Xinxiang Huaxi Sanitary Materials Co., Ltd.

Technical Documentation

Disposable Surgical Face Masks
(Type IIR)

according to

Regulation 2017/745

Drafted by:	张利娜	
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Documents Revision History

Rev.	Date	Revision History	Signature
A/0	2020-03-26	Initial Document	

Table of Contents

Chapter 1 DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSIRIES

1.1 Device description and specification

1.1.1 Name and address of the manufacturer

Name of Manufacturer:

Xinxiang Huaxi Sanitary Materials Co.,Ltd.

Address:

Dingluan Industrial Zone Changyuan, Xinxiang 453400 Henan China.

Contact：

Contact Person: Yun Yong

Tel: +86-0373-8996688

Fax: +86-0373-8996002

Email: 821723930@qq.com

Name of Factory/producer:

Xinxiang Huaxi Sanitary Materials Co.,Ltd.

Address:

Dingluan Industrial Zone Changyuan, Xinxiang 453400 Henan China.

1.1.2 Device name and general description of the device

Device Name:

Disposable Surgical Face Masks

Classfication: Type IIR

General description of the device:

The Disposable Surgical Face Masks are Flat Pleated type mask, utilizing Ear Loops way for wearing, and they all have Nose Piece design for fitting the face mask around the nose.

The Disposable Surgical Face Masks are manufactured with three layers. The outer layer is made of polypropylene (PP) non-woven fabric with blue color. The middle layer is filtration function and is made of polypropylene (PP) melt-blown non-woven fabric.

The inner layer contact with face is made of polypropylene (PP) non-woven fabric with white color.

The Surgical Face Masks, ear loops, is held in place over the user's mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are made of Polyester and Spandex.

The nose piece contained in the proposed device(s) is in the layers of facemask to allow the user to fit the face mask around their nose, which is made of stainless steel wire covered with plastic polypropylene.

The Disposable Surgical Face Masks are sold non-sterile and are intended to be single use. The shelf-life of the product is 3 years.

The size of the face mask is 175mm*95mm

1.1.3 Intended use

The Medical Face Masks are intended to be worn to protect against the spread or transmission of infectious germs during surgical interventions in operating theatres and other medical facilities. The main aim is to protect the patient against infectious germs. In addition, in certain situations the wearer should be protected against splashes of potentially contaminated liquids and viable particles.

1.1.4 Intended users

- Healthcare personnel
- Patient or other persons

1.1.5 Basic UDI-DI

The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.

UDI-DI: The UDI-DI is a unique numeric or alphanumeric code specific to a model of device and that is also used as the 'access key' to information stored in a UDI database.

UDI-PI: The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production. The different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date or both types of date.

A UDI shall be assigned to the device itself or its packaging. The UDI shall contain two parts: a UDI-DI and a UDI-PI. The UDI-DI shall be unique at each level of device packaging.

UDI-DI: it is not applicable

1.1.6 The disease status to be diagnosed/targeted/monitored

None

1.1.7 Contraindications

None

1.1.8 Waring and Cautions

- If there is redness, swelling and itching after usage, please stop using it and consult your physician.
- Only for single use. Discard it after use.
- Stay away from fire.
- Do not reuse it after drying or disinfecting.
- Correctly distinguish the front and back prior to use.
- The device should be stored in a dry room with excellent ventilation and without caustic gases.
- Properly discard the used Disposable Surgical Face Masks according to local policy. Avoiding re-use and cross infection.
- The device should not be used over 24h, allergic reactions may occur with delay use and cross infection.

1.1.9 Description of the principle

Non-woven fabrics have the characteristics of water repellency, air permeability, flexibility and light weight. Therefore, choosing suitable thickness of outer non-woven fabrics can protect the wearer from potential contaminated liquid splashing. In addition, the fiber diameter of the intermediate melt-blown filter layer can be as small as 1-5μm. These fibers with unique capillary structure can increase the number and surface area of fibers per unit area, effectively filter bacteria and dust, and prevent the spread of infectious pathogens. In addition, the design of nose clip and the design of mask stack can make the mask fit the shape of face, thus reducing the probability of infectious pathogens entering from the side.

1.1.10 Rationale for the qualification of the product

We, Xinxiang Huaxi Sanitary Materials Co., Ltd.. hereby claim that, as legal manufacturer, we have established and maintained a quality management system according to Article 10(9) of Regulation 2017/745 for manufacturing of Surgical Face Masks

The copy of the QMS certificates are given in the following attachments:

- **Folder 01 # HX-JS-CE-04-0101: ISO 13485 Certificate**

1.1.11 Classification rule(s)

Device Name: Disposable Surgical Face Masks

According to Regulation (EU) 2017/745(MDR) Appendix VIII Rule 1, the Surgical Face Masks is classified as a Class I medical device.

RULE 1	VERDICT
All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.	Class I
Rationale: The Non-woven face masks are a single use and non-invasive medical device. The devices are intended to be wore to protect both healthcare personnel and others persons from transfer of microorganisms, body fluid and particulate material.	

1.1.12 Explanation for novel features

None

1.1.13 Description of the accessories

None

1.1.14 Description of the Variant configurations/ variants

Classification	Size	Color	Layer
Type IIR	175mm*95mm	blue	3

1.1.15 Description of the key functional elements

Product components:

The Disposable Surgical Face Masks consist of mask body, Nose piece and Elastic bands.

Figure 1- Surgical Face Masks

1.1.16 Raw materials and packaging materials

NO.	Parts name	Material	Specification Material
1.	Face masks Inner layer	Polypropylene nonwoven	30g/m^2 white non-woven fabric
2.	Face masks middle layer	Polypropylene melt-blown non-woven fabric	25g/m^2 melt-blown non-woven fabric
3.	Face masks outer layer	Polypropylene nonwoven	25g/m^2 blue non-woven fabric
4.	Elastic bands	Polyester fiber & Spandex	4mm white round elastic string
5.	Nose piece	PP strip with stainless steel inside	white
6.	Inner box	Paper	/
7.	Outer box	Triap-corrugated box	600-700g/m^2 white or brown double corrugated

1.1.17 Product Specifications

Table 1. Basic dimensions (unit：mm)

Size (mm)	Length(L) (mm)		Width (W) (mm)		Tie length of Nose piece (mm)
	size	deviation	size	deviation	≥80.0
175×95	175	±5%	95	±5%	

Table 2 Performance requirements

Type / Test	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 98%
Differential pressure (Pa/cm^2)	< 60
Splash resistance pressure (kPa)	≥16.0
Microbial cleanliness (cfu/g)	≤ 30

1.2 Previous and similar generation of the device

Overview of the previous generations of the device produced by the manufacturer: None

Overview of identified similar devices available on the Union or international markets:

- **Xiantao Zhibo Non-woven Products Co., Ltd**

Product type :Type I,Type II,Type IIR

Product name: 3 ply Face Mask with Ear loop, Disposable Surgical Masks with Tie on, 3 ply Ear loop Medical Face Mask, 3 ply Ear loop Medical Face Mask etc,.

Item no：ZB-020,ZB-021,ZB-058,ZB-059

Technical Specifications: Conforms to EN 14683 standards, Meterial: PP, 3 layer, nose strip:PE wire,Color:Green,Blue, Size:17.5*9.5cm

- **Zhejiang Lanhine Mask Co.,LTD**

Product type: Type I, Type II, Type IIR

Product name: Tie on Face mask, print Face Mask , splash Resistance Face mask etc.,

Technical Specifications: Conforms to EN 14683 standards, Meterial: PP, nose barrette:Iron with plastic,Color:Green,Blue, Black etc,. Size:17.5*9.5cm

- **Hubei Haixin Protective Products Co.,Ltd**

Product type: Type I, Type II, Type IIR

Product name: 3 ply Face Mask with Ear loop, 3 ply Face Mask with Tie, 3 ply PP Face Mask with with Tie, 3 ply PP Face Mask with with Ear Loop etc,.

Code:F91013,F92613

Technical Specifications: Conforms to EN 14683 standards, Meterial: PP, 3 ply,

Color:pink,Blue,White etc,. Size:17.5*9.5cm, 14.5*9.5cm, 12*7cm,

1.3 EC Authorized Representative

Since the registration address of Xinxiang Huaxi Sanitary Materials Co., Ltd. is located outside the area of EEA, Switzerland and Turkey, a single authorized representative located in EEA, Switzerland and Turkey is appointed to Surgical Face Masks, which is:

Name:	Caretechion GmbH
Add:	Niederrheinstr 71, 40474 Duesseldorf, Germany,
Tel:	+49 211 3003 6618
Fax:	+49 211 3003 6619
Contact Person	Mr. Jian Wang
Dimdi Code	DE/0000048026
E-mail:	info@caretechion.de

The agreement with the appointed EU authorized representative has been signed and is provided in the attachment:

- **Folder 01 # HX-JS-CE-04-0102: EU authorized representative agreement**

1.4 CND code

CND code: T020601 STANDARD SURGICAL FACE MASKS

1.5 Declaration of conformity

Declaration of Conformity for Face Masks is attached in the attachment.

- **Folder 01# HX-JS-CE-04-0103_Declaration of Conformity**

Chapter 2 INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

- Annex I of Regulation (EU) 2017/745
- EN 1041:2008+A1:2013
- EN ISO 15223-1:2016
- EN 14683:2019

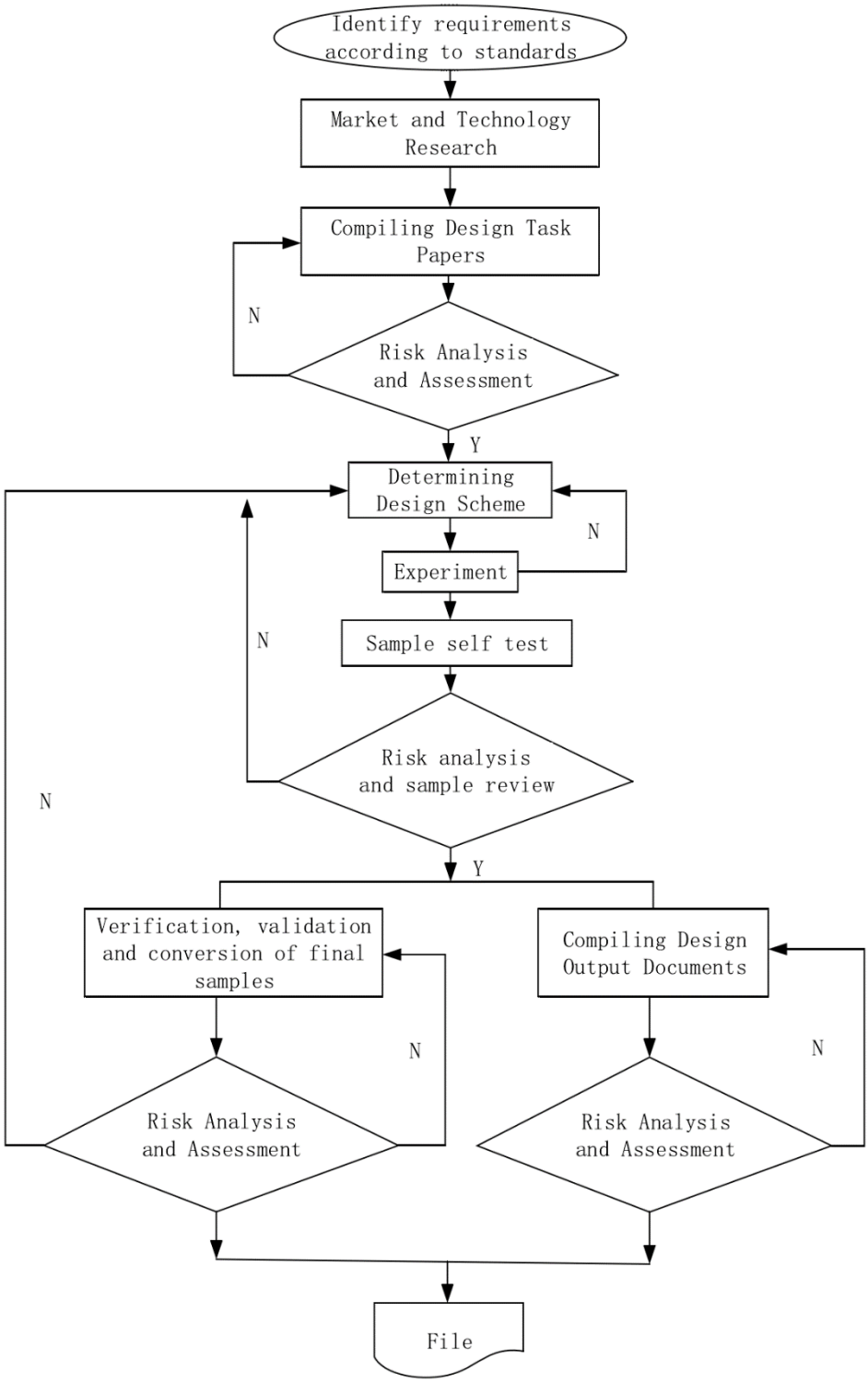
The draft labels are given in the attachments:

- **Folder 02 # HX-JS-CE-04-0201_Label**

Chapter 3 DESIGN AND MANUFACTURING INFORMATION

3.1 Design Information

3.1.1 Design and Development flow chart



3.1.2 Design and Development inputs

- **Information for users**

When breathing, speaking, coughing, sneezing etc., one releases smaller or larger amounts of droplets of secretions from the mucous membranes in the mouth and nose. Those droplets quickly evaporate and leave nuclei suspended in the air. The majority of the nuclei are between 0.5 μm and 12 μm in diameter and especially the larger droplets can contain micro-organisms from the source site. Nuclei can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment.

The medical face masks intended to be used in operating rooms and health care settings with similar requirements are designed to protect the entire working environment. As a minimum, Type I medical face masks are used for patients in order to reduce the risk of the spread of infections, particularly in epidemic or pandemic situations. Type II masks are principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements.

The level of efficiency offered by a mask depends on a number of factors such as the filtration efficiency, quality of the material and the fit of the mask on the wearer's face. Different designs are suited for different applications and the careful choice of mask is therefore important in order to achieve the desired result.

The filtration capacity of mask materials can vary depending on the filter media. The fit of masks varies considerably from those which are held in place by ear loops fastened behind the wearer's ears to those with tie bands around the head and a nose clamp that can be shaped to the wearer's nose. The effect of a very good or less good fit can be tested in vivo whereas the filtration efficiency may be reproducibly tested in vitro.

The considerable variations in results when masks are tested in vivo results in the need for large groups of test subjects and observations. It is thus usual to characterise mask performance using in vitro tests of the material from which the mask is made. It is, however, important to consider the fit of the mask carefully when a mask for a certain application is chosen. Users should request such information from their suppliers.

A further factor to be considered is the capacity of the mask to absorb moisture from the exhaled air and thereby to maintain its performance over a longer period of time. The more advanced designs easily maintain their performance throughout even very long operations whereas the less advanced ones are intended only for short procedures.

The contamination risk resulting from hand contact with a used mask means that it is essential that the mask is taken off and disposed of when no longer worn over nose and mouth. When there is a further need for protection then a new mask should be put on. Touching a used face mask or putting on a new one should always be followed by a full hand disinfection procedure and a used mask should always be disposed of when no longer needed or between two procedures.

In summary, to use an appropriate mask is an effective means to protect the working environment from droplet contamination from nose and throat during health care procedures. Masks with very different performance are, however, available. Therefore

such factors as infection risk and mask fit should be carefully considered when choosing a mask.

- **Conform to EN 14683 standards**

Test \ Type	Type IIR
Bacterial filtration efficiency (BFE), (%)	⩾ 98%
Differential pressure(Pa/cm ^{2})	< 60
Splash resistance pressure (kPa)	⩾16.0
Microbial cleanliness(cfu/g)	⩽ 30

3.1.3 Design and Development Outputs

3.1.3.1 Drawings

3.1.3.2 Purchase list

NO.	Parts name	Material	Supplier
1.	Face masks Inner layer	Polypropylene nonwoven	Xinxiang Huaxi Sanitary Materials Co., Ltd.
2.	Face masks middle layer	Polypropylene melt-blown non-woven fabric	Tianjin Teda Filters Co., Ltd.
3.	Face masks outer layer	Polypropylene nonwoven	Xinxiang Huaxi Sanitary Materials Co., Ltd.
4.	Elastic bands	Polyester fiber & Spandex	Henan Luxiang Protective Equipment Co., Ltd.
5.	Nose piece	PP strip with stainless steel inside	Dongguan Hongtao Plastic Hardware Co., Ltd.

3.1.3.3 Production description

The materials of Surgical face masks are purchased from abroad, and the production process includes feeding, welding, packaging and warehousing. For the main raw materials/purchased parts, we will select the enterprises with good quality and high delivery efficiency from the suppliers for cooperation.

3.1.3.4 Labels on the package

- See Folder 2 # CE-01-02. label for Surgical Face Masks

3.1.4.5 Product specification

Dimension	The size of the mask should meet the design requirements with an allowable tolerance of 5%
Appearance	The appearance of the mask should be smooth, without damage, stains, deformation and other obvious defects.
Nose piece	The mask should be equipped with a nose piece, which is made of flexible materials and should be no less than 8.0cm in length.
Elastic bands	The Elastic bands should be elastic and suitable, the rupture strength of the mask belt and the connection between the mask belt and the mask body should be no less than 10N.
Bacterial filtration efficiency (BFE),	⩾ 98%
Differential pressure	< 60 Pa/cm ^{2}
Splash resistance pressure	⩾16.0 kPa
Microbial cleanliness	⩽ 30 cfu/g

3.1.4.6 Documents on the Process operation

- Technical File

No.	Document Name	Document No.
1	Disposable Surgical Face Masks technical requirements	HX-JS-CE-04-02

- Control procedure and Process SOP

No.	Document Name	Document No.
1	Disposable Surgical Face Masks Production operation instruction	HX-JS-SC 03801
	Disposable Surgical Face Masks technological procedure	HX-JS-GY 01200

- Process/inspection form

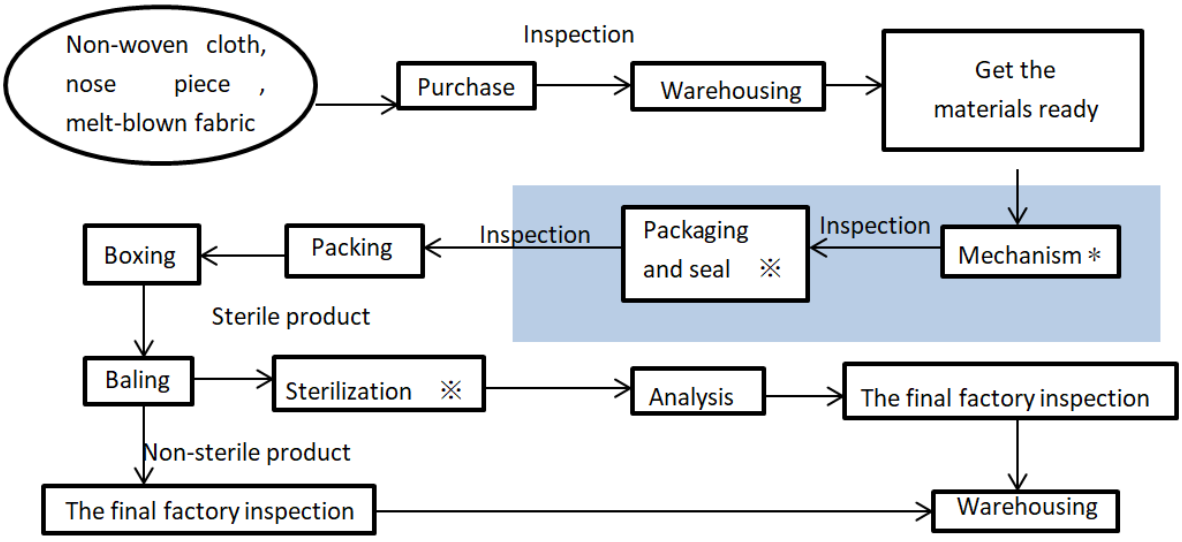
No.	Document Name	Document No.
1	Disposable Surgical Face Masks inspection procedure	HX-JS-CP 01300
2	Disposable Surgical Face Masks inspection record	HX-JL-ZJ 12301

3.1.4.7 Labels on the package

- See Folder 2 # HX-JS-CE-04-0201. label for Surgical Face Masks

3.2 Manufacturing information

3.2.1 Production Process Flow Chart



Symbol description:
(* means critical process, ※ means special projects, ▭ area means clean area of Class 8 clean room)

Plant location: Dingluan Industrial Zone Changyuan, Xinxiang 453400 Henan China.

*Sterilization process and primary package sealing process are not applicable for this non-sterile face masks addressed in this technical file.

3.2.2 Special processing validation

Validation of the elastic bands welding and package heat sealing process has been conducted and the approved parameters are monitored during routine production.

No.	Document Name	Document No.
1	Automatic mask machine verification scheme	HX-JS-YZ 2019065
2	Automatic mask machine verification report	HX-JL-YZ 2019065

3.2.3 Production environment control

The Face Mask is a single-use, disposable device, and therefore the work environment is an essential to the cleanliness of the product and could help eliminate or reduce the chance of contamination, the production environment of the product meets the requirements of Class 8 clean room according to EN ISO 14644-1; see the following tables for specific indicators:

Monitoring item	Technical requirement	Monitoring frequency

Monitoring item	Technical requirement		Monitoring frequency
Temperature	18~28ºC		Once / shift
Relatively Humidity	45~65%RH		Once / shift
Air change rate	≥15 times / hour		Once / month
Static pressure difference	≥ 10Pa (between clean room (area) and outdoors)		Once / month
Dust particle	≥0.5um	≥5um	Once / quarter
	≤3520000 pcs/m^3	≤29300 pcs/m^3	
Airborne microbe	≤ 500pcs/m3		Once / quarter
Settling microbe	≤ 10 pcs/vessel		Once / week
illuminancy	≥150lx (assistant workroom)		Once / week

Chapter 4 GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

4.1 General safety and performance requirements

The device has fulfilled all applicable Essential safety and performance requirements per Annex I of Regulation (EU) 2017/745(MDR). Detailed information is given in the Folder 4 # HX-JS-CE-04-04.

4.2 Applicable standards lists

(Harmonized standards, international standards, partly applicable standards)

Relevant standards applied to the device are listed as follows:

No.	Standards	Reference	Content
1.	MDR (EU) 2017/745	2017	Regulation(EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
2.	MEDDEV2.7.1	Rev4	Clinical Evaluation: A guide for manufacturers and notified bodies under directives
3.	MEDDEV 2.12/2 Rev 2	2012	Guidelines on post market clinical follow-up
4.	MEDDEV 2.12/1 Rev 8	2013	Guidelines on a medical devices vigilance system
5.	EN 1041	2008-A1:2013	Information supplied by the manufacturer with medical devices
6.	EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016)
7.	EN ISO 14971	2012	Medical devices - Application of risk management to medical devices
8.	ISO 10993-1	2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
9.	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity(ISO 10993-5:2009)
10.	EN ISO 10993-10	2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
11.	EN ISO 10993-12	2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
12.	EN ISO 10993-18	2009	Biological evaluation of medical devices — Part 18: Chemical characterization of materials (ISO 10993-18:2005)
13.	EN 62366-1	2015	Medical devices — Part 1: Application of usability engineering to medical devices

14.	EN ISO 13485	2016	Medical devices-Quality management systems-Requirements for regulatory purpose
15.	EN ISO 11737-1	2018	Sterilization of medical devices —Microbiological methods —Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
16.	EN 14683	2019	Medical face masks - Requirements and test methods
17.	ISTA 2A	2011	Packaged-Products 150 Ib (68Kg) or Less

Chapter 5 BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT

Risk management is performed per EN ISO 14971:2012, and the Risk management plan and report is given as attachments

- Folder 5# HX-JS-CE-04-0501, Risk management plan
- Folder 5# HX-JS-CE-04-0502, Risk management analysis
- Folder 5# HX-JS-CE-04-0503, Risk management report

Chapter 6 PRODUCT VERIFICATION AND VALIDATION

The performances and characteristics of the device have been determined based on the intended purposes of the device, essential safety and performance requirements and the identified risks that might happen during the transport, storage and usage. Those factors and the verification result thereof are summarized in the following sections to provide evidence of conformity with the essential safety and performance requirements.

6.1 Biocompatibility test report

Product biocompatibility was evaluated according to EN ISO 10993-1. Based on the test results of type examination report for Medical Face Masks issued by competent authority, concerning cytotoxicity, irritation, and sensitization, it is concluded that the biocompatibility of the product is in line with essential safety and performance requirements from MDR.

- Folder 6# HX-JS-CE-04-0601 Product biocompatibility evaluation report.
- Folder 6# Biocompatibility Test Report

Report Name	Report No.
In Vitro Cytotoxicity test report	CSTBR20030060
Skin Sensitization test report	CSTBR20030062
Skin Irritation test report	CSTBR20030061

The test results meet the requirements of ISO 10993-1 and have good biocompatibility.

6.2 Product performance test report

Physical and chemical performance have been tested per product specification

Sample: near-expired sample

Report Name	Report No.
Product performance test	60358333 001
Bioburden Test	CSTBB20030135

- Test Requierments

Dimension	The size of the mask should meet the design requirements with an allowable tolerance of 5%
Appearance	The appearance of the mask should be smooth, without damage, stains, deformation and other obvious defects.

Nose piece	The mask should be equipped with a nose piece, which is made of flexible materials and should be no less than 8.0cm in length.
Elastic bands	The Elastic bands should be elastic and suitable, the rupture strength of the mask belt and the connection between the mask belt and the mask body should be no less than 10N.
Bacterial filtration efficiency (BFE)	≥98%
Differential pressure	＜60 Pa/cm²
Microbial cleanliness	≤30 cfu/g

6.3 Usability evaluation report

The hazards and hazardous situation related to the usability have been taken into consideration during risk management process, and the mitigation measures are documented in risk management file.

Usability engineering of the device is conducted according to EN 62366 and the result is documented in Usability Evaluation Report.

Refer to the following reports for the scenarios tested.

•Folder 6# HX-JS-CE-04-0602-01 Usability check list

•Folder 6# HX-JS-CE-04-0602-02 Usability evaluation report.

6.4 Packaging aging and Transportation evaluation reports

Product package:

Packing type	Material	Product quantity	Specification
Inner box	Paper	50pcs	/

Outer box	Triap-corrugated box	2000pcs	600-700g/m^2 white or brown double corrugated

The processes will be revalidated if changes are made to the equipment, product, packaging materials or packaging processes and etc., which compromise the original validation and affect the safety or efficacy of the products. Annual revalidation or

reviews will also be performed and documented to evaluate the efficacy of the previous validation result.

- Folder 6# Packaging and Transportation Validation Report

Report Name	Report No.
Packaging and Transportation evaluation Report	50320946 001

Chapter 7 Clinical Evaluation

Since the evaluated products, Surgical Face Masks are traditional low risk medical device and sold & used over decades, its Risk-Benefit-Evaluation is demonstrated through long time device using experiences.

The products' performance and safety is also guaranteed through specific design following relevant standards requirements, bench testing, and the implementation of quality management system.

For applied products, through the comprehensive clinical literature databases and post manufacturing experience, it is found that no new clinical risks are generated yet.

For example, Internet sides and homepages, and literature

- http://www.ncbi.nlm.nih.gov/pubmed/ US National Library of Medicine National Institute of Health

the non-woven face masks, manufactured under the observed controlled conditions as described in intended use and the IFU, are safe in the field of healthcare personnel and no risk above the acceptable level are introduced by them.

Therefore, the Surgical Face Masks are considered to be acceptable for Risk-Benefit-Evaluation since both effectiveness and safety are deemed to be acceptable.

Please refer to folder 7 # HX-JS-CE-04-0701 for Clinical Evaluation Report.

Chapter 8 POST-MARKET SURVEILLANCE

Post-market surveillance is performed per MDR (EU) 2017/745 and MEDDEV 2.12 1/2, and the Post-market surveillance plan and report is given as attachments

- Folder 8 # HX-JS-CE-04-0801, PMS plan