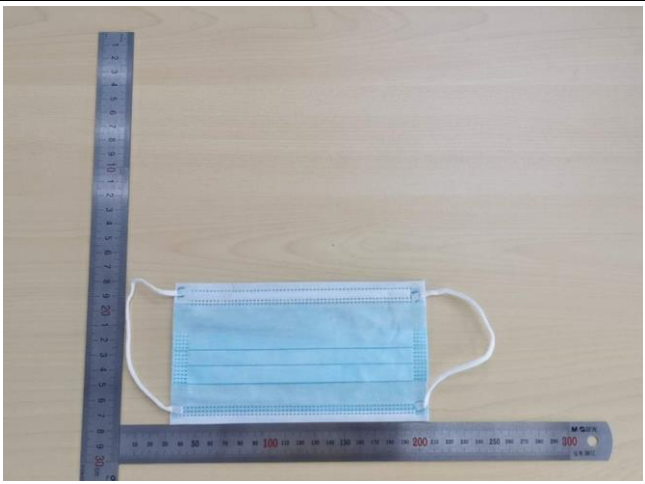


<b>Prüfbericht-Nr.:</b> <i>Test Report No.:</i>	<b>60358333 001</b>	<b>Auftrags-Nr.:</b> <i>Order No.:</i>	<b>190105940</b>	Seite 1 von 12 Page 1 of 12	
<b>Kunden-Referenz-Nr.:</b> <i>Client Reference No.:</i>	<b>N/A</b>	<b>Auftragsdatum:</b> <i>Order date:</i>	<b>2019-11-29</b>		
<b>Auftraggeber:</b> <i>Client:</i>	<b>Xinxiang Huaxi Sanitary Materials Co.,Ltd.</b> Dingluan Industrial Zone, Changyuan, Xinxiang 453400 Henan Province, China				
<b>Prüfgegenstand:</b> <i>Test item:</i>	<b>Disposable Surgical Face Mask</b>				
<b>Bezeichnung / Typ-Nr.:</b> <i>Identification / Type No.:</i>	<b>Elastic Earloop Type</b>				
<b>Auftrags-Inhalt:</b> <i>Order content:</i>	<b>Type test</b>				
<b>Prüfgrundlage:</b> <i>Test specification:</i>	<b>EN 14683:2019+AC:2019</b>				
<b>Wareneingangsdatum:</b> <i>Date of receipt:</i>	<b>2020-02-12</b>				
<b>Prüfmuster-Nr.:</b> <i>Test sample No.:</i>	<b>Engineering sample</b>				
<b>Prüfzeitraum:</b> <i>Testing period:</i>	<b>2020-02-13 to 2020-03-25</b>				
<b>Ort der Prüfung:</b> <i>Place of testing:</i>	<b>TÜV Rheinland (China) Ltd.</b>				
<b>Prüflaboratorium:</b> <i>Testing laboratory:</i>	<b>TÜV Rheinland (China) Ltd.</b>				
<b>Prüfergebnis*:</b> <i>Test result*:</i>	<b>Pass</b>				
<b>geprüft von / tested by:</b>		<b>kontrolliert von / reviewed by:</b>			
2020-03-26	Han Dong / Project Engineer		2020-03-26	Chen Yuhong / Reviewer	
<b>Datum</b> <i>Date</i>	<b>Name / Stellung</b> <i>Name / Position</i>	<b>Unterschrift</b> <i>Signature</i>	<b>Datum</b> <i>Date</i>	<b>Name / Stellung</b> <i>Name / Position</i>	<b>Unterschrift</b> <i>Signature</i>
<b>Sonstiges / Other:</b>					
- Attachment 1. Photographic Documentation (2 pages)					
<b>Zustand des Prüfgegenstandes bei Anlieferung:</b> <i>Condition of the test item at delivery:</i>			<b>Prüfmuster vollständig und unbeschädigt</b> <i>Test item complete and undamaged</i>		
* Legende: 1 = sehr gut      2 = gut      3 = befriedigend      4 = ausreichend      5 = mangelhaft P(ass) = entspricht o.g. Prüfgrundlage(n)      F(ail) = entspricht nicht o.g. Prüfgrundlage(n)      N/A = nicht anwendbar      N/T = nicht getestet Legend: 1 = very good      2 = good      3 = satisfactory      4 = sufficient      5 = poor P(ass) = passed a.m. test specification(s)      F(ail) = failed a.m. test specification(s)      N/A = not applicable      N/T = not tested					
<b>Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens.</b>					
<i>This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.</i>					

<b>EN 14683:2019+AC: 2019                      Medical face masks —                      Requirements and test methods</b>	
<b>Report Reference No.</b> .....	<b>60358333 001</b>
<b>Date of issue</b> .....	See cover page
<b>Total number of pages</b> .....	See cover page
<b>Testing Laboratory</b> .....	<b>TÜV Rheinland (China) Ltd.</b>
<b>Address</b> .....	Unit 707, AVIC Building, No. 10B, Central Road, East 3rd Ring Road,Chaoyang District, Beijing 100022, P,R,China
<b>Applicant's name</b> .....	<b>Xinxiang Huaxi Sanitary Materials Co.,Ltd.</b>
<b>Address</b> .....	Dingluan Industrial Zone, Changyuan, Xinxiang 453400 Henan Province, China
<b>Test specification:</b>	
<b>Standard</b> .....	<b>EN 14683:2019+AC:2019</b>
<b>Test procedure</b> .....	Type test
<b>Non-standard test method</b> .....	N/A
<b>Test Report Form No.</b> .....	EN 14683:2019+AC:2019_A
<b>Test Report Form Originator</b> .....	TÜV Rh (SZ)
<b>Master TRF</b> .....	2020-03
<b>Test item description</b> .....	<b>Disposable Surgical Face Mask</b>
<b>Trade Mark</b> .....	N/A
<b>Manufacturer</b> .....	<b>Xinxiang Huaxi Sanitary Materials Co.,Ltd.</b> Dingluan Industrial Zone, Changyuan, Xinxiang 453400 Henan Province, China
<b>Model/Type reference</b> .....	<b>Elastic Earloop Type</b>
<b>Classification</b> .....	Type IIR

**List of Attachments (including a total number of pages in each attachment):**

- Attachment 1. Photos documentation (2 pages).

**Summary of testing:**

**Tests performed (name of test and test clause):**

**Clause 5.2.2: Bacterial filtration efficiency (BFE);**

**Clause 5.2.3: Breathability**

**Clause 5.2.4: Splash resistance**

**Clause 5.2.5: Microbial cleanliness (Bioburden).**

**Note: All tests listed as above have been conducted in the competent external lab under the supervision of a TUV engineer**

Copy of marking plate

The artwork below may be only a draft.

Label for Elastic Earloop Type



<b>Testing</b>	
<b>Date of receipt of test item(s)</b> .....:	2020-02-13
<b>Dates of tests performed</b> .....	2020-02-13 to 2020-04-02
<b>Possible test case verdicts:</b>	
- test case does not apply to the test object .....	: N/A
- test object does meet the requirement .....	: P (Pass)
- test object was not evaluated for the requirement ....	: N/E (collateral standards only)
- test object does not meet the requirement .....	: F (Fail)
<b>General remarks:</b>	
"(See Attachment #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. The tests results presented in this report relate only to the object tested. This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report.	
Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	
<b>Name and address of factory (ies)</b> .....	<b>Xinxiang Huaxi Sanitary Materials Co.,Ltd.</b> Dingluan Industrial Zone, Changyuan, Xinxiang 453400 Henan Province, China
<b>General product information:</b>	
Intended use: The Disposable Surgical Face Mask 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.	

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
<b>4</b>	<b>Classification</b>		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 IIR	P
<b>5</b>	<b>Requirements</b>		P
<b>5.1</b>	<b>General</b>		P
<b>5.1.1</b>	<b>Materials and construction</b>		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.	Complied	P
	The medical face mask shall not disintegrate, split or tear during intended use.	Complied	P
	In the selection of the filter and layer materials, attention shall be paid to cleanliness.	Complied	P
<b>5.1.2</b>	<b>Design</b>		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.	Complied	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).	Complied	P
<b>5.2</b>	<b>Performance requirements</b>		P
<b>5.2.1</b>	<b>General</b>		P
	All tests shall be carried out on finished products or samples cut from finished products.		P
<b>5.2.2</b>	<b>Bacterial filtration efficiency (BFE)</b>		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 1.1 1.2.	The Bacterial Filtration Efficiency $\geq 98\%$ See appended Table 5.2.2	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.	Not such masks	N/A

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually.		N/A
	The lowest performing panel or area shall determine the BFE value of the complete mask		N/A
<b>5.2.3</b>	<b>Breathability</b>		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 2.1 2.2.	The differential pressure <60 Pa/cm <sup>2</sup> See appended Table 5.2.3	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).	No such respiratory protective device provided	N/A
<b>5.2.4</b>	<b>Splash resistance</b>		P
	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.	See appended Table 5.2.4	P
<b>5.2.5</b>	<b>Microbial cleanliness (Bioburden)</b>		P
	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested (see Table 3.1 3.2).	The bioburden of the medical mask was <30 CFU/g See appended Table 5.2.5	P
<b>5.2.6</b>	<b>Biocompatibility</b>		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 biocompatibility of mask was evaluated in following report: CSTBR20030060 CSTBR20030061 CSTBR20030062	P
	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 biocompatibility of mask was evaluated in following report: CSTBR20030060 CSTBR20030061 CSTBR20030062	P
	The results of testing should be documented according to the applicable parts of the EN ISO 10993 series.	The biocompatibility of mask was evaluated in following report: CSTBR20030060 CSTBR20030061 CSTBR20030062	P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	The test results shall be available upon request.	The biocompatibility of mask was evaluated in following report: CSTBR20030060 CSTBR20030061 CSTBR20030062	P
<b>6</b>	<b>Marking, labelling and packaging</b>		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.	Considered	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 IIR	P
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.	Compliance	P



EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

5.2.2 TABLE: Bacterial filtration efficiency (BFE)								P
Batch/ lot no.:	Test Speci- men no.:	Dimension of the test specimen L x W (mm x mm)	test area (cm <sup>2</sup> )	Flow rate (l/min)	Mean of the total plate counts of the two positive controls	Mean plate count of the negative controls	BFE for each test specimen (%)	Remarks
2006090 6	1	100×100	100	28.3	2419	0	99.0	≥98
	2	100×100	100	28.3	2367	0	99.0	≥98
	3	100×100	100	28.3	2366	0	98.0	≥98
	4	100×100	100	28.3	2412	0	99.0	≥98
	5	100×100	100	28.3	2389	0	98.0	≥98

Supplementary information:

1, Each specimen was conditioned at  $(21 \pm 5)^{\circ}\text{C}$  and  $(85 \pm 5)\%$  relative humidity for 4h to bring them into equilibrium with atmosphere prior to testing.

2, The side of the test specimen was facing towards the challenge aerosol: \_\_\_\_\_

EN 14683:2019+AC:2019					
Clause	Requirement + Test			Result - Remark	Verdict
<b>5.2.3</b>	<b>TABLE: Breathability (Differential pressure)</b>				<b>P</b>
Batch/ lot no.:	Test Specimen number- Test area number	Differential pressure for each test area (Pa/cm <sup>2</sup> )	The averaged differential pressure for each test specimen (Pa/cm <sup>2</sup> )	Flow rate (l/min)	Remarks
200609 06	1-1	28.2	28.0	8	<60
	1-2	27.8		8	<60
	1-3	28.0		8	<60
	1-4	27.9		8	<60
	1-5	28.1		8	<60
	2-1	36.7	36.9	8	<60
	2-2	36.9		8	<60
	2-3	37.0		8	<60
	2-4	36.8		8	<60
	2-5	37.1		8	<60
	3-1	30.5	30.7	8	<60
	3-2	30.9		8	<60
	3-3	30.6		8	<60
	3-4	30.8		8	<60
	3-5	30.7		8	<60
	4-1	31.6	31.9	8	<60
	4-2	31.7		8	<60
	4-3	32.1		8	<60
	4-4	32.3		8	<60
	4-5	31.8		8	<60
5-1	32.7	32.5	8	<60	
5-2	32.6		8	<60	
5-3	32.4		8	<60	
5-4	32.7		8	<60	
5-5	32.1		8	<60	
<b>Supplementary information:</b>					
Each specimen was conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for 4h to bring them into equilibrium with atmosphere prior to testing					

EN 14683:2019+AC:2019				
Clause	Requirement + Test		Result - Remark	Verdict
<b>5.2.4</b>	<b>TABLE: Splash resistance</b>			<b>P</b>
Batch/ lot no.:	Test mask no.:	The material of tested mask	Test result (Pass/fail)	Remarks
20060906	1	Polypropylene, Polyester fiber, Spandex,	Pass	-
	2	Polypropylene, Polyester fiber, Spandex,	Pass	-
	3	Polypropylene, Polyester fiber, Spandex,	Pass	-
	4	Polypropylene, Polyester fiber, Spandex,	Pass	-
	5	Polypropylene, Polyester fiber, Spandex,	Pass	-
	6	Polypropylene, Polyester fiber, Spandex,	Pass	-
	7	Polypropylene, Polyester fiber, Spandex,	Pass	-
	8	Polypropylene, Polyester fiber, Spandex,	Pass	-
	9	Polypropylene, Polyester fiber, Spandex,	Pass	-
	10	Polypropylene, Polyester fiber, Spandex,	Pass	-
	11	Polypropylene, Polyester fiber, Spandex,	Pass	-
	12	Polypropylene, Polyester fiber, Spandex,	Pass	-
	13	Polypropylene, Polyester fiber, Spandex,	Pass	-
	14	Polypropylene, Polyester fiber, Spandex,	Pass	-
	15	Polypropylene, Polyester fiber, Spandex,	Pass	-
	16	Polypropylene, Polyester fiber, Spandex,	Pass	-
	17	Polypropylene, Polyester fiber, Spandex,	Pass	-
	18	Polypropylene, Polyester fiber, Spandex,	Pass	-
	19	Polypropylene, Polyester fiber, Spandex,	Pass	-
	20	Polypropylene, Polyester fiber, Spandex,	Pass	-
	21	Polypropylene, Polyester fiber, Spandex,	Pass	-
	22	Polypropylene, Polyester fiber, Spandex,	Pass	-
	23	Polypropylene, Polyester fiber, Spandex,	Pass	-
	24	Polypropylene, Polyester fiber, Spandex,	Pass	-
	25	Polypropylene, Polyester fiber, Spandex,	Pass	-
	26	Polypropylene, Polyester fiber, Spandex,	Pass	-
	27	Polypropylene, Polyester fiber, Spandex,	Pass	-
	28	Polypropylene, Polyester fiber, Spandex,	Pass	-
	29	Polypropylene, Polyester fiber, Spandex,	Pass	-

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

	<b>30</b>	Polypropylene, Polyester fiber, Spandex,	<b>Pass</b>	-
	<b>31</b>	Polypropylene, Polyester fiber, Spandex,	<b>Pass</b>	-
	<b>32</b>	Polypropylene, Polyester fiber, Spandex,	<b>Pass</b>	-

**Supplementary information:**

- 1, Each specimen was conditioned at  $21 \pm 5^{\circ}\text{C}$  and  $85 \pm 10\%$  relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.
- 2, The description of target area tested: outside
- 3, Any technique used to enhance visual detection of synthetic blood: \_\_\_\_\_
- 4, The temperature and relative humidity for testing: 23 °C and 89 %
- 5, Description of any pre-treatment techniques used: \_\_\_\_\_

<b>5.2.5</b>	<b>TABLE: Microbial cleanliness (Bioburden)</b>				<b>P</b>
Batch/ lot no.:	Mask(under test) no.:	Weight of each mask (g)	Total bioburden per individual mask (CFU/g)	Remarks	
20060906	1	3.2	15.3	$\leq 30$	
	2	3.1	12.9	$\leq 30$	
	3	3.2	14.4	$\leq 30$	
	4	3.1	15.2	$\leq 30$	
	5	3.1	13.2	$\leq 30$	

**Supplementary information:**

The plates are incubated for 3 days at 30 °C and 7 days at (20 to 25) °C for TSA and SDA plates respectively.

**END OF TEST REPORT, CONTINUED AS ATTACHMENT 1**

PHOTO DOCUMENTATION

for

**Disposable Surgical Face Mask**  
**Elastic Earloop Type**  
**Xinxiang Huaxi Sanitary Materials Co.,Ltd.**



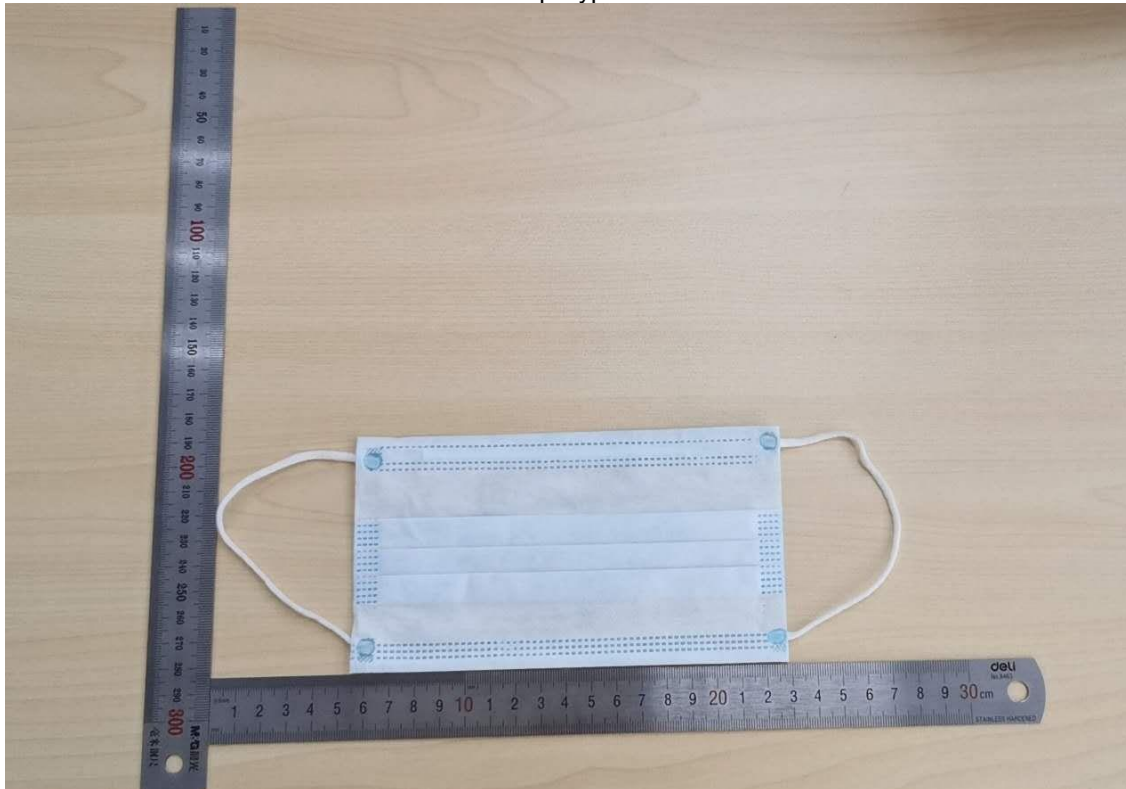
This documentation consists of 2 pages (excluding this cover page).

**Model: Elastic Earloop Type**

Pic.1: The obverse side view of Elastic Earloop Type



Pic.2: The reverse side view of Elastic Earloop Type



Model: Elastic Earloop Type

Pic.3: Marking, labelling and packaging of Elastic Earloop Type



Pic.4: Marking, labelling and packaging of Elastic Earloop Type

