




Prüfbericht-Nr.: <i>Test Report No.:</i>	60377050 001	Auftrags-Nr.: <i>Order No.:</i>	168264746	Seite 1 von 12 Page 1 of 12	
Kunden-Referenz-Nr.: <i>Client Reference No.:</i>	N/A	Auftragsdatum: <i>Order date:</i>	May 13, 2020		
Auftraggeber: <i>Client:</i>	Hunan EEXI Technology & Service Co., Ltd. No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, China				
Prüfgegenstand: <i>Test item:</i>	Disposable Medical Face Mask				
Bezeichnung / Typ-Nr.: <i>Identification / Type No.:</i>	YX005				
Auftrags-Inhalt: <i>Order content:</i>	Type test				
Prüfgrundlage: <i>Test specification:</i>	EN 14683:2019+AC:2019 except for clause 5.2.6				
Wareneingangsdatum: <i>Date of receipt:</i>	May 14, 2020	See Attachment: Photo documentation for details.			
Prüfmuster-Nr.: <i>Test sample No.:</i>	20200504				
Prüfzeitraum: <i>Testing period:</i>	May 14, 2020 to May 28, 2020				
Ort der Prüfung: <i>Place of testing:</i>	See page 3				
Prüflaboratorium: <i>Testing laboratory:</i>	TÜV Rheinland (Shenzhen) Co., Ltd.				
Prüfergebnis*: <i>Test result*:</i>	Pass				
geprüft von / tested by:		kontrolliert von / reviewed by:			
					
May 29, 2020 Lucy Jiang / Assistant Project Engineer		May 29, 2020 Angela Chen / Department Manager			
Datum <i>Date</i>	Name / Stellung <i>Name / Position</i>	Unterschrift <i>Signature</i>	Datum <i>Date</i>	Name / Stellung <i>Name / Position</i>	Unterschrift <i>Signature</i>
Sonstiges / Other:					
- The test report consists of EN 14683 test report including this cover page (12 pages) and attachment: Photo documentation (6 pages).					
- The Biocompatibility (clause 5.2.6) is not evaluated in this test report.					
Zustand des Prüfgegenstandes bei Anlieferung: <i>Condition of the test item at delivery:</i>			Prüfmuster vollständig und unbeschädigt <i>Test item complete and undamaged</i>		
* Legende:	1 = sehr gut P(ass) = entspricht o.g. Prüfgrundlage(n)	2 = gut F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	3 = befriedigend N/A = nicht anwendbar	4 = ausreichend N/A = nicht anwendbar	5 = mangelhaft N/T = nicht getestet
Legend:	1 = very good P(ass) = passed a.m. test specification(s)	2 = good F(ail) = failed a.m. test specification(s)	3 = satisfactory N/A = not applicable	4 = sufficient N/A = not applicable	5 = poor N/T = not tested
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. <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>					

V04

EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods	
Report Reference No.	60377050 001
Date of issue	See cover page
Total number of pages	See cover page
Testing Laboratory	TÜV Rheinland (Shenzhen) Co., Ltd.
Address	1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Applicant's name	Hunan EEXI Technology & Service Co., Ltd.
Address	No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, China
Test specification:	
Standard	EN 14683:2019+AC:2019
Test procedure	Type test
Non-standard test method	N/A
Test Report Form No.	EN 14683:2019+AC:2019_A
Test Report Form Originator	TÜV Rh (SZ)
Master TRF	2020-03
Test item description	Disposable Medical Face Mask
Trade Mark	
Manufacturer	Same as the applicant
Model/Type reference	YX005
Classification	Type I

List of Attachments (including a total number of pages in each attachment):	
Attachment – Photo Documentation (6 pages)	
Summary of testing:	
Tests performed (name of test and test clause): Construction check according to: Clause 5.1.1 Materials and construction Clause 5.1.2 Design	Testing location: TÜV Rheinland (Shenzhen) Co., Ltd. 1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Clause 5.2.2 Bacterial filtration efficiency (BFE) Clause 5.2.3 Breathability Clause 5.2.5 Microbial cleanliness (Bioburden)	Sichuan Testing Center of Medical Devices No. 4-28, Xinye Road, High tech west Area, Chengdu, Sichuan, 611731, P.R.China

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

Article No.: YX005

Instruction

Date of preparation of the manual: April 10, 2020
Manual version number: E 1
Please refer to the instructions before use

Product name: Disposable medical face mask
Type and Specification: Flat earloop, 14.5×9cm
Type: Type I
Applicable standard: EN 14683:2019+AC:2019 YY/T 0969-2013
Production license No.: Hunan Food&Drug Administration permission 20200023
Registration No.: Hunan medical device registration permission 20202140297

Intended Use:
The medical face mask is single-use, disposable device, provided non-sterile, and intended to be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations.

Structure and Components:
This mask is made by blank mask, nose piece and ear loops. The blank mask is made by three layers. The inner and outer layer are non-woven fabric, the middle layer is Melt-blown polypropylene.

Main performance:
 1) Bacterial filtration efficiency: ≥95%;
 2) Differential Pressure: < 40 Pa/cm 2 ;
 3) Microbial cleanliness: ≤30 cfu/g.








Introduction for use:
 1) Open the package and remove a mask.
 2) Hold the mask by the ear loops, confirm that the colored side is front and the nose piece is on the top of the mask. Hang the ear loops over your ears and mold the nose piece to the shape of your nose, pull the bottom of the mask over your mouth and chin.

Precautions:
 1) Check the package is intact before use, conform the masks and date of manufacture on the external package, and use it before the expiry date.
 2) If you are allergic to non-woven fabric, be cautious using this product.
 3) After using the product, please dispose of it according to the requirements of the environments protection agency or related authorities.
 4) This product is a disposable device. It is not recommended to the clean or reuse it. If you feel uncomfortable during use, please stop using it immediately or replace it with a new one.

Storage:
Store in a dry, well-ventilated, non-corrosive gas place, avoid high temperature.

Shelf life: 2 years.

Meaning of package symbols:

symbol	Explanation	symbol	Means
	Means "Do not reuse"		Means "Date of manufacture"
	Means "Do not use if package is damaged"		Means "Use by date"
	Means "Keep away from sunlight"		Means "Batch code"
	Means "Keep dry"		Means "Manufacturer"
			Means "Authorized representative in the European Community"

Batch code: refer to package
Date of manufacture: refer to package
Use by date: refer to package
Authorized representative in the European Community: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Contact Person: SUNGO Secretary **E-mai:** ec.rep@sungogroup.com
Manufacturer: Hunan EEXI Technology & Service Co.,LTD.
Address: No. 6 North of Pingtou Road, Liuyang Hi-tech Industrial Development Zone, Hunan, China.
Website: www.hunaneexi.com

See attachment for other information.

Testing
Date of receipt of test item(s): See cover page Dates of tests performed: See cover page
Possible test case verdicts:
- 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)
General remarks:
"(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.
Name and address of factory (ies) : Same as the applicant
General product information:
1, The tested medical mask classified as Type I. 2, The Biocompatibility (clause 5.2.6) is not evaluated in this test report. 3, The test results are for reference only. Relevant certification may be needed if the mask is intended to be sold in Europe.

EN 14683:2019+AC:2019			
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 I	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 Disposable Medical Face Masks are made of blank mask, nose clip and ear loops. The outer and inner layers of the mask are made of non-woven fabrics, and the middle layer is made of melt-blown polypropylene.	P
	The medical face mask shall not disintegrate, split or tear during intended use.		P
	In the selection of the filter and layer materials, attention shall be paid to cleanliness.		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.		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).	With nose clip.	P
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	Bacterial filtration efficiency (BFE)		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 appended table 5.2.2	P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	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 mask.	N/A
	When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually.	Same characteristics and same layer-composition declared by manufacturer.	N/A
	The lowest performing panel or area shall determine the BFE value of the complete mask	See above	N/A
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.	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).		N/A
5.2.4	Splash resistance		N/A
	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 Type I mask.	N/A
5.2.5	Microbial cleanliness (Bioburden)		P
	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested (see Table 1).	See appended table 5.2.5	P
5.2.6	Biocompatibility		N/E
	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 is not evaluated in this test report.	N/E
	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.		N/E
	The results of testing should be documented according to the applicable parts of the EN ISO 10993 series.		N/E
	The test results shall be available upon request.		N/E
6	Marking, labelling and packaging		P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	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.	See page 4 and attachment.	P
	The following information shall be supplied:		P
	a) number of this European Standard;		P
	b) type of mask (as indicated in Table 1).		P
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.		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 Specimen no.:	Dimension of the test specimen L x W (mm x mm)	test area (cm ²)	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
2020050 4	1	170×120	63.6	28.3	2842	0	97.36%	--
	2	169×119	63.6	28.3			96.11%	--
	3	170×117	63.6	28.3			97.08%	--
	4	170×119	63.6	28.3			97.89%	--
	5	170×119	63.6	28.3			97.25%	--
Supplementary information:								
1, Each specimen was conditioned at <u>21</u> °C and <u>85</u> % relative humidity for <u>16</u> h to bring them into equilibrium with atmosphere prior to testing.								
2, The side of the test specimen was facing towards the challenge aerosol: <u>the inside of the test specimen.</u>								

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

5.2.3		TABLE: Breathability (Differential pressure)				P
Batch/ lot no.:	Test Specimen number- Test area number	Differential pressure for each test area (Pa/cm ²)	The averaged differential pressure for each test specimen (Pa/cm ²)	Flow rate (l/min)	Remarks	
20200 504	1-1	31.0	31.5	8.0	--	
	1-2	34.3		8.0	--	
	1-3	30.0		8.0	--	
	1-4	26.3		8.0	--	
	1-5	35.8		8.0	--	
	2-1	33.5	30.8	8.0	--	
	2-2	32.8		8.0	--	
	2-3	27.9		8.0	--	
	2-4	26.8		8.0	--	
	2-5	33.0		8.0	--	
	3-1	28.7	29.8	8.0	--	
	3-2	32.2		8.0	--	
	3-3	31.1		8.0	--	
	3-4	30.7		8.0	--	
	3-5	26.1		8.0	--	
	4-1	20.3	21.0	8.0	--	
	4-2	20.9		8.0	--	
	4-3	18.5		8.0	--	
	4-4	23.7		8.0	--	
	4-5	21.5		8.0	--	
5-1	35.2	32.0	8.0	--		
5-2	33.4		8.0	--		
5-3	29.1		8.0	--		
5-4	31.1		8.0	--		
5-5	31.4		8.0	--		

Supplementary information:

Each specimen was conditioned at 21 °C and 85 % relative humidity for 16 h to bring them into equilibrium with

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

atmosphere prior to testing.

5.2.4	TABLE: Splash resistance			N/A
Batch/ lot no.:	Test mask no.:	The material of tested mask	Test result (Pass/fail)	Remarks
	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
	11			
	12			
	13			
	14			
	15			
	16			
	17			
	18			
	19			
	20			
	21			
	22			
	23			
	24			
	25			
	26			
	27			
	28			

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

	29		
	30		
	31		
	32		

Supplementary information:

- 1, Each specimen was conditioned at ___ °C and ___ % relative humidity for ___h to bring them into equilibrium with atmosphere prior to testing.
- 2, The description of target area tested: _____.
- 3, Any technique used to enhance visual detection of synthetic blood: _____.
- 4, The temperature and relative humidity for testing: ___ °C and ___ %.
- 5, Description of any pre-treatment techniques used: _____.

5.2.5	TABLE: Microbial cleanliness (Bioburden)			P
Batch/ lot no.:	Mask(under test) no.:	Weight of each mask (g)	Total bioburden per individual mask (CFU/g)	Remarks
20200504	1	2.7	14	--
	2	2.7	<1	--
	3	2.6	7	--
	4	2.7	<1	--
	5	2.7	<1	--
Supplementary information:				

End of EN 14683 test report

Product: Disposable Medical Face Mask

Type Designation: YX005



Figure 1 Top view of Packaging box



Figure 2 Front / Back view of Packaging box

Product: Disposable Medical Face Mask

Type Designation: YX005

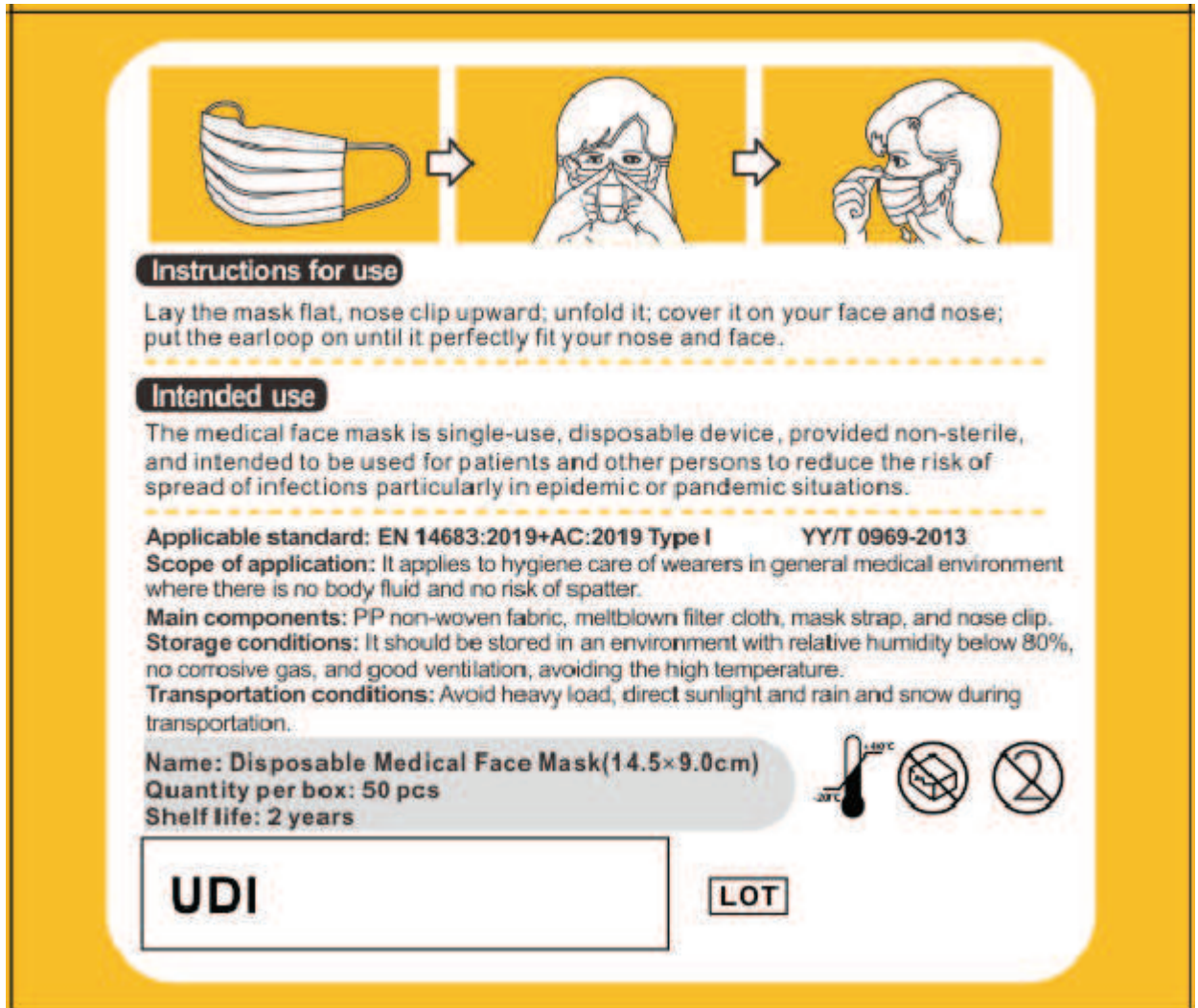


Figure 3 Side view of packaging box

Product: Disposable Medical Face Mask

Type Designation: YX005



Figure 4 Side view of packaging box

Product: Disposable Medical Face Mask

Type Designation: YX005



Figure 5 General view of packaging bag

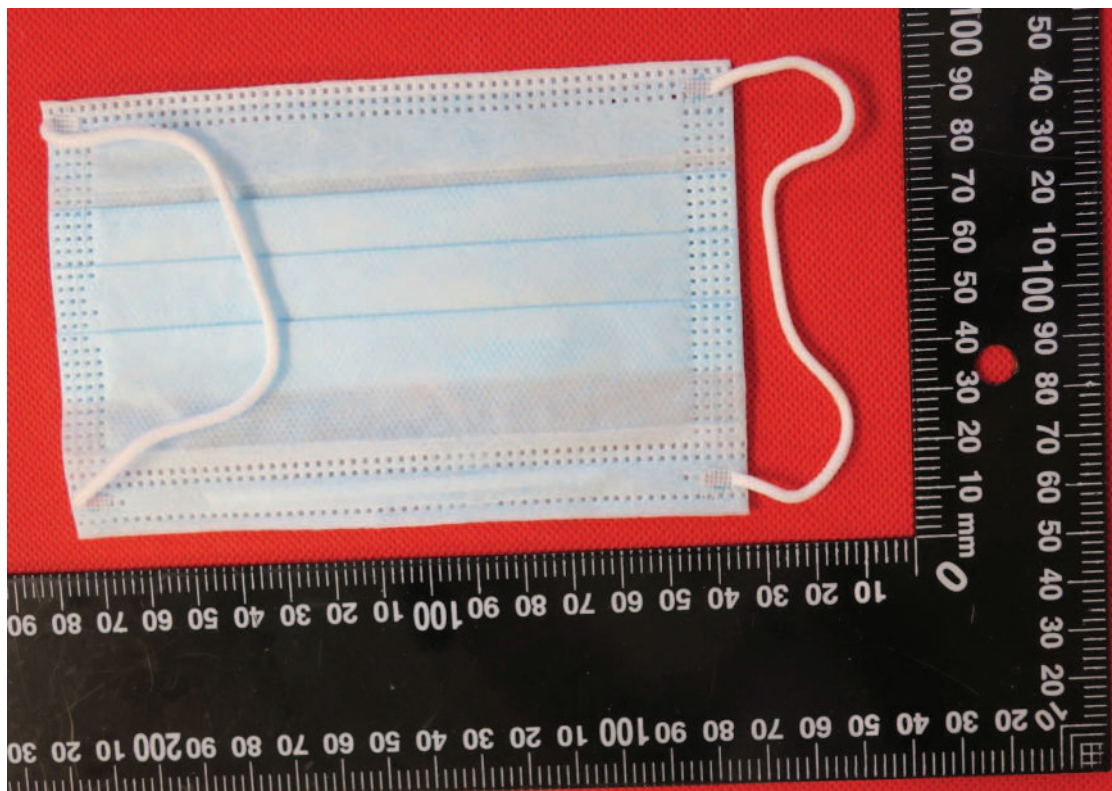


Figure 6 View of medical mask

Product: Disposable Medical Face Mask

Type Designation: YX005

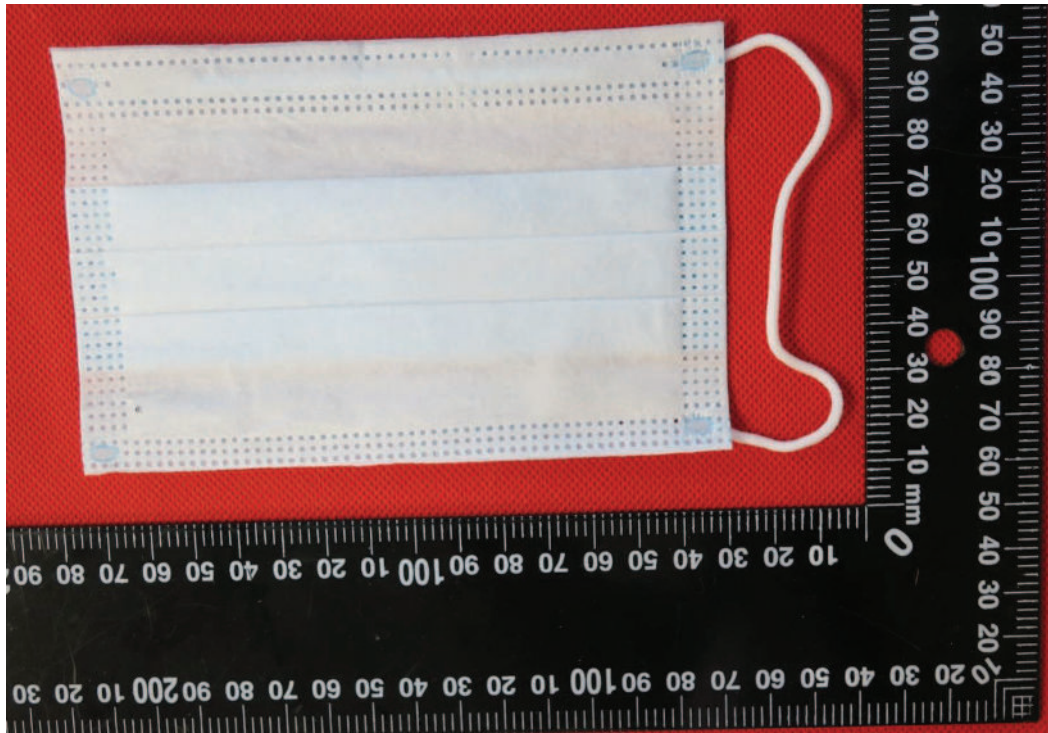


Figure 7 View of medical mask

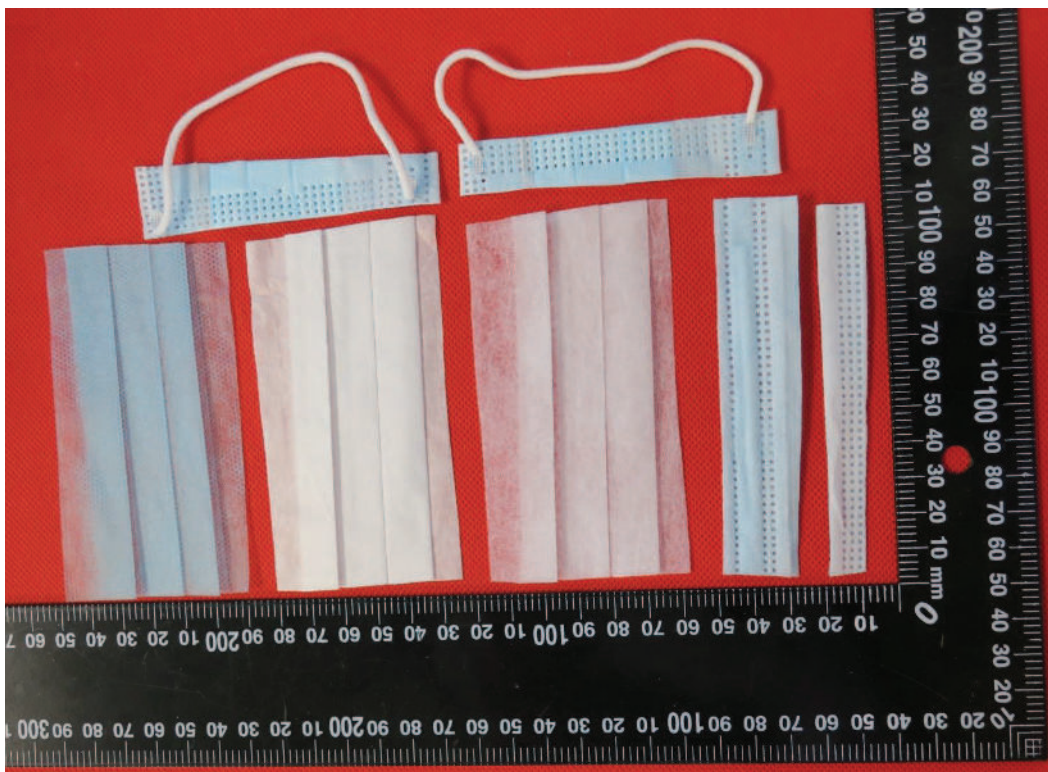


Figure 8 View of medical mask (3 ply)

Product: Disposable Medical Face Mask

Type Designation: YX005

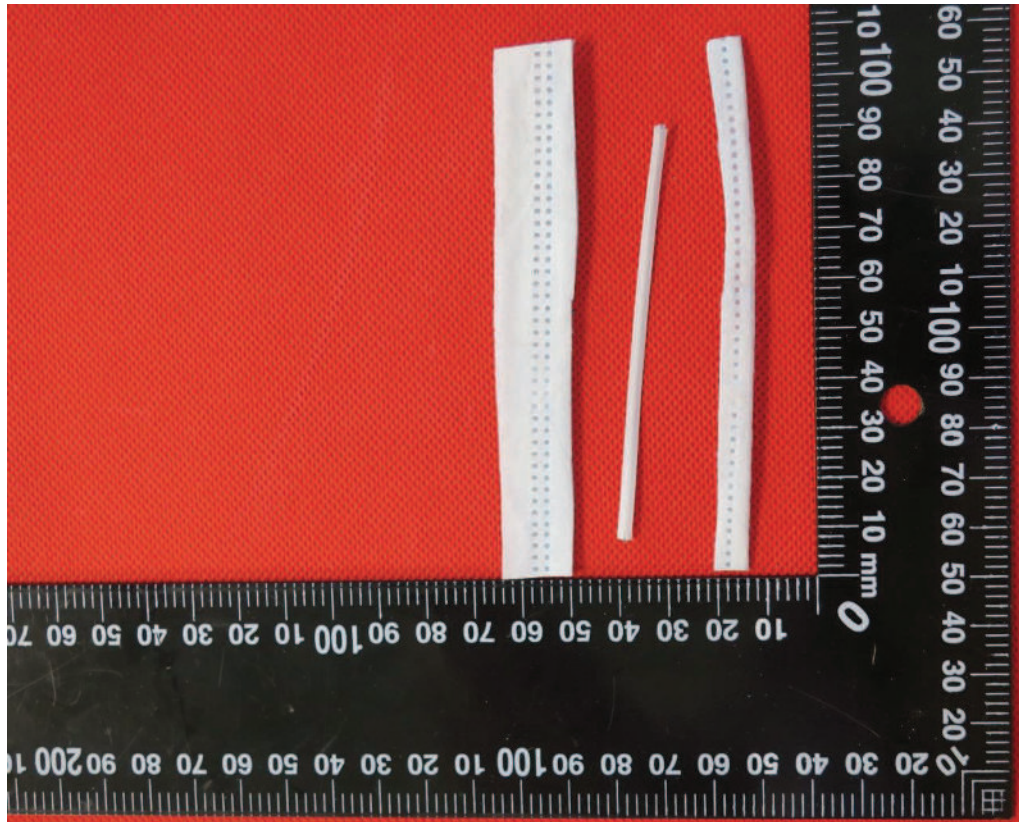


Figure 9 View of nose clip

END OF THE PHOTO DOCUMENTATION