TEST REPORT

MEASUREMENT AND TEST REPORT
For

Wuhan Huashida Protective Products Co.,Ltd .

511 Weihu Rd, Shamao Street，Hannan District, Wuhan, Hubei, China

Models: See page two

March 18, 2020

This Report Concerns:	**Equipment Type:**
☒ Original Report	Surgical face mask

Report Number:	HSD200320013
Test Date:	March 13-18, 2020
Signature:	
Prepared By:	**Wuhan Huashida Protective Products Co.,Ltd .** 511 Weihu Rd, Shamao Street，Hannan District, Wuhan, Hubei, China

Note: This test report is limited to the above client company and the product model only. It may not be duplicated without prior written consent of Wuhan Huashida Protective Products Co.,Ltd .

TEST REPORT
EN 14683
Medical face masks - Requirements and test methods

Report reference No.....	:	HSD200320013
Date of issue.....	:	March 18, 2020

Testing laboratory

Name.....	:	Wuhan Huashida Protective Products Co.,Ltd .
Address.....	:	511 Weihu Rd, Shamao Street，Hannan District, Wuhan, Hubei, China
Test location.....	:	(Same as above)

Client

Name.....	:	Wuhan Huashida Protective Products Co.,Ltd .
Address.....	:	511 Weihu Rd, Shamao Street，Hannan District, Wuhan, Hubei, China

Test specification

Standard.....	:	EN 14683:2019
Test procedure.....	:	CE- MDD
Procedure deviation.....	:	N.A.
Non-standard test method..	:	N.A.

Test Report Form No.....: EN 14683

Test item

Description.....	:	Surgical face mask
Model No.	:	HM11001U, HM12001U, HM13001U, HM14002U, HM21001U, HM22001U, HM23001U, HM24002U
Trade Mark.....	:	N/A
Manufacturer.....	:	Wuhan Huashida Protective Products Co.,Ltd .
Address.....	:	511 Weihu Rd, Shamao Street，Hannan District, Wuhan, Hubei, China
Classification.....	:	Type II

Test case verdicts

Test case does not apply to the test object..... : N(.A.)

Test item does meet the requirement..... : P(ass)

Test item does not meet the requirement..... : F(ail)

Testing

Date of receipt of test item ……..: March 12, 2020

Date(s) of performance of test ……...: March 13-18, 2020

General remarks

This test report shall not be reproduced except in full without the written approval of the testing laboratory.

The test results presented in this report relate only to the item tested.

"(see remark #)" refers to a remark appended to the report.

"(see appended table)" refers to a table appended to the report.

Throughout this report a comma is used as the decimal separator.

Remark :

The EUT complies with the standard EN 14683 requirement.

Copy of marking plate:

Surgical face mask
Model： HM11001U Classification : Type II EN 14683: 2019 CE  Wuhan Huashida Protective Products Co.,Ltd . Made In China

EN 14683			
Clause	Requirement + Test	Result - Remark	Verdict
4	**Classification**		P
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance	Type II	P
5	Requirements		P
5.1	General		P
5.1.1	Materials and construction		P
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness.	Meet the requirements	P
5.1.2	Design		P
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.	The wire holds the shape and makes the mask fit tightly to the nose	P
	Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours)		N
5.2	Performance requirements		P
5.2.1	General		P
	All tests shall be carried out on finished products or samples cut from finished products.		P
5.2.2	All tests shall be carried out on finished products or samples cut from finished products.		P
	When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1	See table 1.	P
	For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE		N
	When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. The lowest performing panel or area		P

EN 14683			
Clause	Requirement + Test	Result - Remark	Verdict
	shall determine the BFE value of the complete mask.		
5.2.3	Breathability		P
	When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1		P
	If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).		N
5.2.4	Splash resistance		N
	When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.		N
5.2.5	Microbial cleanliness (Bioburden)		P
	When tested according to EN ISO 11737-1:2018 the bioburden of the Disposable mask（non-medicial） shall be ⩽ 30 CFU/g tested (see Table 1).	1# : 14.2 CFU/g; 2#: 14.5 CFU/g; 3#: 13.9 CFU/g; 4#: 14.8 CFU/g 5#: 14.0 CFU/g	P
	NOTE EN ISO 11737-1:2018 specifies requirements and provides guidance for the enumeration and microbial characterization of the population of viable microorganisms on or in a medical device, component, raw material or package.		P
	To determine the mask’s bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D.		P
	The number of masks that shall be tested is minimum 5 of the same batch/lot.		P
	Other test conditions as described in EN ISO 11737-1:2018 may be applied.		P
	In the test report, indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram.	24.2	P
5.2.6	Biocompatibility		P
	According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact. The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime. The results of testing should be		P

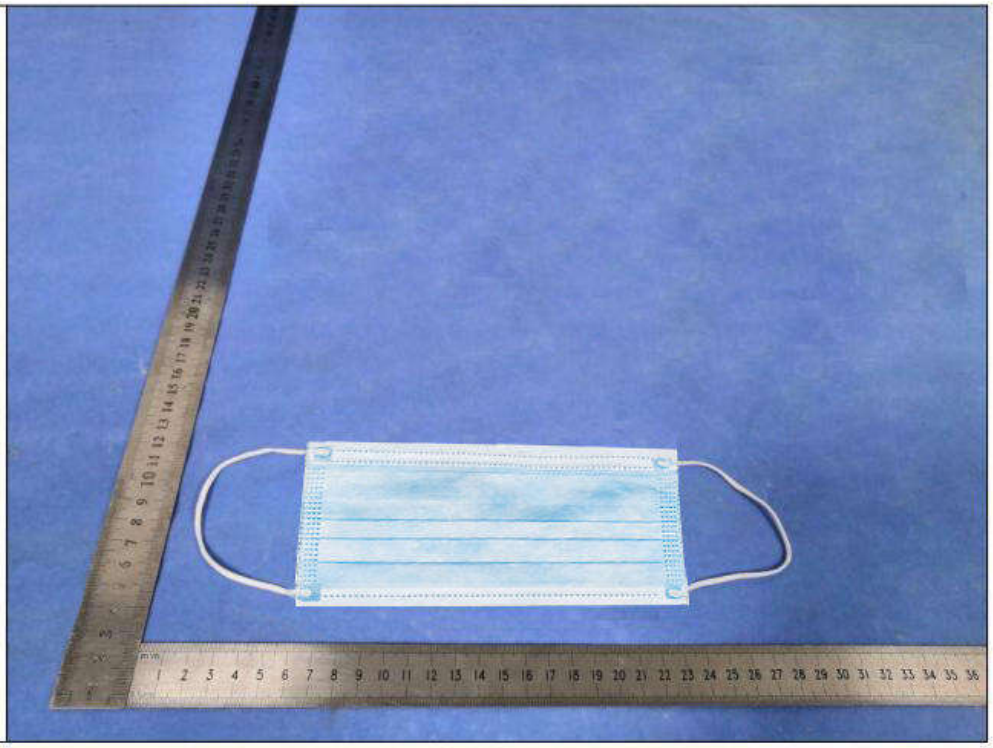
EN 14683			
Clause	Requirement + Test	Result - Remark	Verdict
	documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request.		
5.2.7	Summary of performance requirements		P
6	Marking, labelling and packaging		P
	Annex I, § 13, of the Medical Devices Directive (93/42/EEC) or Annex I, § 23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied.		P
	The following information shall be supplied:		P
	a) number of this European Standard;	EN 14683:2019	P
	b) type of mask (as indicated in Table 1).	Type II	P
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.		P

Table 1 — Performance requirements for medical face masks

Table 1	The performance test			Result
Test	Type I[a]	Type II	Type IIR	Type II
Bacterial filtration efficiency (BFE), (%)	⩾95	⩾98	⩾98	98.9
Differential pressure (Pa/cm 2)	＜40	＜40	＜60	26.8
Splash resistance pressure (kPa)	Not required	Not required	⩾16,0	--
Microbial cleanliness (cfu/g)	⩽30	⩽30	⩽30	22.8
Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.				

Appendix

Photo documentation

View: [√] front [ ] rear [ ] right side [ ] left side [ ] top [ ] bottom [ ] internal	

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