CE Technical File

CE

Product Name: Face Mask

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1. Company Introduction

1.1 Introduction of the Manufacturer

Xiantao Yongli medical products Co,.Ltd is located at 8 xianhan road, xiantao city, hubei province,china, the former name is Xiantao Jinhong Health Products Co.Ltd., which was founded in 2000.Yongli Medical covers an area of 30,000 square meters and has more than 500 employees. We use advanced equipments from Germany and adopt modern science and technology. Our company has systematic training for staff, especially in the production of non-woven products and plastic products for the health care and protection. Our main products include: doctor Face Mask, nurse Face Mask, gowns, shoe covers, PE apron, visiting service, linens. And we also have a variety of choices of woven for customers, for instance: SBPP/SPP, SPP/PE, SPP/CPE, SMS, SMS/PE, Spunlace, LDPE, HDPE, CPE, Tyvek etc. After 10 years' un remitting effort, we have accumulated abundant practical experience also has made great strides in development.

Our company has independent import and export rights. The products are mainly exported to Germany, France, Japan, Mexico, America, Brazil and many other countries and regions We believe that quality and integrity can bring Yongli to the further future. We will treat our old and new customers honestly as always, and contribute to human health together.

1.2 Basic information of the Manufacturer

Manufacturer: XianTao Yongli Medical Products Co. Ltd.

Address: No 8 Xianhan Road, Xiantao City, Hubei, China.

Tel:0086-0728-3333696

Web：www.yonglixt.com

5.1.2e @yonglixt.com

EC Representative

Name: DEMARTA VIRGINIO SAS

Address: via G.Bozzalla n.20 13814 POLLONE (BI)

Tel:(39).015.9555440

E-mail: 5.1.2e @hotmail.com

2. General Description

2.1 Device description

The Face Mask is used in any non-hazardous environment where dirt, grime, splashes and spills are present. It can provide a superior combination of high tensile strength, barrier protection, and breathability. High degree dry particulate holdout to protect against the effects of chemical dusts, paint sprays, asbestos, and other airborne dusts.

The Face Mask is going to contact with the intact skin of the user, and it has been tested according to related compatibility standards such as EN ISO10993-5 and EN ISO 10993-10.

2.2 The product picture and model

Product Name	Picture	Model	Matrerial
Face Mask		17.5*9.5cm	Nonwoven + filter+Nonwoven
		14.5*9cm	

2.3 Product Manual

【Product Name】Face Mask

【Product Type】17.5*9.5cm,14.5*9cm

【Product performance】

The face mask should be flat and wrinkle-free, with a clean surface, no stains and no damage; the stitching/heat sealing should be straight and free from obvious waves and slopes; there should be no debris, whiskers, whiskers and off-line; Non-woven fabrics and filter papers shall not be spliced; they shall be firmly fixed and will not fall off; if they are equipped with nose clips, they shall be leak-free; the nose clips shall be made of bendable plastic materials, and the length of nose clips shall not be Less than 80mm.

【Indications】

This face mask is a one-time use product for general hygiene maintenance in general medical environments and public health places (not for use as a surgical mask or respirator)
Face Mask is especially designed as a disposable device made from fabric or other material placed over the nose and mouth by medical personnel to prevent the transmission of airborne organisms while surgery is being performed.

【Contraindications】
1.Packaging or web damage is prohibited;
2.This product is a one-time use product, it is strictly forbidden to reuse;
3.Please use the package unpacked in time;
4.Face mask should not be worn back and forth;
5.The nose bridge should be compacted when worn;
6.Replace the face mask when it is contaminated or damaged.

【Direction for Use】
Open the bag to take the exit cover, the nose clip is above the mask, the color is facing outward, cover the nose, mouth and chin with the mask, the mask tape is fixed behind the ear, put the tip of the finger on the bridge of the nose, start from the middle position The hand points inside and presses, and gradually moves to the sides, and the nose bridge shapes the nose clip to adjust the tightness of the strap, which is the mask close to the face. When removing the mask, do not touch the front of the mask. First remove the mask strip and pinch the mask strip to the waste container.

【Storage】
Store the products under the environment with less than 80% humidity and with less than 40℃ temperature, non-corrosive gases and with good ventilation.

【Shelf Life】
Two years.

Xiantao Yongli Medical Products Co. Ltd.
No 8 Xianhan Road, Xiantao City, Hubei, China

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Address: via G.Bozzalla n.20 13814 Pollone(BI), Italy

NON STERILE CE

Issued date: 2019-12-10, rev. A/0

3. Applicable Standard

No.	File No.	Version	Title
1	MDR 2017/745/EU	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	EN ISO 10993-1	2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
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+ A1:2013	2013	Terminology, Symbols and Information Related to Medical Devices –Information Provided by Manufacturers of Medical Devices
8	EN 14683	2014	Medical face masks - Requirements and test methods

4. 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 EU Medical Device Regulation (2017/745), base on the intended of Face Mask, it shall be Class I.

UDI

We Xiantao Yongli Medical Products Co.,Ltd. will apply the UDI system to our product once EU release relevant guidance or regulation.

UDI plan:UDI implemented before 2025.05.26, registered in EUDAMED database before 2027.05.26

5. Label and Language

5.1 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.

5.2 Symbol for "DO NOT REUSE"

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

5.3 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".

5.4 Symbol for "DATE OF MANUFACTURE"

This symbol shall be accompanied by a date to indicate the date of manufacture, expressed as given in ISO 8601, as four digits for the year, and where appropriate, two digits for the month and two digits for the day. The date could be a year, year and month, or year, month, and day, as required by the relevant Directive. The date shall be located adjacent to the symbol.

NOTE 1 The relative sizes of the symbol and the date are not specified.

5.5 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".

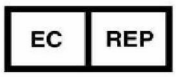
5.6 Symbol for "CAUTION"

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".

5.7 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.

5.8 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 CE
b) Diameter of the pattern shall not be less than 5mm.
c) CE marking shall be distinct, visible durable and in clear writing.

5.10 Symbol for "NON-STERILE"

NOTE 1 This symbol should only be used to distinguish between identical or similar devices

sold in both sterile and non-sterile conditions.

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

A.1 Example of use of symbol for "BATCH CODE"

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			★										

Label Sample

Product: Face Mask

SIZE/MODEL:

YYYY-MM-DD

LOT YYYYMMDD

NON STERILE

YYYYMMDD

1.This is a disposable product.
2.Do not reuse. Reusing may cause cross-contamination.

EC REP Name: DEMARTA VIRGINIO SAS
Address: via G.Bozzalla n.20 13814 POLLONE (BI)

XianTao Yongli Medical Products Co. Ltd.
Address: No 8 Xianhan Road, Xiantao City, Hubei, China.

UDI:

6. General Safety and Performance Performance Requirements

Please refer to the Attachment1 <General Safety and Performance Performance Requirements>

7. Benefit-Risk Analysis and Risk Management

Please refer to Attachment 2 <Risk Management Report>

8. Test Report

8.1.Purpose

Biocompatibility and type testing of Face Mask materials to verify the safety and performance of the device according to MDR EU 2017/745 and other related booths.

8.2. Related standards

EN ISO 10993-5:2009

EN ISO 10993-10:2013

8.3. Related tests

8.3.1. Safety of raw material

Face Mask is composed of PE or PE+PP or PP or Microporous

Seequalified suppliers list-materials list: Annex 3

We tested or inspected parts or material according to Raw material inspection specifications, (technical requirements of Face Mask, and material technical requirements.

The test results show that all of raw materials and parts met related above mentioned requirements

See qualified suppliers list-materials list: Annex 3

8.3.2 Biocompatibility

We evaluated the biocompatibility according to EN ISO 10993-1.The biocompatibility of product is shown safety of Face Mask.

8.4. Related documents and Test reports

Raw material inspection specifications

Raw materials inspection reports related

(Self-testing)Final inspection test report

8.5 The material used to manufacture Face Mask has passed the compatibly test and (Self-testing)Final inspection test report, the test reports are attached as Attachment 4<Test Report>

9. Clinical Evaluation Report

9.1 Pre-Clinical and clinical data

The clinical evaluation of Face Mask was performed according Annex VIII Council Regulation(EU 2017/745), section 1.1, as well as MEDDEV-Guideline 2.7.1-Evaluation of Clinical Data (Rev. 4, June 2016).

Please refer to Attachment5<Clinical Evaluation Report>

10. Post Marketing

10.1 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 Face Mask. Quality and Customer Service gather the customer feedbacks, and reviewing on a monthly basis.

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

c) Device intended use:

To protect medical personnel from blood, body fluids and other infectious substances, and protect patients from infection

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

Methods of post-marketing supervision	Responsible for the department	Timing and frequency
1 Investigation of persons with serious illness	Sales Departmentment	When serious illness occurs using the product
2 Visit people who have been in use for a long time	Sales Departmentment	When there are people who use the product for a long time
3 Conduct research on sensitive groups	Sales Departmentment	When a sensitive person USES the product

4 A continuous review of the literature	The production department	Relevant clinical literature is updated annually
5 Continuous research on similar medical devices after marketing	The production department	Long-term continuous study
6 Continuous research on the materials, operating principles and techniques of medical devices	The production department	Long-term continuous study
7 Continuous research on new technologies	The production department	When there's new technology
8 Continuous study of product life	Quality inspection department	Long-term continuous study
9 Conduct research on adverse events, and establish and implement the monitoring and control procedures for substandard accidents and adverse events	Quality inspection department	When an adverse event occurs
10 Ask customers for relevant improvement Suggestions, measure customer satisfaction, and establish and implement the control procedure of customer related process	Sales Department	Once a year
11 Follow up customer complaints, and establish customer information feedback control process and implement it	Sales Department	When customer complaints occur
12 Pay close attention to the recalled products, and establish and implement	Sales Department	When a product recall is implemented

the "warning notice release and product recall control procedure"		
13 Research on new standards related to products	The production department	When product standards are updated
14 Research on new laws and regulations related to products	The production department	When relevant laws and regulations 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 Face Mask customers and analysis on monthly basis.

10.2 Post-market Surveillance Report

10.2.1 Post-market Surveillance data

Base on the post-market surveillance plan we made in section 10.2, the corresponding data collected are shown as follow,

Sales list

The Face Mask has been placed on the market for 10 years, during 10 years' sale ,we sale 108,000,000 pics per year to EU market and no customer feedback was received up to May, 2019. the sale list and customer feedback of the propose device and similar device are shown in the table below.

Table2 Customer feedback list of the propose device

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

Table3 Post Market experience of similar device

Area	Time	Quantity	Complaints	Adverse events
China	N/	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

Table 4: PMS Study Result

Methods of post-marketing supervision	Responsible for the department	Collect data
1 Investigation of persons with serious illness	Supply and Marketing Department	No, this product is not intended for severe illness
2 Visit people who have been in use for a long time	Supply and Marketing Department	No, the product has no long-term use of personnel
3 Conduct research on sensitive groups	Supply and Marketing Department	No, no sensitive personnel using this product
4 A continuous review of the literature	The production department	See attachment 5
5 Continuous research on similar medical devices after marketing	The production department	See attachment 5
6 Continuous research on the materials, operating principles and techniques of medical devices	The production department	The material, operating principle and technology of the product have not been updated
7 Continuous research on new technologies	The production department	No new technology
8 Continuous study of product life	Quality	No change in life

	inspection department	
9 Conduct research on adverse events, and establish and implement the monitoring and control procedures for substandard accidents and adverse events	Quality inspection department	No, this product has no adverse events
10 Ask customers for relevant improvement Suggestions, measure customer satisfaction, and establish and implement the control procedure of customer related process	Supply and Marketing Department	No, no customer feedback
11 Follow up customer complaints, and establish customer information feedback control process and implement it	Supply and Marketing Department	No, no customer complaints
12 Pay close attention to the recalled products, and establish and implement the "warning notice release and product recall control procedure"	Supply and Marketing Department	No, no customer recall
13 Research on new standards related to products	The production department	See section 10.2 for details
14 Research on new laws and regulations related to products	The production department	See section 10.2 for details

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 the new standard.

B) Product regulation

The Europe Regulation about medical device (2017/745)has released on 20th, May, 2017. We update this CE document based on the new Medical Device Regulation (2017/745). And implement quality management base on the new Medical Device Regulation (2017/745).

10.2.2 Safety and Effectiveness Conclusion

By collecting and analyzing PMS data of the propose device and similar device, the technology of Face Mask is mature. Risk management, bench test, literature analysis and post- market data has prove 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 PMCF data and the clinical investigation result of propose and 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.

11. Declaration of Conformity

Please refer to Attachment 6-(EC Declaration of Conformity)