu?	NO.
A.2.31.7	Is the successful use of the medical device dependent on a user's knowledge,skills and abilities?	NO.
A.2.31.8	Will the medical device be used by persons with special needs?	NO.

A.2.31.9	Can the user interface be used to initiate unauthorised actions?	NO.
A.2.32	Does the medical device include an alarm system?	NO.
A.2.33	In what way(s) might the medical device be misused(deliberately or not)?	YES. Operation hazards
A.2.34	Is the medical device intended to be mobile or portable?	YES.
A.2.35	Does the use of the medical device depend on essential performance?	These products are to be used only by those which have been medical specialist.
A.2.36	Does the medical device have a degree of autonomy?	NO.
A.2.37	Does the medical device produce an output that is used as an input in determining clinical action?	NO.

Form 1.Risk Analysis, Control measurements and risk Evaluation after taking measures)

(According to ISO/TR 24971:2020 Annex C, ISO/TR 24971:2020 clause 7.4,7.5,7.6)

No.	Hazard		Risk Evaluation			RRM Risk Reduction Measure	Evidence	Risk Evaluation			NH	RL
	General	Identify hazards	S	P	RL			S	P	RL		
E.1 Energy Hazards												
1	Line voltage	N/A										
2	Leakage current	N/A										
3	Electric fields	N/A										
4	Magnetic fields	N/A										
5	Ionizing radiation	N/A										
6	Non-ionizing radiation	N/A										
7	High temperature	N/A										
8	Low temperature	N/A										
9	Gravity falling	N/A										
10	Suspended masses	N/A										
11	Vibration	N/A										
12	Stored energy	N/A										
13	Moving parts	N/A										
14	Torsion, shear and tensile force	N/A										
15	Moving and positioning of	N/A										

	patient												
16	Ultrasonic energy	N/A											
17	Infrasound energy	N/A											
18	Sound	N/A											
19	High pressure fluid injection	N/A											
E.2 Biological and Chemical Hazards													
1	Bacteria	A, Patient may have a bacterial infection if did not use the product properly, the package of device is damaged or re-use the product.	3	3	NA C	1. Indicate to users in the Instruction for Use how to use the product and indicate the user not to use the product if the package damaged. And indicate user not to reuse the product. 2.Ensure product quality by strictly follow the QMS	1.Instruction for use: CE/MDR-MDK-01-09 2. Biological Evaluation Report CE/MDR-MDK-01-06	3	1	AC	No	AC
2	Viruses	A, Patient may have a bacterial infection if did not use the product properly or re-use the product.	3	3	NA C	1. Indicate to users in the Instruction for Use how to use the product and indicate the user not to use the product if the package damaged. And indicate user not to reuse the product. 2.Ensure product	1.Instruction for use: CE/MDR-MDK-01-09 2. Biological Evaluation Report CE/MDR-MDK-01-06	3	1	AC	No	AC

						quality by strictly follow the QMS						
3	Other agents (e.g. prions)	N/A										
4	Re- or cross-infection	N/A										
5	Acids or alkalis	N/A										
6	Residues	N/A										
7	Contaminates	N/A										
8	additives or processing aids	N/A										
9	cleaning, disinfecting or testing agent	N/A										
10	Degradation products	A, the product was used after the expiry date and the product was degraded.	3	2	NAC	Indicate on the label do not use the product after expiry date	Label CE/MDR-MDK-01-08	3	1	AC	No	AC
11	medical gasses	N/A										
12	Anaesthetic products	N/A										
13	Toxicity of chemical Constituents	A, the product may cause the user	2	3	NAC	Raw material control	Instruction for Use and raw material inspection report. CE/MDR-MDK-01-0	2	2	AC	No	AC

		uncomfortable if the material is not meet the safety requirements.					9					
14	Bio-incompatibility	A, The product may cause the user uncomfortable if the material is not meet the safety requirements.	3	3	NAC	1.Choose raw materials meeting the requirements; 2.Ensure the product possess good biocompatibility.	1. Incoming inspection report 2. Biological Evaluation Report CE/MDR-MDK-01-06	3	1	AC	No	AC
15	Allergenicity	A, The product contact with patient and lead to allergenicity	3	3	NAC	1.Choose raw materials meeting the requirements; 2. Ensure the product possess good biocompatibility.	1. Incoming inspection report 2. Biological Evaluation Report CE/MDR-MDK-01-06	3	1	AC	No	AC
16	irritancy	A, The product contact with patient and lead to	3	3	NAC	1.Choose raw materials meeting the requirements; 2. Ensure the product possess good	1. Incoming inspection report 2 Biological Evaluation Report CE/MDR-MDK-01-0	3	1	AC	No	AC

		irritancy				biocompatibility.	6					
17	Pyrogenicity	A, The product may cause the user uncomfortable is not meet the safety requirements.	3	3	NAC	Choose raw materials meeting the requirements	Biological Evaluation Report CE/MDR-MDK-01-06	3	1	AC	No	AC
E.3 Environmental hazards and contributory factors												
1	electricity	N/A										
2	Pressure	N/A										
3	radiation	N/A										
4	volume	N/A										
5	Susceptibility to electromagnetic interference	N/A										
6	Emissions of electromagnetic interference	N/A										
7	Inadequate supply of power	N/A										
8	inadequate supply of coolant	N/A										
9	Storage or	The product	2	3	NA	1.Indicate the	Label	2	2	AC	No	AC

	operation outside prescribed environmental conditions	does not reach the intended use, or the product package will be damaged			C	distributor or use to store the product by strictly follow the storage condition; 2.Control storage / operation process	CE/MDR-MDK-01-08					
10	Incompatibility with other devices	N/A										
11	Accidental mechanical damage	N/A										
12	corrosions	N/A										
13	degradation	N/A										
14	contamination	N/A										
E.4. Hazards related to the use of the device and contributory factors												
1	Inadequate labeling	A, the inadequate labeling may cause misuse or use error	2	3	NA C	Strengthen amending the label	Label & Instruction for Use CE/MDR-MDK-01-08&CE/MDR-MDK-01-09	2	2	AC	No	AC
2	Inadequate operating instructions	A, the inadequate operating instructions may cause misuse	2	3	NA C	Strengthen amending the operating instructions	Label & Instruction for Use CE/MDR-MDK-01-08&CE/MDR-MDK-01-09	2	2	AC	No	AC
3	Use by unskilled/untrai	A The device	2	3	NA C	1. To strengthen pre-use checks	Label & Instruction for Use	2	2	AC	No	AC

	ned personnel	may be damaged or do not reach the intended use.				2.Indicate the user how to use the product in the user manual.	CE/MDR-MDK-01-08&CE/MDR-MDK-01-09					
4	Reasonably foreseeable misuse	A, The device can reach its intended use.	2	4	NAC	To strengthen pre-use checks and indicate the user how to use the product.	Instruction for Use CE/MDR-MDK-01-09	2	2	AC	No	AC
5	Insufficient warning of side effects	N/A										
6	Inadequate warning of hazards likely with re-use of single use devices	A, Improper operation and hurt the patient or infect patient or doctor.	2	4	NAC	Indicate the usage in the user manual.	Instruction for Use CE/MDR-MDK-01-09	2	2	AC	No	AC
7	Incorrect measurement and other metrological aspects	N/A										
8	Incompatibility with consumables/accessories/other devices	N/A										
9	sharp edges or	N/A										

	points											
E.5	**Inappropriate, inadequate or over-complicated user interface (man/machine communication)**											
1	Mistakes and judgement errors	N/A										
2	Lapses and cognitive recall errors	N/A										
3	Attentional failure	N/A										
4	Violation or abbreviation of instructions, procedures, etc.,	N/A										
5	Complex or confusing control system	N/A										
6	Ambiguous or unclear device state	N/A										
7	Ambiguous or unclear presentation of settings, measurements or other information	N/A										
8	Mispresentation of results	N/A										

9	Insufficient visibility, audibility or tactility	N/A										
10	Poor mapping of controls to action, or of displayed information to actual state	N/A										
11	Controversial modes or mappings as compared to existing equipment	N/A										
E.6. Hazards arising from functional failure, maintenance and ageing												
1	Erroneous data transfer	N/A										
2	Lack of , or inadequate specification for maintenance including inadequate specification of post maintenance functional	The device may not work well if lack of adequate functional checks	2	3	NA C	1.indicate the use instructions in the user manual;	Instruction for Use CE/MDR-MDK-01-09	2	2	AC	No	AC

	checks											
3	Inadequate maintenance	NA										
4	Lack of adequate determination of end of device life	NA										
5	Loss of electrical / mechanical integrity	NA										
6	Inadequate packaging(contamination and /or deterioration of the device)	The lifetime of the device may be reduced or the product package may be damaged.	3	2	NAC	1.Package the product by strictly follow the QMS 2.Indicate the user do not use the product if the package damaged.	1.Factory inspection records, 2. Instruction for Use CE/MDR-MDK-01-09	3	1	AC	No	AC
7	re-use and / or Improper re-use	N/A										
8	Deterioration in function (e.g. gradual occlusion of fluid/gas path, or change in resistance to flow, electrical	N/A										

	conductivity) as a result of repeated use.											
E.7 Production and post-production information（Foresee）												
1	Inadequate of designing parameters	A, product quality will be deteriorated	3	3	NAC	Design the product to meet the technology requirements	technology requirements	3	1	AC	No	AC
2	Inadequate of operating parameters	A, product quality will be deteriorated	3	3	NAC	1. Design the product to meet the technology requirements; 2.Indicate the user how to use the product	1.Technology requirements; 2. Instruction for Use CE/MDR-MDK-01-09	3	1	AC	No	AC
3	Inadequate of performance requirements	A, product quality will be deteriorated	3	2	NAC	Produce the product by strictly follow the QMS	Factory inspection records;	3	1	AC	No	AC
4	Insufficient control of changes to manufacturing processes	A, product quality will be deteriorated	3	2	NAC	Control the manufacturing processes by strictly follow the QMS	Quality management documents	3	1	AC	No	AC
5	Insufficient control of materials/materials compatibility information	A, product quality will be deteriorated	3	2	NAC	Chose the material which meet the requirement.	Incoming material inspection report.	3	1	AC	No	AC
6	Insufficient control of manufacturing processes	A, product quality will be deteriorated	3	2	NAC	Control the manufacturing processes by strictly follow the QMS	Quality management documents	3	1	AC	No	AC

7	Insufficient control of subcontractors	A, product quality will be deteriorated or get patient infection	3	2	NAC	Chose the material which meet the requirement.	Incoming material inspection report.	3	1	AC	No	AC
8	Lack of, or inadequate specification for, validated procedures for cleaning, disinfection and sterilization	NA										
9	Inadequate conduct of cleaning, disinfection and sterilization	NA										
10	Inadequate collection post-product information	A, the product did not satisfy by the customer or could meet the requirement	2	3	NAC	collect post-product information according to QMS	Quality Procedure	2	2	AC	No	AC

Form 2. Residual risk analysis

(According to ISO/TR 24971:2020 clause 8)

SN.	Hazard code	Whether there is no further reduction in technology (economic factors are not taken into account)	Whether Risk reduction implement the regulation "as far as possible"	Whether adopting the latest technology	Whether it meets MDR GSPR	Whether the clinical benefit is greater than the risk	Whether the residual risk is acceptable	Whether the measures of reducing risk create new risks
1.	H1	yes	yes	yes	yes	yes	yes	NO
2.	H2	yes	yes	yes	yes	yes	yes	NO
3.	H3	yes	yes	yes	yes	yes	yes	NO
4.	H4	yes	yes	yes	yes	yes	yes	NO
5.	H5	yes	yes	yes	yes	yes	yes	NO
6.	H6	yes	yes	yes	yes	yes	yes	NO
7.	H7	yes	yes	yes	yes	yes	yes	NO
8.	H8	yes	yes	yes	yes	yes	yes	NO
9.	H9	yes	yes	yes	yes	yes	yes	NO
10.	H10	yes	yes	yes	yes	yes	yes	NO
11.	H11	yes	yes	yes	yes	yes	yes	NO
12.	H12	yes	yes	yes	yes	yes	yes	NO
13.	H13	yes	yes	yes	yes	yes	yes	NO
14.	H14	yes	yes	yes	yes	yes	yes	NO
15.	H15	yes	yes	yes	yes	yes	yes	NO
16.	H16	yes	yes	yes	yes	yes	yes	NO
17.	H17	yes	yes	yes	yes	yes	yes	NO
18.	H18	yes	yes	yes	yes	yes	yes	NO
19.	H19	yes	yes	yes	yes	yes	yes	NO
20.	H20	yes	yes	yes	yes	yes	yes	NO
21.	H21	yes	yes	yes	yes	yes	yes	NO

22.	H22	yes	yes	yes	yes	yes	yes	NO
23.	H23	yes	yes	yes	yes	yes	yes	NO
24.	H24	yes	yes	yes	yes	yes	yes	NO

Conclusion:

According to the analysis of the risk, all the risk has been identified and the risks which are none accepted have been controlled by measure taken by the manufacturer. In one word, the risk has been managed accordingly.

Clinical Evaluation Report

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<Manufacture: MEDLINK(SONGZI)MEDICAL PRODUCTS CO., LTD>
<Address: LIYE RD, XINJANGKOU TOWN, SONGZI CITY, JINGZHOU CITY, HUBEI PROVINCE, CHINA
>

Prepared by		**Reviewed by**		**Approved by**	
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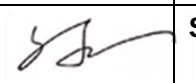
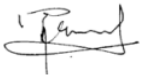
Signature		**Signature**		**Signature**	

Product name: Medical Face Mask
Classification of product: I, according to Rule 1, Annex VIII, Medical Device Regulation (EU) 2017/745
Manufacture: MEDLINK(SONGZI)MEDICAL PRODUCTS CO., LTD
Address: LIYE RD, XINJANGKOU TOWN, SONGZI CITY, JINGZHOU CITY, HUBEI PROVINCE, CHINA

CV for Clinical evaluation team members

Name	**Curriculum Vitae**
Sun Jinfeng	1. Essential information Name： Sun Jinfeng Birthday 1972-01-26 Gender：Male Healthy：Good 2. Education & Qualification **Bachelor of Clinical Medicine** Medical device quality management system chief auditor CCAA Registered QMS Senior Auditor National Registered Medicine Intermediate Attending Physician 3. Honors -For three consecutive years (2013, 2014, 2015) selected CCAA good certification case exchanging, and it is the only case of medical equipment certification. -The case of JS Medical Instrument Co., Ltd was awarded excellent case of Shanghai certification association. 4. Experience -14 years of medical equipment industry consulting and auditing related work experience, consulting and reviewing hundreds of medical device related enterprises. -**More than 10 years of hospital work experience, familiar with the clinical use of medical equipment knowledge, medical equipment clinical use requirements have a certain grasp.** 2009.12- Present As a senior manager of ISO9001/13485 quality management system -The main auditor of the 13485 project has rich experience in the audit of medical enterprises and has audited hundreds of enterprises related to medical devices. -Have a deep background in ISO13485 system certification audit work, can play and perform the ISO13485 quality management system, have strong practical experience in medical device industry management system, familiar with the laws and regulations of medical equipment industry, and familiar with the clinical implementation of medical equipment industry, and from the audit process has accumulated some experience.

	2004.11-2009.11 As a senior auditor of ISO9001/13485/14001 quality management system works in Shanghai JS Certification Co., Ltd. - Mainly engaged in ISO9001, 14001 quality management system audit work - To play company management system, responsible for medical development and tracking project. 2003.3-2004.9 Shanghai Exhibition Management Consulting Company ISO9001/ISO14001/IOS 13485 consultants - Mainly to do the ISO9000/14001/13485 management consulting work, especially in the field of medical equipment industry has a wealth of experience. - The consulting firms involved in trade, chemical industry, medical equipment manufacturing industry, etc. 1990.7-2003.1 As a Physician, party and government office director works in the first hospital of Laohekou, Hubei Province. -Mainly to do the physician and administrative work, the pharmaceutical industry and management work has a wealth of experience. -Familiar with the clinical use of medical equipment knowledge, the clinical use of medical devices has a certain grasp of the requirements.
Tina Cui	1. Essential Information: Name: Tina Cui Gender: Female Date of birth: November,1984 Education: Bachelor Work Experience: more than 10 years experience on medical device regulation in certification body and consulting organization. 2. Education: 2003.02-2006.10 Bachelor of International and Global Studies(International Business) 3. Working Experiences: **2018- Present,** Act as the technical consultant, Consulting for many medical enterprises about CE& ISO13485&ISO9001 and passed the TUV/BSI audit. Training Experiences 2008- IRCA certified auditor training course - QMS9001,13485&product assessor 2017/09, Regulation 2017/745 on Medical devices(MDR) training course, Clinical Evaluation of MEDDEV.2.7/1 REV.4 training course, provided by SGS. 2017/08, Regulation 2017/746 on In-vitro Diagnostic Medical devices(IVDR)

	training(include ISO14971 standard), provided by TUV SUD. 2017.08 ISO13485: 2016 training course, provided by TUV SUD. 2018.11.29-30 EN ISO14971:2012 training course, provided by BSI. 2019.01 MDSAP training course 2020.03 ISO14971:2019 training course, provided by BSI
Raymond Luo	From 2004.3 to present, get more than 10 years' experience on the medical device global regulation compliance in global famous certification body and consulting organization. **Major: Biological engineering** 2004.3 to 2015.3 Production certification director and the manager of the international business unit, manage the business of the global product certification including CE marking and all the certification business in Asia Pacific, which covers 14 countries besides China. 2015.3 to Present Act as the technical manager of SUNGO Technical Service Inc., responsible for the medical device compliance consulting, covers US and EU regulations.

Table of Contents

Executive summary

This clinical evaluation report presents the clinical evaluation of face masks which is suitable for medical workers and family workers working in general medical environment to avoid unwanted inhalation.

Medical Face Mask purchased by MEDLINK(SONGZI)MEDICAL PRODUCTS CO., LTD is made of non-woven and manufactured based on quality management system ISO13485:2016.

The clinical evaluation is conducted by collecting and analyzing clinical literature of the similar device of face masks search from PubMed, ScienceDirect, China CNKI database and other literature database list in section 3.1. PMS data held by manufacture and PMS data of the similar device from FDA Manufacturer and User Facility Device Experience (MAUDE) database.

The clinical data analysis concludes that the face mask complication rates and risks related to the devices remain continuously low and acceptable. No clinically relevant change is detected over time, and no new health or safety risks, no new side effects have been discovered during this evaluation. Anticipated residual risks may occur, but the number is low.

As a result of this clinical evaluation, the evidence provided demonstrates the safety and performance of face mask in their product-specific indications as describable in Instructions for Use, also conformity with the EU General Safety and Performance Requirements.

1. Scope of the clinical evaluation

The objective of this clinical evaluation is to identify, select, review and assess all available clinically relevant data of face mask.

Conformity assessment with the Medical Devices Regulation (EU) 2017/745 requires a medical device manufacturer to demonstrate that the claims made in relation to the device’s safety and performance, under the normal conditions of its use, are attainable. Generally, this requires clinical data, but evidence of the satisfactory clinical safety and performance of a device may be provided in the form of a critical evaluation of published and/or unpublished data on clinical experience with the device, or on a similar device to which equivalence can be demonstrated. This clinical evaluation is submitted to the Medical Devices Regulation (EU) 2017/745.

Based on the General Safety and Performance Requirements and the residual risk findings from the face mask risk analysis, the scope of this clinical evaluation comes from the intended performance and clinical residual risks in the risk analysis of these

products.

2. Device description

Medical Face Mask is used as barrier for user working in general medical environment to avoid unwanted inhalation or protecting from spray and spill to avoid any unexpected infection of flu or disease.

This device is a disposable product, suitable for the health care of the wearer in the general medical environment and the general care in public health places where there is any risk of bodily fluids and spillage

Medical Face Mask is going to contact with the intact skin of the user, and it has been tested according to related compatibility standards including ISO 10993-1:2018, EN ISO10993-5：2009 and EN ISO 10993-10:2013, please refer to Annex 3 < biocompatibility test report>.

The Medical Face Mask also must meet the requirements of EN 14683:2019 (please refer to: Annex 2 <performance test of EN14683>).

Device Introduction
Please refer to file 01 - Technical File Section 1.1 about detailed device description.

Harmonized standards
- Applicable Standard
Please refer to file 01 - Technical File Section 1.1 about applicable standard.

Table 2. Reference Guidance

Item.	Guidance	Title
1	MEDDEV 2.7.1 rev.4 (2016)	Clinical evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
2	MEDDEV 2.12-2 rev 2 (2012)	Guidelines on post market clinical follow up
3	GHTF SG5/N2R8	Clinical Evaluation

3. Clinical background, current knowledge, state of the art

Background:

Medical Face Mask is widely used in China, Hong Kong, Vietnam, and Toronto, Ontario, Canada during outbreaks of the SARS, during the 2007 bird flu pandemic in

Japan, and during the 2009 flu pandemic featuring swine flu and the H1N1 virus in the United States and Mexico City.

Medical Face Mask is intended to be worn by health professionals during surgery and certain health care procedures to catch microorganisms shed in liquid droplets and aerosols from the wearer's mouth and nose. Its first recorded use was by the French surgeon Paul Berger during an 1897 operation in Paris. [citation needed] Modern Medical Face Mask is made from paper or other non-woven material and should be discarded after each use. A Medical Face Mask is not to be confused with a respirator and is not certified as such. Medical Face Masks are designed to protect the wearer from inhaling airborne bacteria or virus particles and are less effective than respirators, which are designed for this purpose.

The design of the Medical Face Masks depends on the mode; usually the masks are 3 ply/3 layers. This 3 ply material is made up from a melt-blown material placed between non-woven fabric. The melt-blown material acts as the filter that stops microbes from entering or exiting the mask. Most Medical Face Masks feature pleats or folds. Commonly, 3 pleats are used allowing the user to expand the mask so it covers the area from the nose to the chin. There are 3 different ways to secure the masks. The most popular is the ear loop, where a string like material is attached to the mask and placed behind the ears. The other is the tie-on and the head band. The tie-on straps consist of four non-woven straps that are tied behind the head. The head band is an elastic strap that is placed behind the head.

Current Knowledge, State of art:

Medical Face Mask is intended to be worn by health professionals during surgery and certain health care procedures to catch microorganisms shed in liquid droplets and aerosols from the wearer's mouth and nose. Simple Medical Face Masks protect wearers from being splashed in the mouth with body fluids, and prevent transmission of body fluids from the wearer to others, e.g. the patient. They also remind wearers not to touch their mouth or nose, which could otherwise transfer viruses and bacteria after having touched a contaminated surface (fomite). They can also reduce the spread of infectious liquid droplets (carrying bacteria or viruses) that are created when the wearer coughs or sneezes [citation needed].

The Medical Face Masks using two materials have properties such as:
1)They have enough strength and good waterproof. They offer a credible barrier for medical personnel and can effectively block liquid splash which is often taken place in operation.
2)They have low rate of falling crumbs, do not have noise in abrasion and don't glisten in lamp, and is easy to sterilize; they can be decomposed, and don't have any pollution to environment.
3)The materials offer safety and comfort for doctor and nurse because of softness and

waterproof. In the meantime, because the Medical Face Masks have good performance of water-resist and liquid-separate, the oozy liquid in operation can be effectively obstruct to prevent the bacteria infection.

4. Identification of relevant clinical data

There are several types of clinical data which are clinical literature of similar device, PMS data of the propose device from manufacture including sales and complaints data, customer feedback, adverse event reports, the medical device reporting data and recall data of similar device of similar device.

4.1 Literature Data

Literature from some databases are used to evaluate the safety and performance of the predicate or similar device which are placed to the market.

4.2 PMS data generated and held by Manufacture

The propose device face mask has been sold many years. PMS data including customer feedback, customer complain, adverse event, recall and corrective actions are used in this evaluation.

4.3 PMS data of similar device

The face mask has been widely used in the world, we will search the adverse event, recall, corrective action of the similar device for a reference for the clinical safety of the propose device.

4.4 Literature search plan

4.4. 1 Literature search database

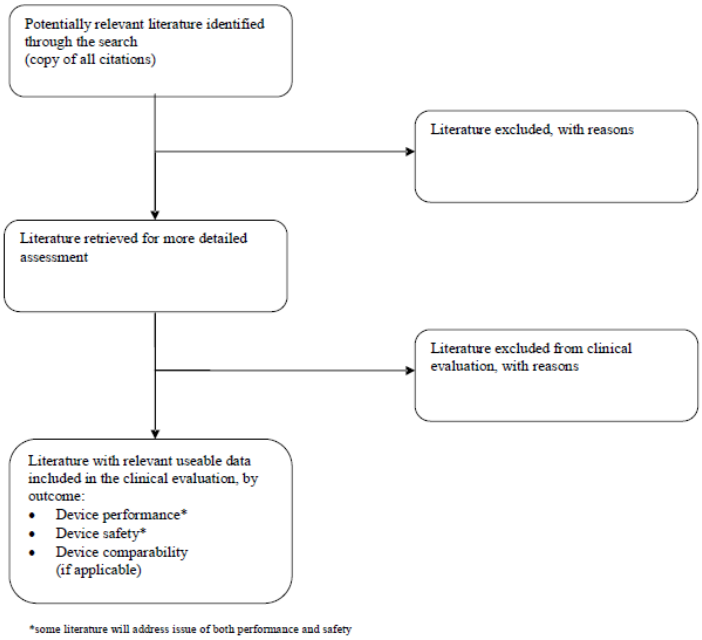
The databases used for literature search are shown as below

- Pubmed
- ScienceDirect
- CNKI

We used “medical face mask” as key word to search on the database list above and select the relevant literature for clinical evaluation.

4.4.2 Literature selection criteria

The literature selection criteria process is as follow:



We select the relevant literature according to the device discussed in the article, if the device is similar to the propose device, we will choose that literature for evaluation. If the device has similar intended use, the same work mechanism to the propose device, the device will be deemed as the similar device.

4.4.3 Literature exclusion criteria

We will review all articles' title and/or abstracts, if the article do not include face mask or the article in question did not examine humans; or no clinical data was available. The article would be excluded. Besides, we will review all the titles and abstracts of all the relevant literature to exclude the same literature.

5.Analysis of Clinical Data

5.1 Analysis of Literature

We use "medical face mask" as key word to search relevant literature in the database listed in section 4.4.1 and search time is 2000-2020. Take the ScienceDirect database for example, when we enter key word "medical face mask", 45,990 literature are found in ScienceDirect, then we review the relevance of literature and download 23 relevant literature for review and completely review the literature, finally 5 literature are chose for evaluation. The search result is as below.

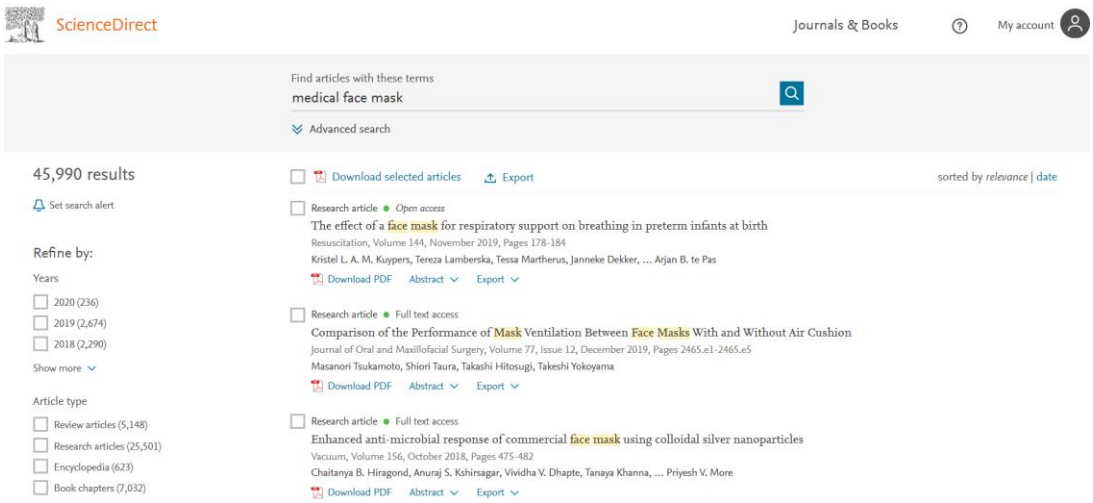


Figure2 Search Result in ScienceDirect

The relevant literature and the literatures used for clinical evaluation of all the databases we searched are shown in table below.

Table3 Literature Collection in different Database

Item	Database	Search Date	Search term	Search Period	Total Literature	Relevant Literature	Literature for Clinical Evaluation
1	Pubmed	10/05/2020	medical face mask	2000-2020	342	15	3
2	Science Direct	10/05/2020		2000-2020	45,990	23	5
3	CNKI	10/05/2020		Not Limited	143	8	0

Base on the Literature search result above, there are 8 literatures are used in this clinical evaluation. Literature analysis is shown in the table below.

Table4 Literature Analysis

Item	Literature	Author& Publication	Abstract
1	Surgical masks as source of bacterial contamination during operative procedures	Liu Zhiqing *, Chang Yongyun *, Chu Wenxiang, Yan Mengning, Mao Yuanqing, Zhu Zhenan, Wu Haishan, Zhao Jie, Dai Kerong, Li Huiwu **, Liu	Background: Disposable Medical Mask (non-sterile) s (SMs) are used to reduce bacterial shedding from the mouth, nose and face. This study aimed to investigate whether SMs may be a potential source of bacterial shedding leading to an increased risk of surgical site infection. Methods: Bacterial contamination of the SMs was tested by making an impression of the external surface of the mask on sterile culture media immediately. We investigated the difference in bacterial counts between the SMs worn by surgeons and those placed unused in the operating room (OR), and the bacterial count variation with indicated wearing time. Moreover, the difference in bacterial counts on the external surface between the first and

		Fengxiang ***, Zhai Zanjing* DOI：10.1016/j.jot.2018.06.002	second layers of double-layered SMs was also assessed. Results: The bacterial count on the surface of SMs increased with extended operating times; significant difference was found between the 4- to 6-hour and 0-hour groups ($p < 0.05$). When we analysed the bacterial counts from the same surgeon, a significant increase was noted in the 2-hours group. Moreover, the bacterial counts were significantly higher among the surgeons than the OR. Additionally, the bacterial count of the external surface of the second mask was significantly higher than that of the first one. Conclusions: The source of bacterial contamination in SMs was the body surface of the surgeons rather than the OR environment. Moreover, we recommend that surgeons should change the mask after each operation, especially those beyond 2 hours. Double-layered SMs or those with excellent filtration function may also be a better alternative. The translational potential of this article: This study provides strong evidence for the identification that SMs as source of bacterial contamination during operative procedures, which should be a cause for alarm and attention in the prevention of surgical site infection in clinical practice.
2	A cluster randomised trial of cloth masks compared with medical masks in healthcare workers	MacIntyre CR, et al. BMJ Open 2015;5:e006577. doi:10.1136/bmjopen-2014-006577	OBJECTIVE: The aim of this study was to compare the efficacy of cloth masks to medical masks in hospital healthcare workers (HCWs). The null hypothesis is that there is no difference between medical masks and cloth masks. SETTING: 14 secondary-level/tertiary-level hospitals in Hanoi, Vietnam. PARTICIPANTS:1607 hospital HCWs aged ⩾18 years working full-time in selected high-risk wards. INTERVENTION: Hospital wards were randomised to: medical masks, cloth masks or a control group (usual practice, which included mask wearing). Participants used the mask on every shift for 4 consecutive weeks. MAIN OUTCOME MEASURE:Clinical respiratory illness (CRI), influenza-like illness (ILI) and laboratory-confirmed respiratory virus infection. RESULTS: The rates of all infection outcomes were

			highest in the cloth mask arm, with the rate of ILI statistically significantly higher in the cloth mask arm (relative risk (RR)=13.00, 95% CI 1.69 to 100.07) compared with the medical mask arm. Cloth masks also had significantly higher rates of ILI compared with the control arm. An analysis by mask use showed ILI (RR=6.64, 95% CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) were significantly higher in the cloth masks group compared with the medical masks group. Penetration of cloth masks by particles was almost 97% and medical masks 44%. CONCLUSIONS: This study is the first RCT of cloth masks, and the results caution against the use of cloth masks. This is an important finding to inform occupational health and safety. Moisture retention, reuse of cloth masks and poor filtration may result in increased risk of infection. Further research is needed to inform the widespread use of cloth masks globally. However, as a precautionary measure, cloth masks should not be recommended for HCWs, particularly in high-risk situations, and guidelines need to be updated.
3	face mask Use and Control of Respiratory Virus Transmission in Households	Emerging Infectious Diseases，Vol. 15, No. 2, February 2009，DOI: 10.3201/eid1502.081167	Many countries are stockpiling face masks for use as a nonpharmaceutical intervention to control virus transmission during an infl uenza pandemic. We conducted a prospective cluster-randomized trial comparing Medical Face Masks, non–fi ttestedP2 masks, and no masks in prevention of influenzalike illness (ILI) in households. Mask use adherence was self-reported. During the 2006 and 2007 winter seasons, 286 exposed adults from 143 households who had been exposed to a child with clinical respiratory illness were recruited. We found that adherence to mask use signifi cantly reduced the risk for ILI-associated infection, but <50% of participants wore masks most of the time. We concluded that household use of face masks is associated with low

			adherence and is ineffective for controlling seasonal respiratory disease. However, during a severe pandemic when use of face masks might be greater, pandemic transmission in households could be reduced.
4	Face masks to prevent transmission of influenza virus : a systematic review	Cowling B , Zhou Y , Ip D , et al, Epidemiology & Infection, 2010, 138(4):449-456	Influenza viruses circulate around the world every year. From time to time new strains emerge and cause global pandemics. Many national and international health agencies recommended the use of face masks during the 2009 influenza A (H1N1) pandemic. We reviewed the English-language literature on this subject to inform public health preparedness. There is some evidence to support the wearing of masks or respirators during illness to protect others, and public health emphasis on mask wearing during illness may help to reduce influenza virus transmission. There are fewer data to support the use of masks or respirators to prevent becoming infected. Further studies in controlled settings and studies of natural infections in healthcare and community settings are required to better define the effectiveness of face masks and respirators in preventing influenza virus transmission.
5	Surgical mask filter and fit performance	Tara Oberg, MS, and Lisa M. Brosseau, ScD Minneapolis, Minnesota ,Vol. 36 No. 4, Oberg and Brosseau May 2008	Background: Medical Face Masks have been used since the early 1900s to minimize infection of surgical wounds from wearer-generated bacteria. There is ongoing debate, however, whether Medical Face Masks can meet the expectations of respiratory protection devices. The goal of this study was to evaluate the filter performance and facial fit of a sample of Medical Face Masks. Methods: Filter penetration was measured for at least 3 replicates of 9 Medical Face Masks using monodisperse latex sphere aerosols (0.895, 2.0, and 3.1 mm) at 6 L/min and 0.075-mm sodium chloride particles at 84 L/min. Facial fit was measured on 20 subjects for the 5 masks with lowest particle penetration, using both qualitative and quantitative fit tests. Results: Masks typically used in dental settings collected particles with significantly lower efficiency than those typically used in hospital settings. All subjects failed the unassisted qualitative fit test on the first exercise (normal breathing). Eighteen subjects

			failed the assisted qualitative fit tests; 60% failed on the first exercise. Quantitative fit factors ranged from 2.5 to 9.6. Conclusion: None of these Medical Face Masks exhibited adequate filter performance and facial fit characteristics to be considered respiratory protection devices. (Am J Infect Control 2008;36:276-82.)
6	Understanding the factors involved in determining the bioburdens of surgical masks	Submitted Jul 18, 2019. Accepted for publication Oct 25, 2019. doi: 10.21037/atm.2019.11.91	Background: Surgical site infection (SSI) continues to be one of the most common postoperative complications. In our previous study, Disposable Medical Mask (non-sterile) (SM) bioburden was identified to be a potential source of SSI. In the present study, we investigated the factors involved in SM bioburden. Methods: Bioburdens of the disposable SM (A: medical mask; B: medical Disposable Medical Mask (non-sterile)) and newly laundered cloth SM (C) were tested by immediately making an impression of the external surface of the mask on sterile culture media. SM microstructure was observed using a scanning electron microscope (SEM). Filtering efficiency and airflow resistance were evaluated with TSI Automated Filter Tester 8130 (TSI Incorporated) according to GB/19083-2010. Whether speaking during operation and washing the face pre-operatively affect SM bioburdens was also evaluated. Surgical procedures were performed in a dynamic operation room. Fifty cases of mask use were enrolled in this study. Results: The bioburden of mask A was the highest. The bioburden of mask B was the lowest. Mask C possessed the lowest filtering efficiency and the highest airflow resistance. SM bioburden was higher in the speaking group. SM bioburden showed no significant difference after washing the face, despite the finding that washing could significantly reduce facial bioburden. Conclusions: Multiple factors influence SM bioburdens. Mask B showed the lowest bioburden and best protection effects. Mask C is not recommended to be used, especially considering that surgeons do not wash the cloth masks daily. Unnecessary talking during operation is not recommended, and washing the face before surgery is not strictly necessary.

7	Contamination by respiratory viruses on outer surface of medical masks used by hospital healthcare workers	Abrar Ahmad Chughtai1*, Sacha Stelzer-Braid2, William Rawlinson3, Giulietta Pontivivo4, Quanyi Wang5, Yang Pan5, Daitao Zhang5, Yi Zhang5, Lili Li6 and C. Raina MacIntyre7,8 https://doi.org/10.1186/s12879-019-4109-x	BACKGROUND: Medical masks are commonly used in health care settings to protect healthcare workers (HCWs) from respiratory and other infections. Airborne respiratory pathogens may settle on the surface of used masks layers, resulting in contamination. The main aim of this study was to study the presence of viruses on the surface of medical masks. METHODS: Two pilot studies in laboratory and clinical settings were carried out to determine the areas of masks likely to contain maximum viral particles. A laboratory study using a mannequin and fluorescent spray showed maximum particles concentrated on upper right, middle and left sections of the medical masks. These findings were confirmed through a small clinical study. The main study was then conducted in high-risk wards of three selected hospitals in Beijing China. Participants (n = 148) were asked to wear medical masks for a shift (6-8 h) or as long as they could tolerate. Used samples of medical masks were tested for presence of respiratory viruses in upper sections of the medical masks, in line with the pilot studies. RESULTS: Overall virus positivity rate was 10.1% (15/148). Commonly isolated viruses from masks samples were adenovirus (n = 7), bocavirus (n = 2), respiratory syncytial virus (n = 2) and influenza virus (n = 2). Virus positivity was significantly higher in masks samples worn for > 6 h (14.1%, 14/99 versus 1.2%, 1/49, OR 7.9, 95% CI 1.01-61.99) and in samples used by participants who examined > 25 patients per day (16.9%, 12/71 versus 3.9%, 3/77, OR 5.02, 95% CI 1.35-18.60). Most of the participants (83.8%, 124/148) reported at least one problem associated with mask use. Commonly reported problems were pressure on face (16.9%, 25/148), breathing difficulty (12.2%, 18/148), discomfort (9.5% 14/148), trouble communicating with the patient (7.4%, 11/148) and headache (6.1%, 9/148). CONCLUSION: Respiratory pathogens on the outer surface of the used medical masks may result in self-contamination. The risk is higher with longer duration of mask use (> 6 h) and with higher rates of clinical

			contact. Protocols on duration of mask use should specify a maximum time of continuous use, and should consider guidance in high contact settings. Viruses were isolated from the upper sections of around 10% samples, but other sections of masks may also be contaminated. HCWs should be aware of these risks in order to protect themselves and people around them.
8	Respiratory source control using a surgical mask: An in vitro study	Journal of Occupational and Environmental Hygiene, 13:7, 569-576, DOI: 10.1080/15459624.2015.1043050	ABSTRACT: Cough etiquette and respiratory hygiene are forms of source control encouraged to prevent the spread of respiratory infection. The use of Disposable Medical Mask (non-sterile) s as a means of source control has not been quantified in terms of reducing exposure to others. We designed an in vitro model using various facepieces to assess their contribution to exposure reduction when worn at the infectious source (Source) relative to facepieces worn for primary (Receiver) protection, and the factors that contribute to each. In a chamber with various airflows, radiolabeled aerosols were exhaled via a ventilated soft-face manikin head using tidal breathing and cough (Source). Anothermanikin, containing a filter, quantified recipient exposure (Receiver). The natural fit Disposable Medical Mask (non-sterile) , fitted (SecureFit) surgicalmask and an N95- class filtering facepiece respirator (commonly known as an “N95 respirator”) with and without a Vaselineseal were tested. With cough, source control (mask or respirator on Source) was statistically superior to mask or unsealed respirator protection on the Receiver (Receiver protection) in all environments. To equal source control during coughing, the N95 respirator must be Vaseline-sealed. During tidal breathing, source controlwas comparable or superior to mask or respirator protection on the Receiver. Source control via Disposable Medical Mask (non-sterile) s may be an important adjunct defense against the spread of respiratory infections. The fit of the mask or respirator, in combination with the airflow patterns in a given setting, are significant contributors to source control efficacy. Future clinical trials should include a surgicalmask source control arm to assess the contribution of source control in overall protection

			against airborne infection.

5.2 Analysis of Post-Marketing Data

The face mask has been placed on the market for many years, during many years' sale, no customer feedback was received so far. the sale list and customer feedback of the propose device and similar device are shown in the table below.

Table2 Customer feedback list of the propose device

NO.	Description	Root Cause	Corrective actions	state
0	/	/	/	/

Table3 Post Market experience of similar device

Area	Time	Quantity	Complaints	Adverse events
USA	2017	0	0	0
	2018	0	0	0
	2019	0	0	0
EU	2017	0	0	0
	2018	0	0	0
	2019	0	0	0
Total	0		0	0

The face mask manufactured by MEDLINK(SONGZI)MEDICAL PRODUCTS CO., LTD intended for medical workers and family workers working in general medical environment to avoid unwanted inhalation. The use of face mask is mature. The manufacture has established quality management system and strictly follow the work instructions to ensure the product quality. And the face mask has been placed on market for several years and a large number of devices has been sold. The PMS data shows the face mask is safety use on the market. The PMS data including customer feedback, customer complain are continuously collect to monitor the safety and effectiveness of face mask.

Literature, the safety tests, biocompatibility tests and General Safety and Performance Requirement demonstrate that the propose device is safe and effectiveness. The risk about propose device has been identified and mitigated to be acceptable or as low as reasonable practice.

Base on the evaluation of clinical literature, PMS data of the propose device, PMS data of similar device, General Safety and Performance Requirement, risk analysis of propose device. The overall clinical risk of the propose device face mask is low and

acceptable. This clinical evaluation is complied with Medical Device Regulation (EU)2017/745.

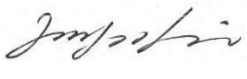
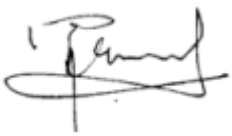
6.Next Clinical Evaluation

As extensively outlined above, the use of face mask is well-established and the safety profile is well-known without significant risks. Safety and performance of this product has been examined and documented in many clinical studies. Moreover, extensive experience in clinical practice and post-marketing data support the performance and safety profile of face mask in the claimed indications.
The clinical evaluation will be updated once per three years normally, but should be updated immediately if significant risk were found.

7. Declaration of interests

Sun Jinfeng, Tina Cui, Raymond Luo, are hired by MEDLINK(SONGZI)MEDICAL PRODUCTS CO., LTD as clinical evaluator of Medical Face Mask from 26/04/2020 to 25/07/2020 to participate in the clinical evaluation. In order to ensure the validity and impartiality of clinical evaluation. We make a declaration of interests as follow.

- The clinical evaluation does not involve any financial interests of ourselves;
- The clinical evaluation does not involve any financial interests of our family members;
- The clinical evaluation does not involve any ownership/ shareholding possibly affected by the outcome of the evaluation;
- The clinical evaluation does not involve any grants sponsored by the manufacturer;
- The clinical evaluation does not involve any benefits such as travelling or hospitality;
- The clinical evaluation does not involve any interests in connection with intellectual property, such as patents, copyrights and royalties possibly affected by the outcome of the evaluation.

NAME	*SIGNATURE*	*DATE* ***26/04/2020***
		

8. Reference

*[1] Liu Zhiqing *, Chang Yongyun *, Chu Wenxiang, Yan Mengning, Mao Yuanqing, Zhu Zhenan, Wu Haishan, Zhao Jie, Dai Kerong, Li Huiwu **, Liu Fengxiang ***, Zhai Zanjing* DOI：10.1016/j.jot.2018.06.002*

[2] MacIntyre CR, et al. BMJ Open 2015;5:e006577. doi:10.1136/bmjopen-2014-006577

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[7] Abrar Ahmad Chughtai1, Sacha Stelzer-Braid2, William Rawlinson3, Giulietta Pontivivo4, Quanyi Wang5, Yang Pan5, Daitao Zhang5, Yi Zhang5, Lili Li6 and C. Raina MacIntyre7,8 DOI:10.1186/s12879-019-4109-x*

[8] Journal of Occupational and Environmental Hygiene, 13:7, 569-576, DOI: 10.1080/15459624.2015.1043050

Biological Evaluation Report

File No.: CE/MDR-MDK-01-06

Version: A/0

Product: Medical Face Mask

Issued By	Reviewed By	Approved By	Effective Date
Yang Mei	Lei Zhenghong	Liao Chan	2020.07.20

MEDLINK(SONGZI)MEDICAL PRODUCTS CO., LTD
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Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A/0	Initial	Yang Mei	2020.07.20

1. Foreword

This report is to describe the biological risk control carried on the Medical Face Mask manufactured by our company. All potential biological hazards and potential cause of each hazard have been determined in this report. Evaluations have been made on possible severity level may led by each hazard and probability of occurrence of each hazard. For unacceptable risks, necessary measures must be taken, and also evaluate the residual risk level after taking relevant measures.

To reduce the risks which may lead to various kinds of potential hazards to the acceptable level and also to reduce the total amount of every kind of hazards to the acceptable level by taking proper measures.

2. Purpose

Aim of this risk control is to carry out determination on the biological risks that may be led by the Medical Face Mask that have been put into production in our company, also to stipulate the necessary relative measures, in order to keep the risk level within an acceptable level.

By taking risk control the company may take relative measures of continuously improving quality of the products, to meet customer stipulated or potential requirements constantly.

3. Documents reference

EN ISO14971:2019, Medical devices - Application of risk management to medical devices

ISO10993-1:2018 Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process

4. Categorization of medical devices

4.1 Categorization by nature of body contact

Surface-contacting devices

These include medical devices in contact with the following.

Non-woven is intended contact with patient

4.2 Categorization by duration of contact

Medical devices shall be categorized according to the anticipated duration of contact as follows.

a) Limited exposure (A) – devices whose cumulative single, multiple or repeated use or contact is up to 24 h.

The framework for the development of an assessment programme is as below:

Table 1 — Evaluation tests for consideration

Table A.1 — Endpoints to be addressed in a biological risk assessment

Medical device categorization by			Endpoints of biological evaluation															
Nature of body contact		Contact duration																
Category	Contact	A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – Long term (>30 d)	Physical and/or chemical information	Cytotoxicity		Irritation or intracutaneous reactivity	Material mediated pyrogenicity[a]	Acute systemic toxicity[b]	Subacute toxicity[b]	Subchronic toxicity[b]	Chronic toxicity[b]	Implantation effects[b,c]	Hemocompatibility	Genotoxicity[d]	Carcinogenicity[d]	Reproductive/ developmental toxicity[d,e]	Degradation[f]	
Surface medical device	Intact skin	A	X[g]	E[h]	E	E												
		B	X	E	E	E												
		C	X	E	E	E												
	Mucosal membrane	A	X	E	E	E												
		B	X	E	E	E		E	E			E						
		C	X	E	E	E		E	E	E	E	E		E				
	Breached or compromised surface	A	X	E	E	E	E	E										
		B	X	E	E	E	E	E	E			E						
		C	X	E	E	E	E	E	E	E	E	E		E	E			
Externally communicating medical device	Blood path, indirect	A	X	E	E	E	E	E					E					
		B	X	E	E	E	E	E	E				E					
		C	X	E	E	E	E	E	E	E	E	E	E	E	E			
	Tissue/ bone/ dentin[i]	A	X	E	E	E	E	E										
		B	X	E	E	E	E	E	E			E		E				
		C	X	E	E	E	E	E	E	E	E	E		E	E			
	Circulating blood	A	X	E	E	E	E	E					E	E[j]				
		B	X	E	E	E	E	E	E			E	E	E				
		C	X	E	E	E	E	E	E	E	E	E	E	E	E			

Table A.1 *(continued)*

Medical device categorization by			Endpoints of biological evaluation														
Nature of body contact		Contact duration															
Category	Contact	A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – Long term (>30 d)	Physical and/or chemical information	Cytotoxicity		Irritation or intracutaneous reactivity	Material mediated pyrogenicity[a]	Acute systemic toxicity[b]	Subacute toxicity[b]	Subchronic toxicity[b]	Chronic toxicity[b]	Implantation effects[b,c]	Hemocompatibility	Genotoxicity[d]	Carcinogenicity[d]	Reproductive/developmental toxicity[d,e]	Degradation[f]
Implant medical device	Tissue/bone[i]	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Blood	A	X	E	E	E	E	E				E	E	E			
		B	X	E	E	E	E	E	E			E	E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		

[a] Refer to ISO 10993-11:2017, Annex F.

[b] Information obtained from comprehensive implantation assessments that include acute systemic toxicity, subacute toxicity, subchronic toxicity and/or chronic toxicity may be appropriate if sufficient animals and timepoints are included and assessed. It is not always necessary to perform separate studies for acute, subacute, subchronic, and chronic toxicity.

[c] Relevant implantation sites should be considered. For instance medical devices in contact with intact mucosal membranes should ideally be studied/ considered in contact with intact mucosal membranes.

[d] If the medical device can contain substances known to be carcinogenic, mutagenic and/or toxic to reproduction, this should be considered in the risk assessment.

[e] Reproductive and developmental toxicity should be addressed for novel materials, materials with a known reproductive or developmental toxicity, medical devices with relevant target populations (e.g. pregnant women), and/or medical devices where there is the potential for local presence of device materials in the reproductive organs.

[f] Degradation information should be provided for any medical devices, medical device components or materials remaining within the patient, that have the potential for degradation.

[g] X means prerequisite information needed for a risk assessment.

[h] E means endpoints to be evaluated in the risk assessment (either through the use of existing data, additional endpoint-specific testing, or a rationale for why assessment of the endpoint does not require an additional data set). If a medical device is manufactured from novel materials, not previously used in medical device applications, and no toxicology data exists in the literature, additional endpoints beyond those marked "E" in this table should be considered. For particular medical devices, there is a possibility that it will be appropriate to include additional or fewer endpoints than indicated.

[i] Tissue includes tissue fluids and subcutaneous spaces. For gas pathway devices or components with only indirect tissue contact, see device specific standards for biocompatibility information relevant to these medical devices.

[j] For all medical devices used in extracorporeal circuits.

4.3 Biological safety assessment

According to ISO10993-1:2018, The assess route is performing Cytotoxicity, Sensitization, Irritation (including intracutaneous reactivity) test and completing risk management.

Besides, according to ISO10993-1:2018 Annex A.1 Endpoints to be addressed in a biological risk assessment, non-woven is intended to contact with the intact skin of human body, the contact time is less than 24H. Cytotoxicity, Sensitization, Irritation (including intracutaneous reactivity) were performed on the concerned product. In Vitro Cytotoxicity Test Using EN ISO10993-5:2009 Test Method MTT Method MEM with 10% FBS extract, Skin Sensitization Test Using EN ISO10993-10:2013 Test Methods Guinaea Pig Maximization Test 0.9% Sodium Chloride Injection Extract, Intracutaneous Reactivity Test using EN ISO 10993-10:2013 Test Method 0.9% Sodium Chloride Injection Extract were performed, all the tests results showed the handpiece possess a good biocompatibility properties.

5. Testing and test reports

Biocompatibility Evaluation Report

Item	Standard	Test Item	Test report

1	EN ISO10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	Cytotoxicity test	Refer to Annex 3_Biocompatibility Test Report
2	EN ISO10993-10:2013 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	Skin sensitization test	
3		Skin irritation test	

6. Conclusion

According to ISO14971 and ISO 10993-1 requirements, we have completed the biological evaluation for the Medical Face Mask, the available information is sufficient to meet the purpose of the evaluation of biological safety, the Medical Face Mask biological risks are acceptable, needn't further control measures.

Annex1: biological evaluation process

This process only applies to those medical devices that contact the patient's body directly or indirectly.

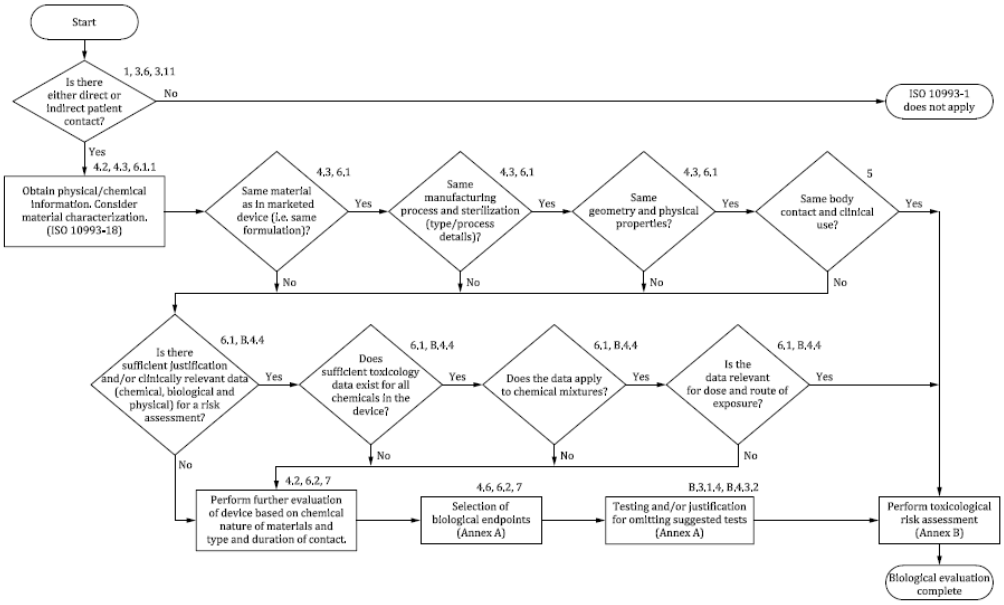

Figure 1 — Summary of the systematic approach to a biological evaluation of medical devices as part of a risk management process

Usability Evaluation Report

File No.: CE/MDR-MDK-01-07

Version: A/0

Product: Medical Face Mask

Issued By	Reviewed By	Approved By	Effective Date
Yang Mei	Lei Zhenghong	Liao Chan	2020.07.20

MEDLINK(SONGZI)MEDICAL PRODUCTS CO., LTD
LIYE RD, XINJANGKOU TOWN, SONGZI CITY, JINGZHOU CITY, HUBEI PROVINCE, CHINA

Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A/0	Initial	Yang Mei	2020.07.20

TEST REPORT

EN 62366-1:2015
Medical devices – Application of usability engineering to medical devices

Report Reference No. ..... :	CE/MDR-MDK-01-07
Total number of pages.....	16Pages
Compiled by (+ signature) ..... :	
Approved by (+ signature)..... :	
Date of issue..... :	2020.07.20
Test Standard ..... :	EN 62366-1:2015
Test procedure..... :	usability engineering Testing
Non-standard test method…….. :	N/A
Testing ambient Condition ..... :	
Test Report Form No. ..... :	EN 62366-1:2015 A/0
TRF modified by ..... :	
Manufacturer ..... :	MEDLINK(SONGZI)MEDICAL PRODUCTS CO., LTD
Address..... :	LIYE RD, XINJANGKOU TOWN, SONGZI CITY, JINGZHOU CITY, HUBEI PROVINCE, CHINA
Test object ..... :	
Trademark ..... :	
Model/Type reference ..... :	
Rating ..... :	

Summary of testing:
The equipment is complied with EN 62366-1:2015.

General information
Test item particulars (see also clause 5) Classification of installation and use .....: Supply Connection..... :
Accessories and detachable parts included in the evaluation..... : N/A Options included ..... : N/A
Possible test case verdicts: - test case does not apply to the test object ..... : N/A - test object does meet the requirement ..... : P (Pass) - test object does not meet the requirement..... : F (Fail)
General remarks: The evaluation results presented in this report relate only to the object evaluated. This report shall not be reproduced, except in full, without the written approval of the Issuing evaluation". This Evaluation Report contains the general safety requirements as related to the usability of Medical Equipment.
General product information and considerations: The Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

EN 62366-1:2015			
Clause	Requirement + Test	Result - Remark	Verdict
EN 62366-1:2015 Test Report			
4	General requirements		
4.1	General requirements		
4.1.1	Usability Engineering Process		
	Has the manufacturer established, documented and maintained a usability engineering process to provide safety for the patient, user and others related to usability for the product?	Quality manual—QMS+QP	P
	Does the process address user interactions with the medical device according to the accompanying document including, but not limited to transport, storage, installation, operation, maintenance, repair and disposal?	Yes Label and instruction for use	P
4.1.2	Risk Control as It Relates to User Interface Design		
	To reduce use-related risk, the manufacturer shall use one or more of the following options, in the priority listed A) inherent safety by design; B) protective measures in the medical device itself or in the manufacturing process; C) information for safety.	Label and instruction for use Information for safety	P
4.1.3	Information for Safety as It Relates to Usability		

	When, in accordance with the priorities of 4.1.2, information for safety is used as a risk control measure, the manufacturer shall subject this information to the usability engineering process to determine that the information – is perceivable by, – is understandable to, and – supports correct use of the medical device by users of the intended user profiles in the context of the intended use environment. conscious disregard of such information for safety by the user is considered to be an intentional act or intentional omission of an act that is counter to or violates normal use and is also beyond any further reasonable means of user interface-related risk control by the manufacturer (i.e. Abnormal use). Compliance is checked by inspection of the information for safety and the usability engineering file.	Quality manual—QMS+QP Risk Management Report	P
4.2	Usability Engineering File		
	The results of the usability engineering process shall be stored in the usability engineering file. The records and other documents that form the usability engineering file may form part of other documents and files.	Risk Management Report The results were recorded in the product production, transport, storage, operation disposal documentation.	P
	Compliance is checked by inspection of the usability engineering file.	The results were recorded in the product production, transport, storage, operation disposal documentation.	P
4.3	Tailoring of the usability engineering effort		

	The level of effort and the choice of methods and tools used to perform the usability engineering process may vary based on: A) the size and complexity of the user interface; B) the severity of the harm associated with the use of the medical device; C) the extent or complexity of the use specification; D) the presence of user interface of unknown provenance; and E) the extent of the modification to an existing medical device user interface that had been subjected to the usability engineering process.	Risk Management Report The results were recorded in the product production, transport, storage, operation disposal documentation.	P
5	Usabilty Engineering Process		
5.1	Prepare Use Specification		
	The manufacturer shall prepare a use specification. The use specification shall include:	-	-
	– * intended medical indication;	Label and instruction for use	P
	– intended patient population;	Label and instruction for use	P
	– intended part of the body or type of tissue applied to or interacted with;	Label and instruction for use	P
	– intended conditions of use (e.g. Environment including hygienic requirements, frequency of use, location, mobility); and	Label and instruction for use	P
	– operating principle(s)	Label and instruction for use	P
5.2	* Identify User Interface Characteristics Related to Safety and Potential Use Errors		
	The manufacturer shall identify user interface characteristics that could be related to safety as part of a risk analysis performed according to ISO 14971:2019, 4.2. this identification may also be performed using the tools and techniques from the usability engineering process. This identification shall include consideration of the primary operating functions that are provided in applicable particular medical device safety standards.	Risk Management Report The results were recorded in the product production, transport, storage, operation disposal documentation.	P

	Based on the identified user interface characteristics and use specification, the manufacturer shall identify the use errors that could occur and are related to the user interface. This identification may be accomplished by conducting a task analysis.	Label and instruction for use	P
	The results of this identification of characteristics related to safety shall be stored in the usability engineering file.	The results were recorded in the product production, transport, storage, operation disposal documentation.	P
5.3	* Identify Known or Foreseeable Hazards and Hazardous Situations		
	The manufacturer shall identify known or foreseeable hazards and hazardous situations, which could affect patients, users or others, related to use of the medical device. This identification shall be conducted as part of a risk analysis performed according to ISO 14971:2019, 4.3 and the first paragraph of ISO 14971:2019, 4.4.	Risk Management Report The results were recorded in the product production, transport, storage, operation disposal documentation.	P
	During the identification of hazards and hazardous situations, the following shall be considered:	---------	--------
	– use specification, including user profile(s) (see 5.1);	Label and instruction for use	P
	– information on hazards and hazardous situations known for existing user interfaces of medical devices of a similar type, if available; and	N/A	
	– Identified Use Errors (see 5.2).	Label and instruction for use	P
	The results of this identification of hazards and hazardous situations shall be stored in the usability engineering file.	Risk Management Report The results were recorded in the product production, transport, storage, operation disposal documentation.	
5.4	Identify hazard-related use scenarios		
	The manufacturer shall identify and describe the reasonably foreseeable hazard-related use scenarios associated with the identified hazards and hazardous situations. The description of each identified hazard-related use scenario shall include all tasks and their sequences as well as the severity of the associated harm.	Risk Management Report The results were recorded in the product production, transport, storage, operation disposal documentation.	P

	Compliance is checked by inspection of the usability engineering file.	The results were recorded in the product production, transport, storage, operation disposal documentation.	P
5.5	Select Scenarios for Summative Evaluation		
	The manufacturer shall select the hazard-related use scenarios to be included in the summative evaluation. The manufacturer shall select either:	--	--
	– all hazard-related use scenarios; or – the subset of the hazard-related use scenarios based on the severity of the potential harm that could be caused by use error (e.g. For which medical intervention would be needed). The choice of the scheme used to select the hazard-related use scenarios may additionally depend on other circumstances specific to the medical device and the manufacturer. Note examples of selection schemes are given in annex a, 5.5, and IEC 62366-2. a summary of any selection scheme, the rationale for its use and the results of applying it shall be stored in the usability engineering file. Compliance is checked by inspection of the usability engineering file.	The results were recorded in the product production, transport, storage, operation disposal documentation.	P
5.6	Establish user interface specification		
	The manufacturer shall establish and maintain a user interface specification. The user interface specification shall consider:	Label and instruction for use	P

	– the use specification (see 5.1); – the known or foreseeable use errors associated with the medical device (see 5.2); and – the hazard-related use scenarios (see 5.4). The user interface specification shall include: – testable technical requirements relevant to the user interface, including the requirements for those parts of the user interface associated with the selected risk control measures; note technical requirements for the user interface can include display colour, character size, or placement of the controls. – an indication as to whether accompanying documentation is required; and – an indication as to whether medical device-specific training is required. The user interface specification shall be stored in the usability engineering file. The user interface specification may be integrated into other specifications. Compliance is checked by inspection of the usability engineering file.	Risk Management Report Label and instruction for use	P
5.7	Establish user interface evaluation plan		
5.7.1	The manufacturer shall establish and maintain a user interface evaluation plan for the user interface specification.		NA
	The user interface evaluation plan shall a) document the objective and identify the method of any planned formative evaluations and summative evaluations;		NA
	B) if usability tests are employed, – document the involvement of the representative intended users and user profile to which they belong. – document the test environment and other conditions of use, based on the use specification; – specify whether accompanying documentation is provided during the test; – specify whether medical device-specific training is provided prior to the test and the minimum elapsed time between the training and the beginning of the test.		NA

	User interface evaluation methods may be quantitative or qualitative. User interface evaluation may be performed in a variety of locations, such as, in a laboratory setting, in a simulated use environment or in the actual use environment		NA
5.7.2	Formative evaluation planning		
	The user interface evaluation plan for formative evaluation shall address: A) the evaluation methods being used; B) which part of the user interface is being evaluated; and C) when in the usability engineering process to perform each of the user interface evaluations.	Product Test Report	P
5.7.3	Summative evaluation planning		
	For each selected hazard-related use scenario (see 5.5), the user interface evaluation plan for summative evaluation shall specify:		N/A
	A) the evaluation method being used and a rationale that the method produces objective evidence;		N/A
	B) which part of the user interface is being evaluated		N/A
	C) where applicable, the criteria for determining whether the information for safety is perceivable, understandable and supports correct use of the medical device (4.1.3); note 2 the summative evaluation of the information for safety is typically completed prior to initiating the summative evaluation of the remainder of the user interface. It is usually a separate usability test with different users.		N/A
	D) * the availability of the accompanying documentation and provision of training during the summative evaluation; and note 3 a summative evaluation can include training as part of the protocol, as appropriate, to simulate realistic use. An appropriate wait time might be needed between the training and the rest of the summative evaluation to allow for representative learning decay.		

	E) * for a usability test, – the test environment and conditions of use and a rationale for how they are adequately representative of the actual conditions of use; and – the method of collecting data during the usability test for the subsequent analysis of observed use errors. The summative evaluation may be performed in a single evaluation or multiple evaluations. Note 4 the planning for summative evaluation will likely not be finalized until after the formative evaluation has been completed. Note 5 guidance on the evaluation of the adequacy of risk control measures can be found in ISO 14971:2019, clause d.4. compliance is checked by inspection of the usability engineering file.		N/A
5.8	* perform user interface design, implementation and formative evaluation		
	The manufacturer shall design and implement the user interface, including the accompanying documentation if needed, and training capability, if needed, as described in the user interface specification.	Label and instruction for use	p
	The manufacturer shall utilize, as appropriate, usability engineering methods and techniques, including formative evaluation to accomplish this design and implementation. The results of the utilized formative evaluation shall be stored in the usability engineering file. Where new use errors, hazards, hazardous situations or hazard-related use scenarios are discovered during this step, the manufacturer shall repeat the steps of clause 5 as appropriate.	Label and instruction for use The results were recorded in the product production, transport, storage, operation disposal documentation.	p
	If training on the specific medical device is required for the safe use of the medical device by the intended user, the manufacturer shall design and implement a training capability for the expected service life of the medical device by doing at least one of the following:	The device is easy to operate. The user can use according to the IFU	P

	– provide the materials necessary for training; – ensure that the materials necessary for training are available; – make the training available; or – make training available to the responsible organization that enables it to train its users.	N/A	
	Compliance is checked by inspection of the usability engineering file, including for evidence of the formative evaluation, if performed, and the existence of the training strategy, if required.	N/A	
5.9	* perform summative evaluation of the usability of the user interface		
	Upon completion of the design and implementation of the user interface, the manufacturer shall perform a summative evaluation of each hazard-related use scenario selected in 5.5 on the final or production equivalent user interface according to the user interface evaluation plan. For summative evaluation, the manufacturer may use data obtained from the summative evaluations of products with an equivalent user interface together with a technical rationale for how this data is applicable. The results shall be stored in the usability engineering file.	The results were recorded in the product production, transport, storage, operation disposal documentation.	p
	The data from the summative evaluation shall be analysed to identify the potential consequences of all use errors that occurred. If the consequences can be linked to a hazardous situation, the root cause of each use error shall be determined. The root causes should be determined based on observations of user performance and subjective comments from the user related to that performance.	Risk Management Report	p
	If new use errors, hazards, hazardous situations or hazard-related use scenarios are discovered during this data analysis:	---	p

	– if yes, then the manufacturer shall repeat the activities of clause 5 as appropriate; – if not, the manufacturer shall determine whether further improvement of the user interface design as it relates to safety is necessary and practicable.	Risk Management Report	P
	1) if yes, then the manufacturer shall re-enter the usability engineering process at 5.6; 2) if not, then the manufacturer shall: note 1 there can be risk controls that are not user interface-related that are practicable solutions to reduce user interface-related risk. I) document why improvement is not practicable; note 2 guidance for how to determine that further risk reduction in the user interface is not practicable is found in ISO 14971:2019, 6.2. ii) identify the data from the usability engineering process needed to determine the residual risk related to use; and iii) evaluate the residual risk according to ISO 14971:2019, 6.4.	Risk Management Report The results were recorded in the product production, transport, storage, operation disposal documentation.	p
	Note 3 ISO 14971:2019, subclause 6.6 requires that design changes resulting from the usability engineering process be reviewed to determine non-user interface related hazards or hazardous situations have been generated. Note 4 ISO 14971:2019, clause 7 requires that all residual risk be considered when evaluating the overall residual risk of the medical device, including the residual risk associated with usability of the medical device.		p
	If the usability engineering process detailed in this international standard has been complied with, then the usability of a medical device as it relates to safety is presumed to be acceptable, unless there is objective evidence to the contrary.		p
	Note 5 such objective evidence can subsequently originate from post-production surveillance. Compliance is checked by inspection of the usability engineering file and by application of the requirements of ISO 14971:2019, 6.4.		p
5.10	User Interface of Unknown Provenance		

	Instead of all the requirements of 5.1 through 5.9, uoup may be evaluated according to annex c.	No	
	Compliance is checked by application of annex c.	No	
C.1	General		
	This annex was created in recognition of the fact that many manufacturers will be interested in applying the tools defined in this standard to user interfaces or parts of user interfaces that have already been commercialized prior to the publication of this edition of this standard. Such user interfaces or parts of user interfaces were not developed using the processes of iec 62366-1 and as a result are of unknown provenance with respect to these processes. Since this standard focuses on usability engineering as part of the product development process, it was determined that an appropriately scaled (as described in 4.3) and alternative process should be developed to cover these user interfaces or parts of user interfaces of unknown provenance.	-----	
	The following represents such a process that relies wherever possible on existing documentation that was created during the development of a legacy user interface or part of a user interface. It also attempts to allow the process to be applied utilizing organizational resources as efficiently as possible. When completed, it will result in the creation of a usability engineering file and assure that the risk management file identifies risks caused by usability problems of the user interface.	-----	
	The process of this annex can be applied to uoup for a user interface or part of a user interface for which adequate records of the development using the usability engineering process of iec 62366-1:— are not available. However, if any modifications are made to the user interface or its parts, only the unchanged parts of the user interface remain uoup and the changed parts of the user interface are subject to 5.1 to 5.8.	-----	

C.2	Usability engineering process for user interface of unknown provenance	-----	
C.2.1	* use specification		
	The manufacturer shall establish a use specification as required in 5.1. the manufacturer shall store this use specompliance is checked by inspection of the usability engineering file. Cification in the usability engineering file.	-----	
C.2.2	* review of post-production information		
	The manufacturer of the medical device with uoup shall review available post-production information including complaints and field reports for incidents or near incidents.	-----	
	All identified cases of use error that could result in a hazardous situation or those cases where field information suggests hazards or hazardous situations that could have been caused by inadequate usability shall be stored in the usability engineering file and addressed in c.2.3 and c.2.4. Compliance is checked by inspection of the usability engineering file.	-----	
C.2.3	Hazards and hazardous situations related to usability		
	The manufacturer shall review the risk analysis of the medical device with uoup and ensure that the hazards and hazardous situations associated with usability have been identified and documented. Compliance is checked by inspection of the usability engineering file.	-----	
C.2.4	Risk control		
	The manufacturer shall verify and document that adequate risk control measures have been implemented for all identified hazards and hazardous situations identified in c.2.3 and that all risks are reduced to an acceptable level as indicated by the risk assessment.	-----	

	If the manufacturer determines that changes to any part of the user interface are required to reduce risk to an acceptable level, those changes shall not be considered uoup and shall be subject to the requirements of 5.1 through 5.8. Compliance is checked by inspection of the usability engineering file.	-----	
C.2.5	Residual risk evaluation		
	Based on any new information identified in performing steps c.2.3 and c.2.4, the manufacturer shall re-evaluate the overall residual risk according to ISO 14971:2019, 6.4, and document the result in either the usability engineering file or the risk management file.	-----	
	Compliance is checked by inspection of the usability engineering file or the risk management file.	-----	
6	Accompanying documents		
	The accompanying document includes a summary of the medical device application specification	Yes, Label and instruction for use	P
	A concise description of the medical device, its operating principles, significant physical and performance characteristics and intended user profile are included in the accompanying document.	Label and instruction for use	P
	The accompanying document is written at a level consistent with the intended operator profile	Label and instruction for use	P
	The accompanying document for equipment are, optionally, provided electronically.	Label and instruction for use	P
	Usability engineering process includes the information that will need to be provided as a hard copy or as markings on medical device when accompanying documents are provided electronically。	Label and instruction for use	P

Labelling

File No.: CE/MDR-MDK-01-08

Version: A/0

Product: Medical Face Mask

Issued By	Reviewed By	Approved By	Effective Date
Yang Mei	Lei Zhenghong	Liao Chan	2020.07.20

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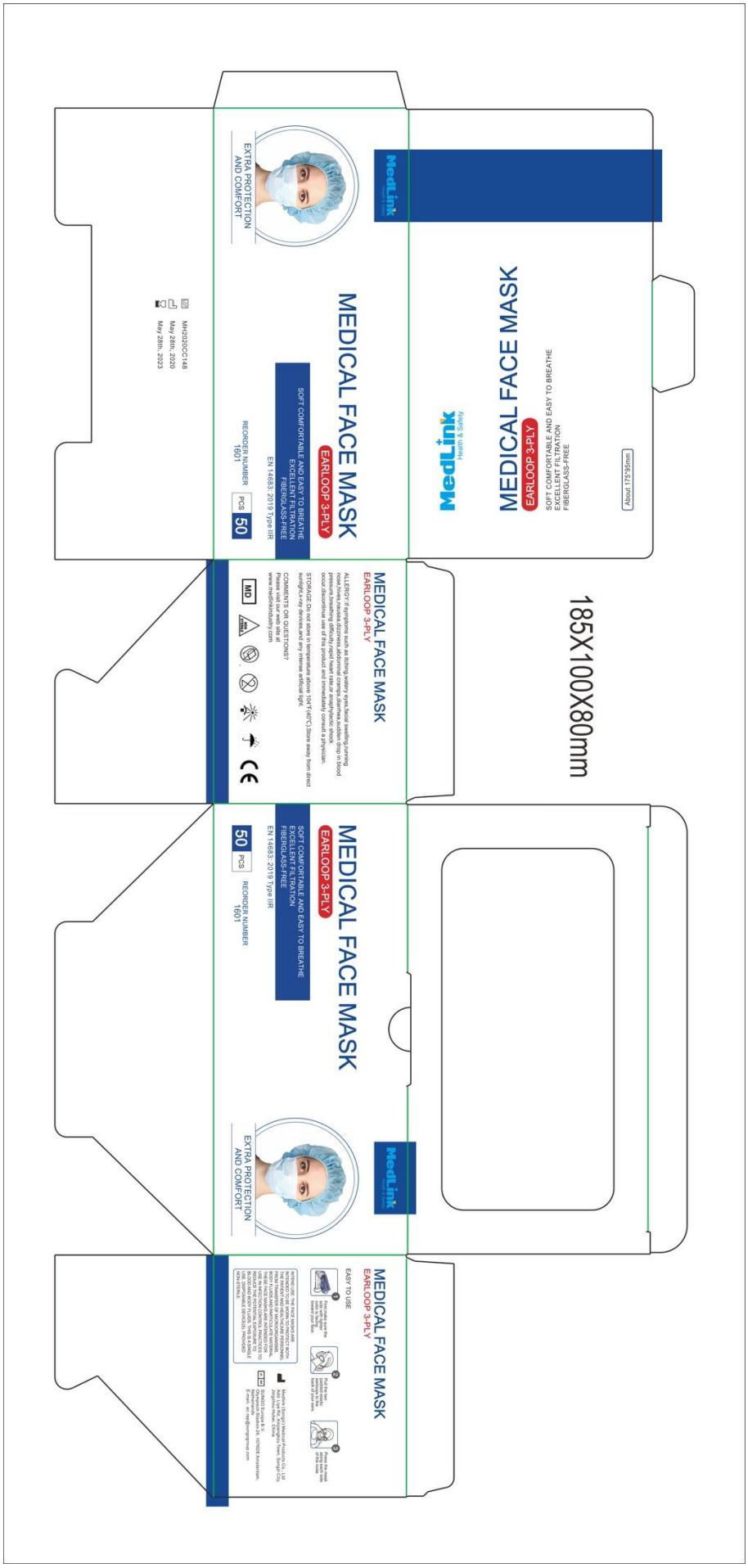
MEDICAL FACE MASK
EARLOOP 3-PLY
SOFT COMFORTABLE AND EASY TO BREATHE
EXCELLENT FILTRATION
FIBERGLASS-FREE
Abput 175±5mm
185X100X80mm
MEDICAL FACE MASK
EARLOOP 3-PLY
EXTRA PROTECTION AND COMFORT
SOFT COMFORTABLE AND EASY TO BREATHE
EXCELLENT FILTRATION
FIBERGLASS-FREE
EN 14683: 2019 Type IIR
50 PCS
REORDER NUMBER 1601
MH2020CC148
May 28th, 2020
May 28th, 2023
MEDICAL FACE MASK
EARLOOP 3-PLY
ALLERGY: If symptoms such as itching watery eyes,facial swelling,running nose,hives,nausea,dizziness,abdominal cramps,diarrhea,sudden drop in blood pressure,shock,etc occur discontinue use of this product and immediately consult a physician.
STORAGE:Do not store in temperature above 104°F(40°C).Store away from direct sunlight,x-ray devices,and any intense artificial light.
COMMENTS OR QUESTIONS?
Please visit our web site at
www.medlinkindustry.com
MEDICAL FACE MASK
EARLOOP 3-PLY
EASY TO USE
MEDICAL FACE MASK
EARLOOP 3-PLY
EXTRA PROTECTION AND COMFORT
SOFT COMFORTABLE AND EASY TO BREATHE
EXCELLENT FILTRATION
FIBERGLASS-FREE
EN 14683: 2019 Type IIR
50 PCS
REORDER NUMBER 1601

Instruction for Use

File No.: CE/MDR-MDK-01-09

Version: A/0

Product: Medical Face Mask

Issued By	Reviewed By	Approved By	Effective Date
Yang Mei	Lei Zhenghong	Liao Chan	2020.07.20

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Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A/0	Initial	Yang Mei	2020.07.20

Instructions for Use

CE

Name: Medical Face Mask
Model: 17.5cm*9.5cm
Applicable Standard： EN 14683:2019+AC:2019 Type IIR
Intend Use: The Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

Cautions:

1. Check the package completeness before using. Check the label, manufacturing date and validity time, to make sure the product is in valid date.
2. Do not use if the package damaged.
3. Do not reuse. Reusing may cause cross-contamination.

Instruction for use:

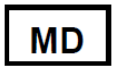
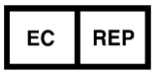
1. Open the packaging pouch and take out the mask.
2. Place the side with nose piece upward. Hang the ear loops on the ears.
3. Press the nose piece to fit the bridge of the nose, then press the nose piece and pull the lower end of the mask to the lower jaw.
4. Adjust the mask so that it covers the bridge of the nose to the lower jaw in order to get the best protection effect.

Storage： Do not store in temperature above 104"F (40'C). Store away from direct sunlight, x-ray devices,and any intense artificial light.

Shelf life: 3 years

Labels, Packing Logo Design:

Symbol	Introductions	Symbol	Introductions
LOT	Batch Code		Do not reuse" are "single use, "Use only once
	Warnings and Precautions		non-sterile

	medical device		Manufacture Date
	Manufacturer Name Address		Name and Address of European Union Representative
	Use until year & month (Expiration date)		Don't use when packing damaged
	Keep dry		Keep away from sunlight
	CE Symbol		

Manufacturer Information

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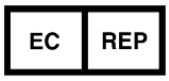
European Authorized Representative



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