CE Technical Files

Disposable Medical Mask
(non-sterile type)

File No.: CE/MDR-MC-01

Version: A

Issued By	Zhou Jing	Date	2020.04.20
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Address: No.18 Building, Lian dong U gu Business Zone, Beitang District, Wuxi City, Jiangsu Province, China.

Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A	Initial	Zhou Jing	2020-04-20

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Technical File

<Product: Disposable Medical Mask (non-sterile type) >
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Date	2020.04.20	**Date**	2020.04.20	**Date**	2020.04.20
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WUXI CITY Macheng Accessories CO., LTD
No.18 Building , Lian dong U gu Business Zone, Beitang District, Wuxi City, Jiangsu Province, China.

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1 General Description

1.1 Device description and specification

The Disposable Medical Masks (non-sterile type) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These Disposable Medical Masks (non-sterile type) 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.

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

The material of medical mask is common non-woven fabric, and its biocompatibility meets the relevant requirements.

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

The product images and specification of Disposable Medical Masks (non-sterile type) are shown as below.

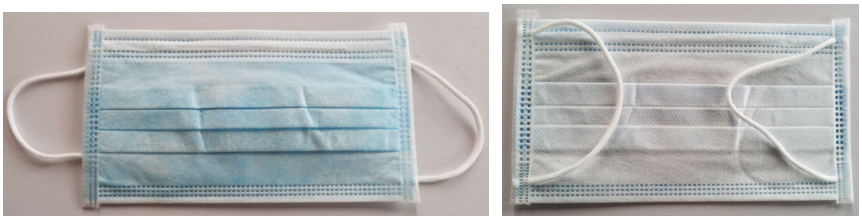


Figure Product picture
Specifications：Flat-type: FM001 17.5*9.5cm

Intended Use
The Disposable Medical Masks (non-sterile type) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These Disposable Medical Masks (non-sterile type) 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 product should be stored in a cool dry area, away from heat and direct sunlight.

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 Disposable Medical Mask (non-sterile type), he shall first move to the safety environment and then remove the Disposable Medical Mask (non-sterile type).

Shelf Life

2 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	Regulation (EU) 2017/745	2017	Medical Device Regulation
2	EN ISO 14971	2012	Medical Device -Application of Risk Management in Medical Device
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 Device –Part 10: Irritation and Sensitization Test
7	EN 1041	2008	Terminology, Symbols and Information Related to Medical Devices –Information Provided by Manufacturers of Medical Devices
8	EN 14683	2019	Medical Face Mask — 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 Regulation (EU) 2017/745, based on the intended use of Disposable Medical Mask (non-sterile type), 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 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 Regulation (EU) 2017/745.

1.2 Reference to previous and similar generations of the device

The Disposable Medical Mask (non-sterile type) consists of three layers:
Outside Layer, Spunbond Polypropylene
Middle Layer, Meltblown Polypropylene
Inside Layer, Spunbond Polypropylene
The accessories contain ear loops, bridge of nose.

2 Information to be supplied by the manufacturer

2.1 Label and Language

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, date 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.

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

a) Pattern 

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

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

A.4 Examples of use of symbol for "DATE OF MANUFACTURE"

2004-06

A.5 Examples of use of symbol for "CATALOGUE NUMBER"

REF ABC123

A.6Example of use of symbol for "MANUFACTURER"

A.7Example of use of symbol for “MANUFACTURER” combined with “DATE OFMANUFACTURE”

A.8Example of use of symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"

Language Requirements for Labeling in the EU Member States

Language / Country	Denish	Dutch	English	Finnish	French	Germany	Greek	Icelandic	Italian	Norwegian	Portuguese	Spanish	Swedish
Austria						★							
Belgium		★			★	★							
Denmark	★												
Finland				★									★
France					★								
Germany						★							
Greek							★						
Holland		★											
Iceland								★					
Ireland			★										
Italy									★				
Luxembourg					★	★							
Norway										★			
Portugal											★		
Spain												★	
Sweden													★
Switzerland					★	★							
United Kingdom			★										

2.2 label

Please refer to <label> (CE/MDR-MC-01-08)

2.3 Instruction for use

Please refer to <Instruction For Use> (CE/MDR-MC-01-07)

3 Design and Manufacturing Information

Introduction of Manufacture

Name: WUXI CITY Macheng Accessories CO., LTD
Address: No.18 Building , Lian dong U gu Business Zone, Beitang District, Wuxi City, Jiangsu Province, China.
Website: http://www.wxmacheng.cn/

Our 3m product website: http://www.3mmc.cn, Wuxi, is a modern fashion accessories company, the company is a professional custom-made all kinds of signs, printing, embossing company. The company has first-class production equipment, experienced design, R & D personnel. Since the company was founded in 2004, adhere to the "reputation first, quality first!" The spirit of the company. Through many high-quality customers to our strict requirements, so that we have accumulated a lot of experience in the garment accessories industry, for our development has laid a solid foundation. Now it has cooperated with 3M company Suneo Honekawa to become 3m distributor in east China. The company has developed the production line of drop plastic, high frequency wave, and now it has developed the production line of Silicon Likon, embossing, printing and so on. At the same time each production line all has the specialized technical personnel, is engaged in the design, the production, the sale, the service. At present, the company has the ability to undertake high and medium-grade clothing accessories design and production. The company has pursued the highest level of customer satisfaction since its inception, Seek truth from facts to solve difficult problems for customers. Through the unremitting efforts of all staff, we have won the trust and support of our customers. Customers are the source of our life, no matter how close and end of the world we will always provide you with quality service our sincere cooperation, mutual benefit, hand in hand, create brilliant!

口罩生产工艺流程图：Flow chart of mask production process

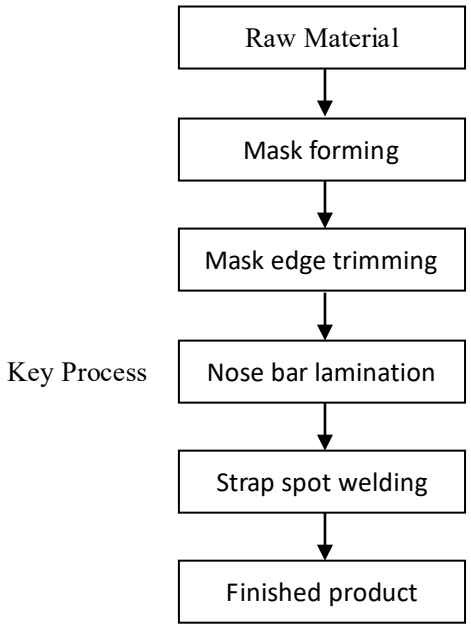


Figure Manufacturing process

We control our product quality based on our quality management system. We control the product quality from following aspects: 1) In coming inspection, 2) Manufacture process, 3) Process and final product inspection.

4 General Safety and Performance Requirements

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

5 Benefit-Risk Analysis and Risk Management

Please refer to file CE/MDR-MC-01-04 <Risk Management Report>
Risk Management was conducted according to standard EN ISO 14971:2012 medical devices – Application of risk management to medical devices. The below table is the risk management team and its responsibilities.

Name	Department	Position	Responsibility scope

Cheng Zhenghua	QC Dept	Risk management team leader	To establish risk management team, risk management planning, directing and coordinating the risk management activity. To ensure that risk management activities conform to the requirements of the risk management, control, and guide the implementation of risk management activities in medical product design, manufacturing process and final product inspection.
Cheng Yayan	Sales Dept	Risk management team member	Responsible for the post-marketing risk information collection and feedback.
Zhou Jing	Technical	Risk management team member	Involved in risk analysis, risk evaluation, risk control, comprehensive residual risk evaluation, review the risk management document.
An An	V.P.	--	Review risk management of the document
Cheng Yaquan	G.M.	--	Responsible for risk management of the document for approval.

6 Product Verification and Validation

The material of medical mask is common non-woven fabric, and its biocompatibility meets the relevant requirements, please refer to CE/MDR-MC-01-06 <Biocompatibility evaluation>.
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-MC-01- 05 <Clinical Evaluation Report>

6.2 Additional information required in specific cases

Disposable Medical Mask (non-sterile type) 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 Disposable Medical Mask (non-sterile type). 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:

Disposable Medical Mask (non-sterile type) is suitable for medical workers and family workers working in general medical environment to avoid unwanted inhalation.

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	When there are people who use

	Department	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	Sale Department	When there was customer complain happened

survey control procedure		
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 Disposable Medical Mask (non-sterile type) 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	0	0
	2018	0	0	0

	2019	0	0	0
USA	2017	0	0	0
	2018	0	0	0
	2019	0	0	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-MC-01-05 Clinical Evaluation Report
5 Continuing research on similar medical devices aftermarket release	Production Department	Refer to file CE/MDR-MC-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 technologies	Production Department	No new technology
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	Quality Department	None, no adverse event

procedures		
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 IS0:10993-1:2018, 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 5th, May, 2017. We update this CE document based on the new Medical Device Regulation (EU) 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 Disposable Medical Mask (non-sterile type) 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-MC-01-02 < Declaration of conformity >.

DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745

Manufacturer: Wuxi Macheng Garment Accessories Co.，Ltd

Address: no.18 Building , Lian dong U gu Business Zone,Beitang District,Wuxi City,Jiangsu Province ,China.

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: Disposable Medical Mask (non-sterile type)

Model: FM001 Ear Loop, 17.5*9.5cm

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: 2012

EN 1041:2008+A1:2013

EN ISO 10993-5: 2009

EN 14683:2019+AC:2019

EN ISO 15223-1: 2016

ISO 10993-1: 2018

EN ISO 10993-10: 2013

Signature: chengyaquan

Name / Position: chengyaquan / General Manager

Date: 2020.6.16

Place:jiangsu / China

General Safety and Performance Requirements

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

Version: A

Product: Disposable Medical Mask (non-sterile type)

Issued By	Reviewed By	Approved By	Effective Date
Zhou Jing	Cheng Zhenghua	Cheng Yaquan	2020-04-20

WUXI CITY Macheng Accessories CO., LTD
No.18 Building, Lian dong U gu Business Zone, Beitang District, Wuxi City, Jiangsu Province, China.

Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A	Initial	Zhou Jing	2020-04-20

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 ENISO14971：2012 ISO10993-1：2018 ENISO10993-5：2009 ENISO10993-10：2013 EN 14683:2019	Label & IFU Risk Management Report Biocompatibility Test Report Product Verification 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	ENISO14971：2012	Risk Management Report
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) 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	A	ENISO14971：2012	Risk Management Report

	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	ENISO14971：2012	Risk Management Report
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 (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).	A	ENISO14971：2012	Risk Management Report

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 ENISO14971：2012 ISO10993-1：2018 ENISO10993-5：2009 ENISO10993-10：2013 EN 14683:2019	Label & IFU Risk Management Report Biocompatibility Test Report Product Verification Report
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	ENISO14971：2012	Risk Management Report
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	ENISO14971：2012	Risk Management Report
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		
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	A	ENISO15223-1:2016 EN1041:2008	Label & IFU

	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.		ISO10993-1：2018 ENISO10993-5:2009 ENISO10993-10:2013	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 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.	A	ENISO15223-1:2016 EN1041:2008	Label & IFU
	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	NA		

	maintained in accordance with their respective indications and intended use.			
	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 (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.	A	ENISO14971：2012	Risk Management Report
	10.4.2. Justification regarding the presence of CMR and/or endocrine-disrupting substances	NA		

	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.			
	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 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.	NA		
	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	NA		

	(b) of Section 10.4.1., where appropriate.			
	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	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	ENISO14971：2012	Risk Management Report
	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 patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials.	A	ENISO14971：2012	Risk Management Report
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,	A	ENISO14971：2012	Risk Management Report

	(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.			
	11.2. Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation.	A	ENISO15223-1:2016 EN1041:2008	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		
	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		
	11.5. Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.	NA		
	11.6. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	NA		
	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		
	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		
12	12. Devices incorporating a substance considered to be a medicinal product and devices that are	NA		

	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		
	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		
	13. Devices incorporating materials of biological origin	NA		
	13.1. For devices manufactured utilising derivatives of tissues or cells of human origin which are 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;	NA		

	(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.			
	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 derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply	NA		
	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		

14	14. Construction of devices and interaction with their environment	NA		
	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		
	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, 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.	NA		
	14.3. Devices shall be designed and manufactured in such a way as to minimise the risks of fire	NA		

	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.			
	14.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.	NA		
	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		
	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		
	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. Such procedures shall be described in the instructions for use.	NA		
15	15. Devices with a diagnostic or measuring function	NA		
	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		
	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		
16	16. Protection against radiation	NA		
	16.1. General (a) Devices shall be designed, manufactured and packaged in such a way that exposure of	NA		

	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.			
	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. (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.	NA		
	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		
	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.	NA		

	(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.			
17	17. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves	NA		
	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 of performance.	NA		
	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		
	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		
	17.4. Manufacturers shall set out minimum requirements concerning hardware, IT networks	NA		

	characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.			
18	18. Active devices and devices connected to them	NA		
	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		
	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		
	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		
	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		
	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 device in question or other devices or equipment in the intended environment.	NA		
	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		
	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		
	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		

19	19. Particular requirements for active implantable devices	NA		
	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		
	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		
	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		
	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		
20	20. Protection against mechanical and thermal risks	NA		
	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	NA		

	moving parts.			
	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		
	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		
	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		
	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 of movement needs to be known in order to avoid a risk.	NA		
	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		
21	21. Protection against the risks posed to the patient or user by devices supplying energy or substances	NA		
	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		
	21.2. Devices shall be fitted with the means of preventing and/or indicating any inadequacies in	NA		

	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.			
	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		
22	22. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons	NA		
	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		
	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, — 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.	NA		
	22.3. Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person:	NA		

	— 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.			
	REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE			
23	23. Label and instructions for use	A	ENISO15223-1:2016 EN1041:2008	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. (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.	A	ENISO15223-1:2016 EN1041:2008	label & IFU

	(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.			
	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 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	A	ENISO15223-1:2016 EN1041:2008	label & IFU

	— 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 t 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; (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.			
	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’, (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.	NA		
	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;	A	ENISO15223-1:2016 EN1041:2008	label & IFU

	(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; (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 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 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; (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.			

Chapter One Introduction

1. Product Introduction

The product is composed of mask body, nose clip and mask belt, which is a plane ear hanging structure. The mask body is of three-layer structure, the inner and outer layers are PP spunbond non-woven fabric, and the middle filter layer is PP melt blown fabric. The nose clip is made of plasticity material. The material of the mask belt is nylon.

1.1 Product Name

Disposable Medical Mask (non-sterile type)

1.2 Product Function

The Disposable Medical Masks (non-sterile type) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These Disposable Medical Masks (non-sterile type) 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.

1.3 Product Composition and Material

The Disposable Medical Mask (non-sterile type) consists of three layers:
Outside Layer, Spunbond Polypropylene
Middle Layer, Meltblown Polypropylene
Inside Layer, Spunbond Polypropylene
The accessories Ties, Spunbond Polypropylene, Ear loops, Spandex core-spun yarn.
This specification are common, we also can make the device according to the customer's requirements.

2. Standard List

No.	File No.	Version	Title
1	EN ISO 14971	2012	Medical Device -Application of Risk Management in Medical Device
2	EN ISO 15223-1	2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements.
3	ISO 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
4	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests

			for in vitro cytotoxicity (ISO 10993-5:2009)
5	EN ISO 10993-10	2013	Biological Evaluation of Medical Device –Part 10: Irritation and Sensitization Test
6	EN 1041	2008	Terminology, Symbols and Information Related to Medical Devices –Information Provided by Manufacturers of Medical Devices
14	EN 14683	2019	Medical face masks — Requirements and test methods

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

Title	Assignment of responsibility
Production	Responsible for the risk management implementation After production and production various stages collection of information and appraisal
QA	Responsible for the risk management plan, the implementation, the risk appraisal and the confirmation and the establishment documents

QC	From product examination and confirmation angle appraisal risk
Sales	From customer and service angle appraisal risk

5. Risk Management Plan

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.

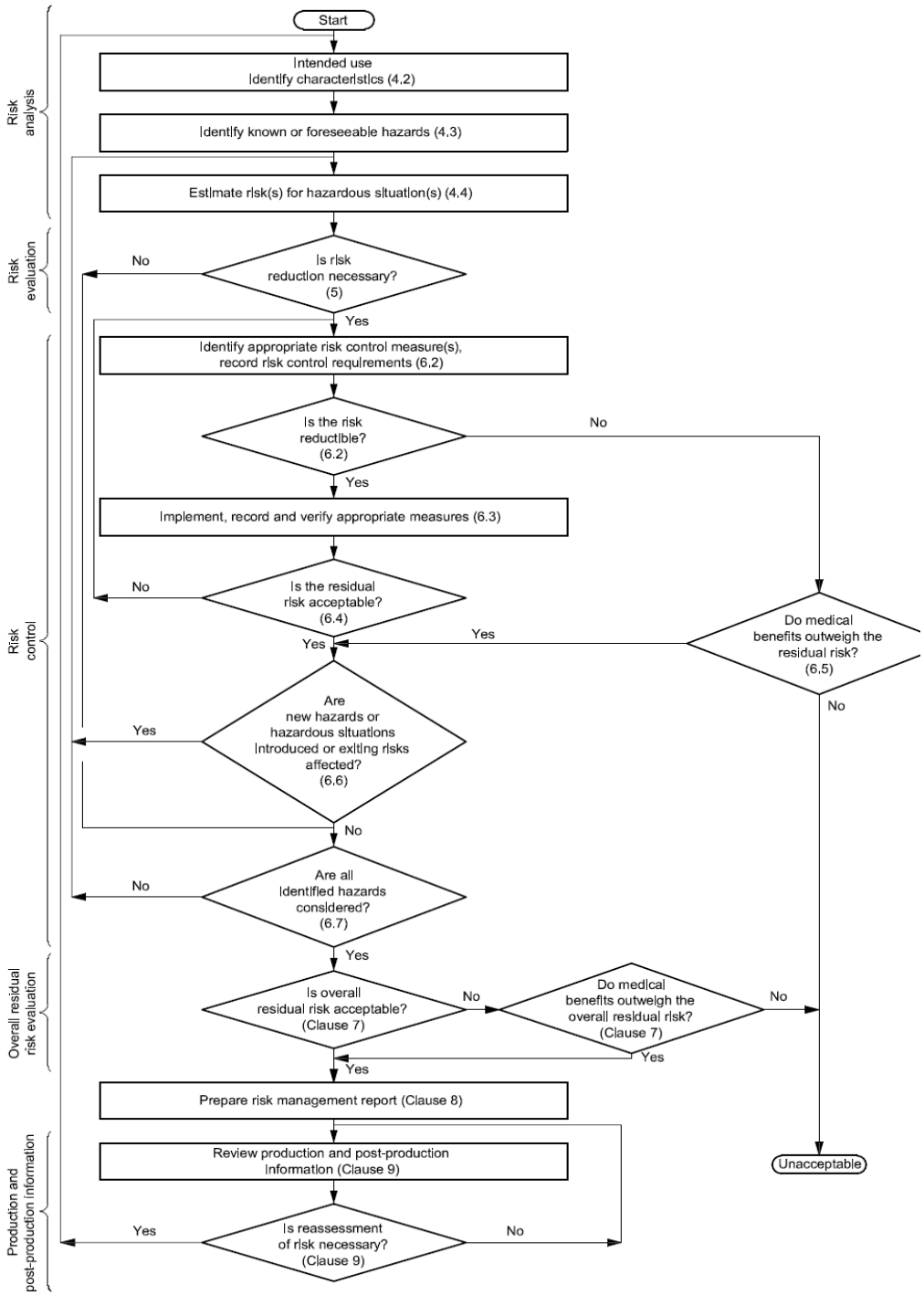
4) The acceptable criteria for risk acceptability are determined by the manufacturer to determine the acceptable risk criteria for determining the risk acceptable to the first section of the second chapter.

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.

6. Risk Management Process

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


Start
Intended use
Identify characteristics (4,2)
Identify known or foreseeable hazards (4,3)
Estimate risk(s) for hazardous situation(s) (4,4)
Is risk reduction necessary? (5)
No
Yes
Identify appropriate risk control measure(s), record risk control requirements (6,2)
Is the risk reductible? (6.2)
No
Yes
Implement, record and verify appropriate measures (6.3)
Is the residual risk acceptable? (6.4)
No
Yes
Do medical benefits outweigh the residual risk? (6.5)
Yes
No
Are new hazards or hazardous situations introduced or exiting risks affected? (6.6)
Yes
No
Are all identified hazards considered? (6.7)
No
Yes
Is overall residual risk acceptable? (Clause 7)
No
Do medical benefits outweigh the overall residual risk? (Clause 7)
No
Yes
Yes
Prepare risk management report (Clause 8)
Review production and post-production information (Clause 9)
Is reassessment of risk necessary? (Clause 9)
Yes
No
Unacceptable
Risk analysis
Risk evaluation
Risk control
Overall residual risk evaluation
Production and post-production information

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	$\geq 10^{-3}$

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

P1. Improbable	AC	AC	AC	NAC	NAC

2.1.3 Acceptance Criteria

NAC=unacceptable AC= Acceptable

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

Identification of qualitative and quantitative characteristics (acc.to EN ISO14971:2012, cl. 4.2)

Questions	Answer
C.2.1 What is the intended use and how is the medical device to be used?	Refer to Instruction for Use
C.2.2 Is the medical device intended to be implanted?	NO.
C.2.3 Is the medical device intended to be in contact with the patient or other persons?	Contact with the user
C.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Main raw materials for the made of non-woven fabrics in testing, product testing materials, meet the health standards.
C.2.5 Is energy delivered to or extracted from the patient?	NO.
C.2.6 Are substances delivered to or extracted from the patient?	NO.
C.2.7 Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	NO.
C.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	NO
C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user?	NO.
C.2.10 Is the medical device intended to modify the patient environment?	NO.
C.2.11 Are measurements taken?	NO.
C.2.12 Is the medical device interpretative?	NO.
C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	NO.
C.2.14 Are there unwanted outputs of energy or substances?	NO.
C.2.15 Is the medical device susceptible to environmental influences?	The product should be stored in a cool dry area, away from heat and direct sunlight.
C.2.16 Does the medical device influence the environment?	NO.
C.2.17 Are there essential consumables or accessories associated with the medical device?	NO.
C.2.18 Is maintenance or calibration necessary?	NO.
C.2.19 Does the medical device contain software?	NO.
C.2.20 Does the medical device have a restricted shelf-life?	YES. See device introduction
C.2.21 Are there any delayed or long-term use effects?	It will reduce your protection

	levels against disease
C.2.22 To what mechanical forces will the medical device be subjected?	NO.
C.2.23 What determines the lifetime of the medical device?	Packaging
C.2.24 Is the medical device intended for single use?	YES. Single use.
C.2.25 Is safe decommissioning or disposal of the medical device necessary?	Never touch the front of the product when removing. Placed straight into a bin once worn. Never share your product with another.
C.2.26 Does installation or use of the medical device require special training or special skills?	NO.
C.2.27 How will information for safe use be provided?	Instruction for use
C.2.28 Will new manufacturing processes need to be established or introduced?	NO.
C.2.29 Is successful application of the medical device critically dependent on human factors such as the user interface? C.2.29.1 Can the user interface design features contribute to use error?	NO.
C.2.29.2 Is the medical device used in an environment where distractions can cause use error?	NO.
C.2.29.3 Does the medical device have connecting parts or accessories?	NO.
C.2.29.4 Does the medical device have a control interface?	NO.
C.2.29.5 Does the medical device display information?	NO.
C.2.29.6 Is the medical device controlled by a menu?	NO.
C.2.29.7 Will the medical device be used by persons with special needs?	NO.
C.2.29.8 Can the user interface be used to initiate user actions?	NO.
C.2.30 Does the medical device use an alarm system?	NO.
C.2.31 In what way(s) might the medical device be deliberately misused?	NO.
C.2.32 Does the medical device hold data critical to patient care?	NO.
C.2.33 Is the medical device intended to be mobile or portable?	YES, portable
C.2.34 Does the use of the medical device depend on essential performance?	NO.

No.	Hazard		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 patient	N/A										
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	3	3	NAC	1. Indicate to users in the	1.Instruction for use	3	1	AC	No	AC

		have a bacterial infection if did not use the product properly, the package of blanket is damaged or re-use the product.				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.Eusure product quality by strictly follow the QSM	2.Product performance test report 3. Biocompatibility Test Report					
2	Viruses	A, Patient may have a bacterial infection if did not use the product properly or re-use the product.	3	3	NAC	1. Indicate to users in the Instruction for Use how to use the product and indicate the user not to use the product id the package damaged 2.Eusure product quality by strictly follow the QSM	1.Instruction for Use 2.Product performance test report 3. Biocompatibility Test Report	3	1	AC	No	AC
3	Other agents (e.g. prions)	N/A										
4	Re- or cross-infection	A, Patient may got infection if the product were re-used	3	3	NAC	Indicate to users in the Instruction for Use do not re-use the product	Instruction for Use	3	1	AC	No	AC
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	N/A										
11	medical gasses	N/A										
12	Anaesthetic products	N/A										

13	Toxicity of chemical Constituents	A, the product may cause the user uncomfortable if the material is not meet the safety requirements.	2	3	R	Single use and raw material control	Instruction for Use and raw material inspection report.	2	2	AC	No	AC
14	Bio-incompatibility	A, The product may cause the user uncomfortable if the material is not meet the safety requirements.	3	3	NAC	Choose raw materials meeting the requirements	Biocompatibility Test Report	3	1	AC	No	AC
15	Allergenicity	N/A										
16	irritancy	A, The product may cause the user uncomfortable if the material is not meet the safety requirements.	3	3	NAC	Choose raw materials meeting the requirements	Biocompatibility Test Report	3	1	AC	No	AC
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	Biocompatibility Test Report	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 operation outside prescribed environmental conditions	The product can not reach the intended use, or the product package will be damaged	2	3	R	1.Indicate the distributor or use to store the product by strictly follow the user manual. 2.Control storage / operation process	IFU; Warehouse management practices	2	2	AC	No	AC
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	R	Strengthen amending the label for warning	Refer to label& Instruction for Use	2	2	AC	No	AC
2	Inadequate operating instructions	A, the inadequate operating	2	3	R	Strengthen amending the operating instructions	Instruction for Use	2	2	AC	No	AC

		instructions may cause misuse										
3	Use by unskilled/untrained personnel	A The device may be damaged or hurt patient	2	4	NAC	1. To strengthen pre-use checks 2.Indicate the user how to use the product in the user manual.	Instruction for Use	2	2	AC	No	AC
4	Reasonably foreseeable misuse	A, The device can reach its intended use.	2	4	NAC	To strengthen pre-use checks and indicate the cautions in the user manual.	Instruction for Use	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	2	4	NAC	Indicate the users that the product is a single use device.	Label	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 points	N/A										
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 checks	The device may not work well if lack of inadequate functional checks	2	3	R	1.indicate the use instructions in the user manual; 2. Indicate the user that the product is a single use product.	Instruction for Use	2	2	AC	No	AC
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	R	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	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 conductivity) as a result of repeated use.	N/A										
E.7 Production and post-production information（Foresee）												

1	Inadequate of designing parameters	N/A											
2	Inadequate of operating parameters	N/A											
3	Inadequate of performance requirements	A, product quality will be deteriorated	3	2	R	Package the product by strictly follow the QMS	Factory inspection records, Product performance test report	3	1	AC	No	AC
4	Insufficient control of changes to manufacturing processes	A, product quality will be deteriorated	3	2	R	Control the manufacturing processes by strictly follow the QMS	Quality Procedure	3	1	AC	No	AC
5	Insufficient control of materials/materials compatibility information	A, product quality will be deteriorated or hurt patient	3	2	R	Chose the material which meet the requirement.	1.Biocompatibility Test Report 2.Incoming material inspection report.	3	1	AC	No	AC
6	Insufficient control of manufacturing processes	A, product quality will be deteriorated	3	2	R	Control the manufacturing processes by strictly follow the QMS	Quality Procedure	3	1	AC	No	AC
7	Insufficient control of subcontractors	A, product quality will be deteriorated or hurt patient	3	2	R	Chose the material which meet the requirement.	1.Biocompatibility Test Report 2.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 satisfied by the customer or could meet the requirement	2	3	R	collect post-product information according to QMS	Quality Procedure	2	2	AC	No	AC

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.

Risk Management Report

COMPANY NAME:	WUXI CITY Macheng Accessories CO., LTD
COMPANY ADDRESS:	No.18 Building, Lian dong U gu Business Zone, Beitang District, Wuxi City, Jiangsu Province, China.
PRODUCT:	Disposable Medical Mask (non-sterile type)
DOCUMENT NO.	CE/MDR-MC-04
VERSION	A
Accessories:	NA
PROCEDURE:	EN ISO 14971：2012
CONCLUSION:	All risks associated with the identified hazards have been evaluated considering EN ISO14971 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.

Drafted by: Zhou Jing Date：2020-04-20

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Clinical Evaluation Report

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<Manufacture: WUXI CITY Macheng Accessories CO., LTD >
<Address: No.18 Building, Lian dong U gu Business Zone, Beitang District, Wuxi City, Jiangsu Province, China.>

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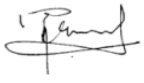
Signature		**Signature**		**Signature**	

Table of Contents

Executive summary

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

The Disposable Medical Mask (non-sterile type) 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 Disposable Medical Mask (non-sterile type) 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 Disposable Medical Mask (non-sterile type) 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 Disposable Medical Mask (non-sterile type) 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 Disposable Medical Mask (non-sterile type).

Conformity assessment with the Medical Devices Regulation (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 MDR 2017/745.

Based on the General Safety and Performance Requirements and the residual risk findings from the Disposable Medical Mask (non-sterile type) 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

The Disposable Medical Masks (non-sterile type) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These Disposable Medical Masks (non-sterile type) 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.

This mask 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 no risk of bodily fluids and spillage.

The Disposable Medical Mask (non-sterile type) is going to contact with the intact skin of the user, and it has been tested according to related compatibility standards such as ISO 10993-1:2018, EN ISO10993-5：2009 and EN ISO 10993-10：2013.

For detailed information of the product, please refer to Chapter 3 of this Technical Document.

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

Surgical masks have been in widespread use since the early 1900s to help prevent infection of surgical wounds from staff-generated nasal and oral bacteria. Today, surgical masks vary widely in style and intended application and can be found in a broad range of hospital and health care settings. In some health care settings, applications have evolved from prevention of patient wound infection to prevention of employee exposures. There is ongoing debate, however, about the use of surgical masks as respiratory protection devices.

The Food and Drug Administration (FDA) oversees the sale and marketing of medical devices, including surgical masks, which may be known as procedure masks, dental masks, and laser masks as well as masks used in surgery settings. FDA recommends that manufacturers demonstrate surgical mask performance in 4 areas: fluid resistance, filter efficiency, differential pressure, and flammability. Two types of filter efficiency tests are recommended: (1) particulate filtration efficiency (PFE) using a nonneutralized aerosol of 0.1- mm latex spheres at a challenge velocity between 0.5 and 25 cm/s (approximately 8 to 380 L/min for a 9-cm radius mask) and (2) bacterial filtration efficiency (BFE) using a nonneutralized 3 6 0.3-mm Staphylococcus aureus aerosol and a flow rate of 28.3 L/min.6-8 The FDA requires no minimum level of filter

performance. The Centers for Disease Control and Prevention (CDC) publishes guidelines on the use of surgical masks in health care settings.

The National Institute for Occupational Safety and Heaoth (NIOSH) classifies masks into N (non-oil resistanceance) and P (oil proof) categories. The N-protected objects are non-oily particles, and the R and P-protected objects are oily particles. The aerosol used in the N-type mask test was NaCl dust, and the arithmetic mean of the particle size was 0.075 gm. The aerosol used in the R-type mask is dioctyl ester (DOP). The flow rate used in the test was 8.5 L/min, which is equivalent to the adult ventilation per minute. The inspiratory resistance of all kinds of masks shall not be higher than 343.2Pa (3.5cm water column), the expiratory resistance shall not be higher than 245Pa (2.5cm water column), and the filtration efficiency is divided into three levels of 95 (99%) and 100 (99.97%). European standard FFP1 (80% performance), FFP2 (94% performance) and performance three levels. In 2003, WHO cited the US standard N95 (95% performance) or the European standard FFP2 (94% performance) as an anti-SARS anti-smoke mask. The Centers for Disease Control and Prevention (CDC) recommends that N95 masks be used by medical staff exposed to SARS patients. The mandatory national standard GB19083200361 for medical protective masks promulgated by China on April 29, 2003, in principle, adopts the American standard, that is, the N95 standard. For a long time, China's medical masks are made of cotton gauze, which has low barrier efficiency. infection. The high-efficiency glass fiber used in the early years, after the superfine maturation of the synthesis, plus the improvement of raw materials and the addition of electrostatic technology, the filtration efficiency of the electrostatic fiber is better than that of the early stage, and the air resistance is also reduced a lot. At present, many countries in the world have used medical material masks, which are manufactured by the method of spunlace, in which the polypropylene melt-blown method is non-woven and has a diameter of 0.5 to 4 m, which is particularly suitable for filter mat

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 proposed device Disposable Medical Mask (non-sterile type) has been sold for 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 Disposable Medical Mask (non-sterile type) 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

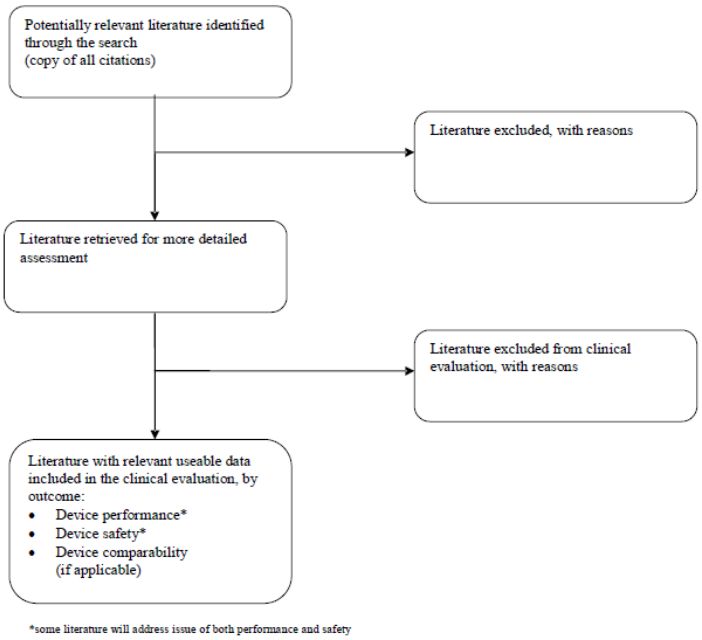
The databases used for literature search are shown as below

- 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 Disposable Medical Mask (non-sterile type) 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 till now. Take the ScienceDirect database for example, when we enter key word "medical face mask", 45990 literature are found in ScienceDirect, then we review the relevance of literature and download 8 relevant literature for review and completely review the literature, finally 2 literature are chosen for evaluation. The search result is as below.

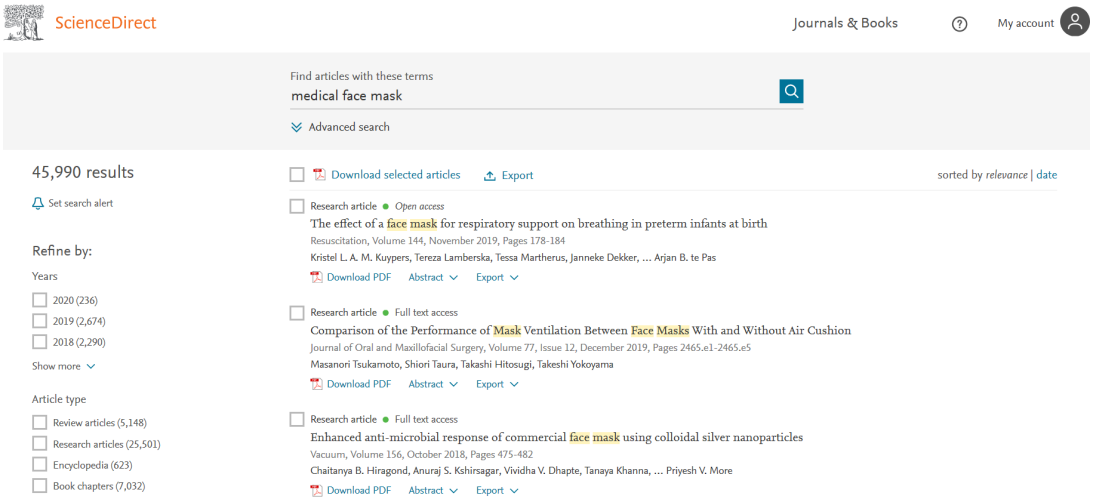


Figure1 Search Result in ScienceDirect

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

Table1 Literature Collection in different Database

Item	Database	Search term	Search Period	Total Literature	Relevant Literature	Literature for Clinical Evaluation
1	Pubmed	medical face mask	2000 till now	342	4	1

2	Science Direct		2000 till now	45990	8	2
3	CNKI		Not Limited	143	23	6

Base on the Literature search result above, there are 9 literature are used in this clinical evaluation. Literature analysis is shown in the table below.

Table 2 Literature Analysis

Item	Literature	Author& Publication	Abstract
1	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 surgical masks, non–fittestedP2 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.
2	Face masks to prevent transmission of influenza virus : a systematic review	[2] 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.
3	Surgical mask filter	Tara Oberg, MS, and Lisa M.	Background: Surgical masks have been used since the early 1900s to minimize infection of surgical wounds from

	and fit performance	Brosseau, ScD Minneapolis, Minnesota ,Vol. 36 No. 4, Oberg and Brosseau May 2008	wearer-generated bacteria. There is ongoing debate, however, whether surgical 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 surgical masks. Methods: Filter penetration was measured for at least 3 replicates of 9 surgical 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 surgical masks exhibited adequate filter performance and facial fit characteristics to be considered respiratory protection devices. (Am J Infect Control 2008;36:276-82.)
4	Development and clinical application of nonwoven surgical mask	Qiu Dongying, Cai Yingyun, Pharm Care & Res, 2005 Mar;5 (1)	Nonwoven surgical mask is a filter material made of ultrafine fiber produced by melting spray at high temperature. It has the advantages of effective resistance to droplets and dust, low airflow resistance, asepsis and corrosion resistance. It is an ideal material for preventing pathogenic microorganisms from inhaling into human body
5	Current situation of research on the use and protective effect of masks for medical staff	Wang Huiwen, Zhang Zhen, Ji Jinwen, Zhou Hongling, Chu Yanhui, Journal of preventive medicine intelligence, vol. 25, no. 8, August 2009	As a high-risk group of respiratory infectious diseases, medical staff need effective self-protection. Medical masks are one of the personal protective equipment for medical personnel. Experiments have shown that adherence to masks can play a key role in preventing SARS. However, research on the use of medical personnel masks at home and abroad, especially the research on the protective effect of masks, is still in its infancy. Therefore, the current research status of the use of medical personnel masks and their protective effects is reviewed, in order to provide a theoretical basis for the formulation of relevant policies such as the use of masks and the evaluation of protective effects of medical personnel in China.
6	STUDY ON	SHEN Wei, HE J	Physical and microbiological test methods were used to

	BARRIER PROPERTY OFMEDICAL PROTECTIVE CLOTHING AND PROTECTIVE MASK	ing - fang, SU Y i, WANG Y i -m ing,	study the structural characteristics, filtration efficiency and liquid and microbial barrier properties of 7 types of protective clothing and 4 protective masks used in disease prevention and medical institutions. Result, the protective clothing of cotton and nylon fabrics has a filtration efficiency of only 6% to 14%, which is completely incapable of blocking the penetration of water and artificial blood, and has no blocking effect on the permeation of Staphylococcus aureus and Escherichia coli F2 phage suspension. The protective clothing for melt-blown nonwovens and hot-bonded nonwovens has a filtration efficiency of 16% to 33% and does not block artificial blood permeation, but can block Staphylococcus aureus and Escherichia coli F2 phage suspension under no pressure. Penetration; the protective clothing of the composite nonwoven fabric and the Tyvek nonwoven fabric has a filtration efficiency of 43% to 93%, and can block the penetration of artificial blood, Staphylococcus aureus and Escherichia coli F2 phage under no pressure. The protective clothing of the coated fabric has a filtration efficiency of over 99% and can block the penetration of artificial blood, Staphylococcus aureus and Escherichia coli F2 phage, but its gas permeability is zero. The filtration efficiency of the 12-layer gauze mask is only 11% to 15%, and it is completely incapable of blocking the penetration of artificial blood, Staphylococcus aureus and Escherichia coli F2 phage. The filtration efficiency of the activated carbon filter mask is 11% to 17%, which can not block the penetration of artificial blood, but can block the penetration of Staphylococcus aureus and Escherichia coli F2 phage. Disposable nonwoven masks have a filtration efficiency of 46% to 48% and block the penetration of artificial blood, Staphylococcus aureus and Escherichia coli F2 phage under no pressure. The filtration efficiency of the disposable N95 respirator is 95%, and the medical mask can block the penetration of artificial blood, Staphylococcus aureus and Escherichia coli F2 phage.
7	Protective effect of medical masks	Sun Kai, Liu Xinming, Pang Zongbiao, Fan Minjun., Chi J Nosocomiol Vol,23 No,8 2013	Objective To explore the protective effects of various types of medical masks, determine the scope of use, and rationally select them. Methods Analyze the technical standards implemented by various medical masks and guide medical personnel to make reasonable choices. Results The medical protective mask has the national technical standard, and the particle filtration efficiency is ⩾95%, which determines that it can block the airborne infectious factor of <5 μm in

			diameter or close contact with the infectious agent transmitted by droplets; medical surgical masks have industry technical standards. The filtration efficiency of the aerosol is >30%, the bacterial filtration efficiency is >95%; when the body fluid is sprayed to the outer side of the mask at a pressure of 16.0 kPa (120 mm Hg), the inner side of the mask is not permeable; the general medical mask is only 0.3 μm in diameter The aerosol achieves a protective effect of 20.0% to 25.0%. Conclusion Medical respirators can prevent most of the bacteria, viruses and other pathogens that are transmitted by air or droplets. They are suitable for respiratory diseases, fever clinics, etc.; medical surgical masks It can block most bacteria and some viruses, can block the splash of blood, body fluids, secretions, etc. It can prevent medical personnel from being infected and prevent medical personnel from transmitting pathogens to the outside world. It is suitable for the basic protection of clinical medical staff.
8	Detection and evaluation on protective performanc e of surgical mask	Hu Wenjuan, Chen Zongnan, Wang Weili, Chin J Nosocomiol Vol, 21 No. 18 2011	Objective to understand the protective effect of surgical mask.Method According to the national standard, artificial aerosol was used to monitor and analyze the parameters of mask material and wear leakage.Results the domestic non - woven surgical mask was 0.An aerosol three microns in diameter is only 20.0% ~ 25.0%.Conclusion the standards of surgical masks, personal protection awareness of medical staff should be improved, and the medical environment should be improved.
9	EVALUATION OF THE EFFICACY OF SURGICAL MASK IN FILTERING BACTERIAL AEROSOL	Wen Zhanbo, Chen Jiejun, Zhao Jianjun, Wang Jie, Lu Jianchun, Li Jinsong.	Objective To evaluate the effect of medical surgical masks produced by different companies on bacterial aerosol retention. Methods Filtration efficiency tests were performed using artificially occurring bacterial aerosols and quantitative air sampling methods. Results In 2004, the average filtration effect of masks produced by a domestic enterprise on Staphylococcus aureus aerosol particles reached 98%, and the pass rate reached 100% according to the standard. In 2005, the masks produced by five domestic enterprises were sampled, and four of them had a 100% pass rate for the filtration efficiency of Staphylococcus aureus aerosols. In 2006, the masks produced by six domestic companies were sampled. Only one mask produced by one company met the standard requirements; two of the masks produced by the enterprises were all unqualified. Conclusion Continuously testing medical surgical masks produced by 12 enterprises from 2004 to 2006, there are only 6 enterprises

			that have reached the standard of bacterial aerosol filtration efficiency; the quality of medical surgical masks produced by different enterprises is uneven.

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.

Table5 Customer feedback list of the propose device

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

Table6 Post Market experience of similar device

Area	Time	Quantity	Complaints	Adverse events
China	N/A	0	0	0
EU	N/A	0	0	0
USA	N/A	0	0	0
Other	N/A	0	0	0
…	N/A	0	0	0
Total	NA	0	0	0

The proposed Disposable Medical Mask (non-sterile type)s are intended for medical workers and family workers working in general medical environment to avoid unwanted inhalation. The device has been sold to many countries for many years and the use of Disposable Medical Mask (non-sterile type) is mature. The manufacture has established quality management system and strictly follow the work instructions to ensure the product quality. And the Disposable Medical Mask (non-sterile type) has been placed on market for several years and a large number of devices has been sold. The PMS data shows the Disposable Medical Mask (non-sterile type) is safety use on the market. The PMS data including customer feedback, customer complain are continuously collect to monitor the safety and effectiveness of Disposable Medical Mask (non-sterile type).

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 Disposable Medical Mask (non-sterile type) is low and acceptable. This clinical evaluation is complied with MDR2017⁄745.

6.Next Clinical Evaluation

As extensively outlined above, the use of Disposable Medical Mask (non-sterile type) 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 Disposable Medical Mask (non-sterile type) in the claimed indications.

The clinical evaluation will update if significant risk were found.

7. Declaration of interests

Persons who signed on the cover of the CER are hired as clinical evaluator of Disposable Medical Mask (non-sterile type) to participate in the clinical evaluation. In order to ensure the validity and impartiality of clinical evaluation. A declaration of interests was made 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;

8. Appendix

8.1 Reference

[1] Macintyre C R , Cauchemez S , Dwyer D E , et al. Face Mask Use and Control of Respiratory Virus Transmission in Households[J]. Emerging Infectious Diseases, 2009, 15(2):233-241.

[2] Cowling B , Zhou Y , Ip D , et al. Face masks to prevent transmission of influenza virus: a systematic review[J]. Epidemiology & Infection, 2010, 138(4):449-456.

[3] Tara Oberg, MS, and Lisa M. Brosseau, ScD Minneapolis, Minnesota，Surgical mask filter and fit performance，Oberg and Brosseau May 2008.

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[5] Wang Huiwen, Zhang Zhen, Ji Jinwen, Zhou Hongling, Chu Yanhui , Current situation of research on the use and protective effect of masks for medical staff, Journal of preventive medicine intelligence, vol. 25, no. 8, August 2009.

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[8] Hu Wenjuan, Chen Zongnan, Wang Weili, Detection and evaluation on protective performance of surgical mask, Chin J Nosocomiol Vol, 21 No. 18 2011.

[9] Wen Zhanbo, Chen Jiejun, Zhao Jianjun, Wang Jie, Lu Jianchun, Li Jinsong,EVALUATION OF THE EFFICACY OF SURGICAL MASK IN FILTERING BACTERIAL AEROSOL, Chinese Journal of Disinfection 2007, 24(4).

8.2 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.
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.

Bio-compatibility Evaluation Report

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

Version: A

Product: Disposable Medical Mask (non-sterile type)

Issued By	Reviewed By	Approved By	Effective Date
Zhou Jing	Cheng Zhenghua	Cheng Yaquan	2020.04.20

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Document Revision History

REV	DESCRIPTION	ORIGINATOR	DATE
A	Initial	Zhou Jing	2020-04-20

1. Foreword

This report is to describe the biological risk control carried on the Disposable Medical Mask (non-sterile type) 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 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 Disposable Medical Mask (non-sterile type) 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 ISO14971:2012, 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

These include medical devices in contact with the following.

Table 1. Components materials and duration

Components	Raw material	Contact/ non-contact	Duration
mask body	Polypropylene (PP)	Contact with human tissue	< 24 hours
Ear loop	Nylon	Contact with human tissue	< 24 hours

Table 2.Raw material details

Material	Physical Property	Chemical Property
Polypropylene (PP)	Polypropylene is a low-density resin that offers a good balance of thermal, chemical, and electrical properties, along with moderate strength. Strength can be significantly increased by using reinforcing agents such as glass fiber. Polypropylene has limited heat resistance, but it can be used in applications that must withstand boiling water or steam sterilization.	CAS#:9003-07-0 Polypropylenes can resist chemical attack and are unaffected by aqueous solutions of inorganic salts or mineral acids and bases, even at high temperatures. They are not attacked by most organic chemicals, and there is no solvent for these resins at room temperature. The resins are attacked, however, by halogens, fuming nitric acid, other active oxidizing agents, and by aromatic and chlorinated hydrocarbons at high temperatures . Polypropylene is translucent and autoclavable. Properties can be improved by compounding with fillers, by blending with synthetic elastomers, and by copolymerizing with small amounts of other monomers.
Nylon	A synthetic polymer that can be formed into fibers, lines, sutures, sheets, and fabrics. It is used in a variety of medical applications, including nonabsorbable sutures.	(Elements & Compounds) a class of synthetic polyamide materials made by copolymerizing dicarboxylic acids with diamines. Any of a family of high-strength, resilient synthetic polymers, the molecules of which contain the recurring amide group CONH.

Table 3.Literature search

Literature(Polypropylene (PP))	Abstract	Conclusion
Author: HAN Rong , Yan bin , ZHANG Tongcheng , ZHANG Yonghong Title: Studies on Biocompatibility of Biomedical Materials Publication: Journal of Soochow University (Medical Edition) 2010; 30 (4), DOI: CNKI: SUN: SYXU.0.2010-04-032	Abstract：Objective To evaluate the biocompatibilities of four species of biomedical materials. Methods According to the standard of the ISO 10993，the bioc0mpatibilities of the biomedical materials were evaluated by using the cell cytotoxic test，sensitization test，intracutaneous stimulation tests，acute toxicity test，hemolysis test，implantation test，chromosomal aberration tests，micronucleus tests，Ames tests and pyrogen tests. Results The qualification rate of the biomedical metals , biomedical polymers，medical dressings and other materials was 98．63％ , 89．40％ , 99．91％ and 99．63％ respectively. Conclusion Four species of biomedical materials all have good biocompatibility.	The pass rates of cytotoxicity test, sensitization test, intradermal stimulus test and pyrogen test of biomedical polymer materials were 62.16%, 99.70%, 99.69%, and 95,000%, respectively. The qualified rates of cytotoxicity test, sensitization test, intradermal stimulus test, hemolysis test and pyrogen test of medical dressings were 99.39%, 99.69%, 99.34%, 97.50% and 96. 27%, the pass rate of the remaining biocompatibility tests is 100%. The study showed that PE possesses good biocompatibility.
Authors:Liang Huigang, Huang Ke Title:The development status and trend of biomedical polymer materials. Publication: Advanced Materials Industry 2016 (2) :12-15	With the progress of science and technology, the improvement of living standards, the improvement in human health, which has given rise to many new needs, such as the development of artificial organ, artificial joints, slow release drugs, etc. The emergence of these requirements has led to a combination of biology, medicine, chemistry, physics	In the case of China's gradual population aging society and the increasing demand for trauma, biomedical materials will usher in a new round of rapid development. This paper mainly focuses on the biological macromolecule material which is very important in biomedical materials.

	and materials science, and the emergence of biomedical materials. Biological medical materials consume less raw materials, energy saving and environmental protection, and high added value of technology. It is a typical strategic emerging industry that has maintained annual growth rate of over 20 percent in the last 10 years. In the case of China's gradual population aging society and the increasing demand for trauma, biomedical materials will usher in a new round of rapid development.	PP material has good biocompatibility and meet the requirements of ISO10993 series standards. Its worth to use in clinic.

Literature (Nylon)	**Abstract**	**Conclusion**
Author: HAN Rong , Yan bin , ZHANG Tongcheng , ZHANG Yonghong Title: Studies on Biocompatibility of Biomedical Materials Publication: Journal of Soochow University (Medical Edition) 2010; 30 (4), DOI: CNKI: SUN: SYXU.0.2010-04-032	Abstract：Objective To evaluate the biocompatibilities of four species of biomedical materials. Methods According to the standard of the ISO 10993，the bioc0mpatibilities of the biomedical materials were evaluated by using the cell cytotoxic test，sensitization test，intracutaneous stimulation tests，acute toxicity test，hemolysis test，implantation test，chromosomal aberration tests，micronucleus tests，Ames tests and pyrogen tests. Results The qualification rate of the biomedical metals , biomedical polymers，medical dressings and other materials was 98．63％ , 89．40％ , 99．91％ and 99．63％ respectively. Conclusion	The pass rates of cytotoxicity test, sensitization test, intradermal stimulus test and pyrogen test of biomedical polymer materials were 62.16%, 99.70%, 99.69%, and 95,000%, respectively. The qualified rates of cytotoxicity test, sensitization test, intradermal stimulus test, hemolysis test and pyrogen test of medical dressings were 99.39%, 99.69%, 99.34%, 97.50% and 96. 27%, the pass rate of the remaining biocompatibility tests is 100%. The study showed that PE possesses good biocompatibility.

	Four species of biomedical materials all have good biocompatibility.	
Authors: C.C. Chu Title: Newly made antibacterial braided nylon sutures. I. In vitro qualitative and in vivo preliminary biocompatibility study Publication: Journal of Biomedical Materials Research, Vol. 21, 1281-1300 (	A new type of braided nylon thread with a silver compound coating was made for the purpose of designing a biocidal suture material. The study used standard bacterial culture techniques to evaluate the antibacterial prop-erty of the new Ag-coated nylon thread. Seven types of bacterial species were tested; S. aureus, E. coli, P. aeruginosa, K. pneumoniae, S. dysenteriae, S. maruslene, and P. mirabilis. The commercial size 210 Nurolon suture from Ethicon served as the control. A weak direct current ranging from 0.4-400 pA was applied to the specimens to examine whether the biocidal property of silver could be enhanced by current. The antibacterial property was evaluated by the width and sterility of the clear zone in the bacterial culture plates.	It was found that the new nylon thread exhibited very good to moderate bactericidal property toward these seven bacterial species. P. aeruginosa was the most sensitive species, while P. mirabilis was the least sensitive one. Application of direct current through the Ag-coated specimens positively enhanced their antibacterial property and the degree of enhancement depended on the direct current level. The material also exhibited an antibacterial property toward well-established bacterial colonies, but the effect was less strong than the case when direct current was applied simultaneously with incubation. Silver ions released from the coated nylon thread were responsible for the observed antibacterial property; and the application of a weak direct current to the material enhanced this effect. A preliminary biocompatibility study of this new material in rat gluteal muscle indicated that the new material caused less inflammatory reaction than the control Nurolon suture up to 60 days after implantation.

5. Conclusion

According to ISO14971 and ISO 10993-1 requirements, the literature list in section 4, we have completed the biological evaluation for the Disposable Medical Mask (non-sterile type), the available information is sufficient to meet the purpose of the evaluation of biological safety, the Disposable Medical Mask (non-sterile type) biological risks are acceptable.

Instructions for use

Name: Disposable Medical Mask (non-sterile type)

Model: Flat-type: FM001 17.5*9.5cm

Standards: EN14683：2019 Type IIR

Intend Use: The Disposable Medical Masks (non-sterile type) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These Disposable Medical Masks (non-sterile type) 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.

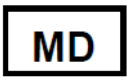
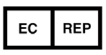
Storage:

The product should be stored in a cool dry area, away from heat and direct sunlight.

Shelf life: 2 years

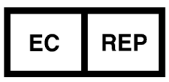
Symbols meaning:

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
	CE Symbol		Symbol for " USE BY"

Manufacturer Information

Company: WUXI CITY Macheng Accessories CO., LTD
Address: No.18 Building, Lian dong U gu Business Zone, Beitang District, Wuxi City, Jiangsu Province, China.
Website: http://www.wxmacheng.cn/



Company：SUNGO Europe B.V.
Address：Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Contact Person：SUNGO Secretary
E-mail：ec.rep@sungogroup.com

Label

Product Name: Disposable Medical Mask (non-sterile type)

CE MD

MODEL: Flat-type: FM001 17.5*9.5cm

Standards：EN14683：2019 Type IIR

 YYYY-MM-DD

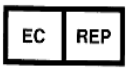
YYYYMMDD

 YYYYMMDD

1. The packaging is intact
2. Only for single use.

UDI

Company: WUXI CITY Macheng Accessories CO., LTD
Address: No.18 Building, Lian dong U gu Business Zone, Beitang District, Wuxi City, Jiangsu Province, China.
Website: http://www.wxmacheng.cn/



Company: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
E-mail：ec.rep@sungogroup.com