

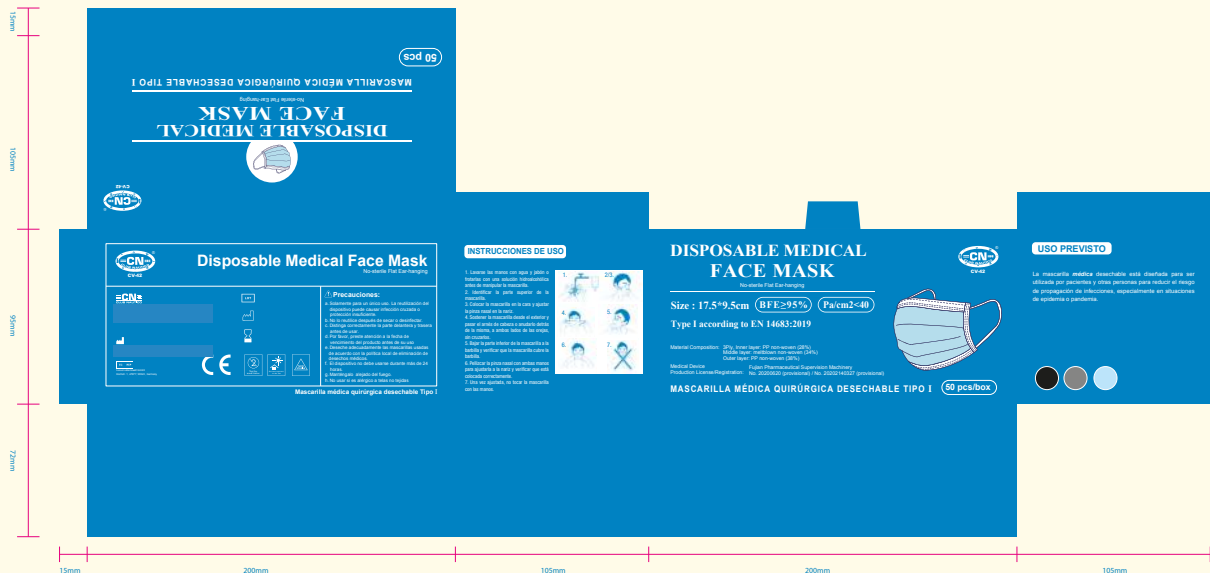


DOCUMENTATION

SURGICAL MEDICAL MASK SINGLE USE TYPE 1 MASCARILLA MÉDICA QUIRÚRGICA DESECHABLE TIPO 1 MASQUE CHIRURGICALE POUR USAGE MÉDICAL MASQUE JETABLE TYPE 1 MASCHERINA MEDICA CHIRURGICA MONOUSO TIPO 1



BOX: 50 pcs



Colaboramos con



Reconocimiento a la responsabilidad ambiental



Universidad Politécnica de Cartagena



UCAM UNIVERSIDAD CATOLICA DE MURCIA

UIMP Cartagena Universidad Internacional Menéndez Pelayo



CIFP CARLOS III FP DE CALIDAD



Asociaciones y Entidades a las que pertenecemos



Declaration of Conformity

Manufacturer:

whose single
Authorized EU-
Representative:

Luxus Lebenswelt GmbH Kochstr.1, 47877,
Willich, Germany DIMDI:DE/0000047791
Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

Product Name: Disposable Medical Face Mask
Non-sterile Flat Ear-hanging (Type 1)

Classification: **I of ANNEX IX of Directive 93/42/EEC**
Conformity Assessment Route: **Annex VII**

We, the manufacturer, herewith declare that the above mentioned product meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC. This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

General Applicable Directives:
Medical Devices DIRECTIVE
Harmonized Standards:

EN ISO 13485:2016
EN 14683:2019

EN 980:-2003
EN ISO 14971:-2007

Signature: *Cai Yanzhi*
Date: *2020.8.5*
Title: *Quanzhou*
Position: *General Manager*



Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code DE/CA20		
	Bezeichnung / Name Bezirksregierung Düsseldorf, Dezernat 24		
	Staat / State Deutschland		Land / Federal state Nordrhein-Westfalen
	Ort / City Düsseldorf		Postleitzahl / Postal code 40474
	Straße, Haus-Nr. / Street, house no. Cecilienallee 2		
	Telefon / Phone +49-211-4750		Telefax / Fax +49-211-4752671
	E-Mail / E-mail dez24.mpg@brd.nrw.de		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority		Registriernummer / Registration number
	Typ der Anzeige / Notification type <input checked="" type="checkbox"/> Erstanzeige / Initial notification <input type="checkbox"/> Änderungsanzeige / Notification of change <input type="checkbox"/> Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG <input type="checkbox"/> Hersteller / Manufacturer <input checked="" type="checkbox"/> Bevollmächtigter / Authorised Representative <input type="checkbox"/> Einführer / Importer <input type="checkbox"/> Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG <input type="checkbox"/> Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV <input type="checkbox"/> Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anzeigender / Reporting organisation (person)	
Code	DE/0000047791
Bezeichnung / Name	Luxus Lebenswelt GmbH
Staat / State	Deutschland
Land / Federal state	Nordrhein-Westfalen
Ort / City	Willich
Postleitzahl / Postal code	47877
Straße, Haus-Nr. / Street, house no. Kochstr. 1	
Telefon / Phone	0049-1715605732
Telefax / Fax	
E-Mail / E-mail	info.m@luxuslw.de

Hersteller / Manufacturer	
Bezeichnung / Name	
Staat / State	
Ort / City	
Postleitzahl / Postal code	
Straße, Haus-Nr. / Street, house no.	
Telefon / Phone	
Telefax / Fax	
E-Mail / E-mail	

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG	
Bezeichnung / Name	Lin Sun
Staat / State	Deutschland
Land / Federal state	Nordrhein-Westfalen
Ort / City	Willich
Postleitzahl / Postal code	47877
Straße, Haus-Nr. / Street, house no. Kochstr. 1	
Telefon / Phone	0049-1715605732
Telefax / Fax	
E-Mail / E-mail	info.m@luxuslw.de

Vertreter / Deputy (optional)					
	Bezeichnung / Name				
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; background-color: #cccccc;"></td> <td style="width: 50%; background-color: #cccccc;"></td> </tr> <tr> <td>Telefon / Phone</td> <td>Telefax / Fax</td> </tr> </table>			Telefon / Phone	Telefax / Fax
Telefon / Phone	Telefax / Fax				
	E-Mail / E-mail				
	<input checked="" type="checkbox"/> Erstanzeige / Initial notification <input type="checkbox"/> Änderungsanzeige / Notification of change				

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)

	<p>Klasse / Class</p> <p><input checked="" type="checkbox"/> I</p> <p><input type="checkbox"/> I - steril / sterile</p> <p><input type="checkbox"/> I - mit Messfunktion / with measuring function</p> <p><input type="checkbox"/> I - steril und mit Messfunktion / sterile and with measuring function</p> <p><input type="checkbox"/> IIa</p> <p><input type="checkbox"/> IIb</p> <p><input type="checkbox"/> III</p> <p><input type="checkbox"/> III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012</p> <p><input type="checkbox"/> Aktives implantierbares Medizinprodukt / Active implantable medical device</p> <p><input type="checkbox"/> Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012 Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012</p>
	<p>App (Software auf mobilen Endgeräten) <input type="checkbox"/> ja / yes <input checked="" type="checkbox"/> nein / no</p>
	<p>Nummer(n) der Bescheinigung(en) / Certificate number(s)</p>
	<p>Handelsname des Produktes / Trade name of the device Disposable Medical Mask</p>
	<p>Produktbezeichnung / Name of device Disposable Medical Mask</p>
	<p>Nomenklaturcode / Nomenclature code 15-230</p>
	<p>Nomenklaturbezeichnung / Nomenclature term Maske, sonstige</p>
	<p>Kategoriecode / Category code 10</p>
	<p>Kategorie / Category Produkte zum Einmalgebrauch</p>
	<p>Kurzbeschreibung deutsch / German short description Die Maske besteht aus der Maske, dem Nasenclip und dem Ohrgurt, von denen die äußere Schicht der Maske aus gesponnenem Vliesstoff besteht, die mittlere Schicht aus schmelzgesprühtem Vliesstoff und die innere Schicht aus gesponnenem Vliesstoff. Das Produkt ist wegwerfbar und nicht steril. Die Maske ist für das klinische Personal während des nicht-invasiven Betriebs zu tragen und dient zum Abdecken von Mund, Nase und Kiefer des Benutzers. Sie bietet eine physikalische Barriere, um den direkten Durchtritt von Partikeln zu verhindern Krankheitserreger und Mikroorganismen.</p>
	<p>Kurzbeschreibung englisch / English short description The mask consists of the mask,nose clip and ear belt, of which the outer layer of the mask is spunbonded non-woven cloth,the middle layer is melt-sprayed non-woven cloth and the inner layer is spunbonded non-woven cloth.The product is disposable and non-sterile.The mask is for clinical personnel to wear during non-invasive operation,and is used to cover the user's mouth,nose and jaw,providing a physical barrier to prevent the direct passage of particulate from pathogens and microorganisms .</p>



Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
	<input type="checkbox"/> Semikritische Medizinprodukte / Semicritical medical devices <input type="checkbox"/> Gruppe A / Group A <input type="checkbox"/> Gruppe B / Group B
	<input type="checkbox"/> Kritische Medizinprodukte / Critical medical devices <input type="checkbox"/> Gruppe A / Group A <input type="checkbox"/> Gruppe B / Group B <input type="checkbox"/> Gruppe C / Group C Nummer der Bescheinigung / Certificate number
	Sterilisationsverfahren / Sterilisation procedures <input type="checkbox"/> Dampfsterilisation / Steam sterilisation <input type="checkbox"/> Gassterilisation / Gas sterilisation <input type="checkbox"/> Strahlensterilisation / Radiation sterilisation <input type="checkbox"/> andere / others Angewandtes Verfahren / Applied procedure

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
 I affirm that the information given above is correct to the best of my knowledge.

Ort City	Willich	Datum Date	2020-05-17
		Name	Lin Sun
			Unterschrift Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible		Telefon / Phone

Prüfbericht-Nr.: <i>Test Report No.:</i>		Auftrags-Nr.: <i>Order No.:</i>		Seite 1 von 11 Page 1 of 11	
Kunden-Referenz-Nr.: N/A <i>Client Reference No.:</i>		Auftragsdatum: Jun. 28, 2020 <i>Order date:</i>			
Auftraggeber: <i>Client:</i>					
Prüfgegenstand: <i>Test item:</i>		disposable medical mask (non-sterile)			
Bezeichnung / Typ-Nr.: <i>Identification / Type No.:</i>					
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: Jun. 28, 2020 <i>Date of receipt:</i>		See Attachment: Photo documentation for details.			
Prüfmuster-Nr.: <i>Test sample No.:</i>					
Prüfzeitraum: Jun. 28, 2020 to Jul. 15, 2020 <i>Testing period:</i>					
Ort der Prüfung: See page 3 <i>Place of testing:</i>					
Prüflaboratorium: TÜV Rheinland (Shenzhen) <i>Testing laboratory:</i> Co., Ltd.					
Prüfergebnis*: Pass <i>Test result*:</i>					
geprüft von / tested by: <i>Larry Yuan</i> Jul. 28, 2020 Larry Yuan/Assistant Project Engineer			kontrolliert von / reviewed by: <i>Angela Chen</i> Jul. 28, 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: <ul style="list-style-type: none"> - The test report consists of EN 14683 test report including this cover page (11 pages) and attachment: Photo documentation (5 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 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					
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>					

EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods	
Report Reference No. :	
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	:
Address :	
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 mask (non-sterile)
Trade Mark	 
Manufacturer	Same as the applicant
Model/Type reference :	
Classification :	Type I

List of Attachments (including a total number of pages in each attachment):	
Attachment – Photo Documentation (5 pages)	
Summary of testing:	
Tests performed (name of test and test clause):	Testing location:
Construction check according to: Clause 5.1.1 Materials and construction Clause 5.1.2 Design	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
<p>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.</p> <p>See attachment.</p>

<p>Testing</p> <p>Date of receipt of test item(s).....: See cover page</p> <p>Dates of tests performed.....: See cover page</p>
<p>Possible test case verdicts:</p> <ul style="list-style-type: none"> - 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)
<p>General remarks:</p> <p>"(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.</p> <p>Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.</p>
<p>Name and address of factory (ies): Same as the applicant</p>
<p>General product information:</p> <p>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.</p>

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.	It is made up of two layers non-woven, one layer filtration material (melt-blown fabric), mask belt and nose clip.	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
	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

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.	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	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
	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 attachment.	P
	The following information shall be supplied:		P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	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
	1	153 × 154	63.6	28.3	2773	0	99.59%	--
	2	155 × 154	63.6	28.3			99.86%	--
	3	156 × 153	63.6	28.3			99.72%	--
	4	155 × 153	63.6	28.3			99.59%	--
	5	155 × 152	63.6	28.3			99.79%	--

Supplementary information:

1, Each specimen was conditioned at 21 °C and 85 % relative humidity for 16 h to bring them into equilibrium with atmosphere prior to testing.

2, The side of the test specimen was facing towards the challenge aerosol: inside of mask

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
	1-1	35.2	33.6	8.0	--
	1-2	34.0		8.0	--
	1-3	35.6		8.0	--
	1-4	31.5		8.0	--
	1-5	31.8		8.0	--
	2-1	28.6	28.1	8.0	--
	2-2	31.5		8.0	--
	2-3	26.1		8.0	--
	2-4	29.0		8.0	--
	2-5	25.2		8.0	--
	3-1	29.6	32.3	8.0	--
	3-2	35.1		8.0	--

EN 14683:2019+AC:2019				
Clause	Requirement + Test		Result - Remark	Verdict
	3-3	33.1	8.0	--
	3-4	30.9	8.0	--
	3-5	32.6	8.0	--
	4-1	35.3	8.0	--
	4-2	35.1	8.0	--
	4-3	33.1	8.0	--
	4-4	36.4	8.0	--
	4-5	34.6	8.0	--
	5-1	31.2	8.0	--
	5-2	30.3	8.0	--
	5-3	29.3	8.0	--
	5-4	26.3	8.0	--
	5-5	29.3	8.0	--

Supplementary information:
 Each specimen was conditioned at __21__ °C and __85__ % relative humidity for _16_ h to bring them into equilibrium with 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	See clause 5.1.1		--
	2			--
	3			--
	4			--
	5			--
	6			--
	7			--
	8			--
	9			--
	10			--
	11			--
	12			--
	13			--

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

	14		--
	15		--
	16		--
	17		--
	18		--
	19		--
	20		--
	21		--
	22		--
	23		--
	24		--
	25		--
	26		--
	27		--
	28		--
	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: ___

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

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	
	1	3.1	4	--	
	2	3.1	1	--	
	3	3.2	< 1	--	
	4	3.1	3	--	
	5	3.0	1	--	
Supplementary information:					

End of test report

Product: disposable medical mask (non-sterile)

Type Designation: (non-sterile flat ear-hanging)



Figure 1 Top/back view of packaging box

Product: disposable medical mask (non-sterile)

Type Designation: (non-sterile flat ear-hanging)

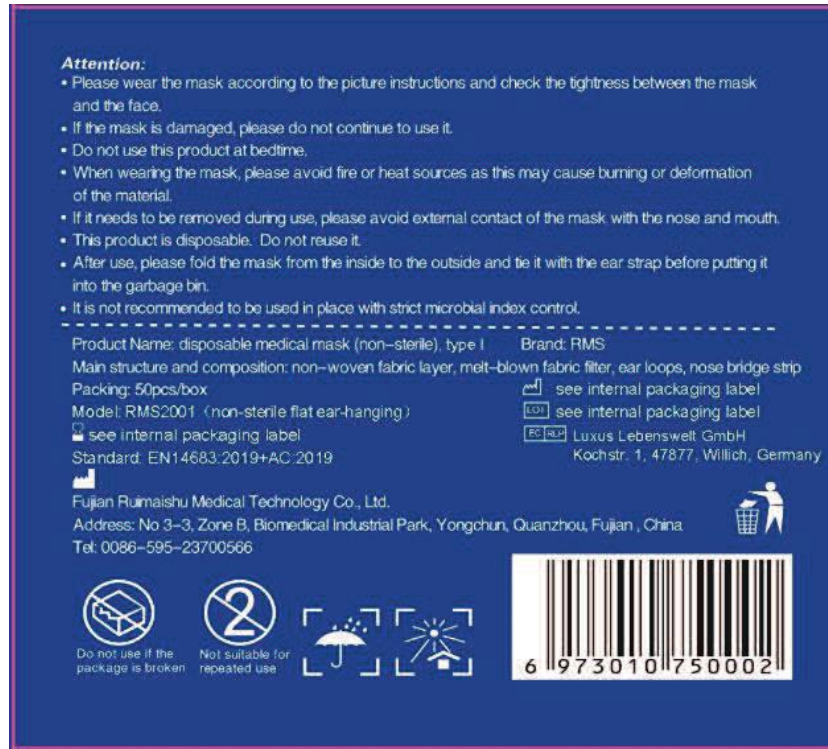


Figure 2 Side view of packaging box

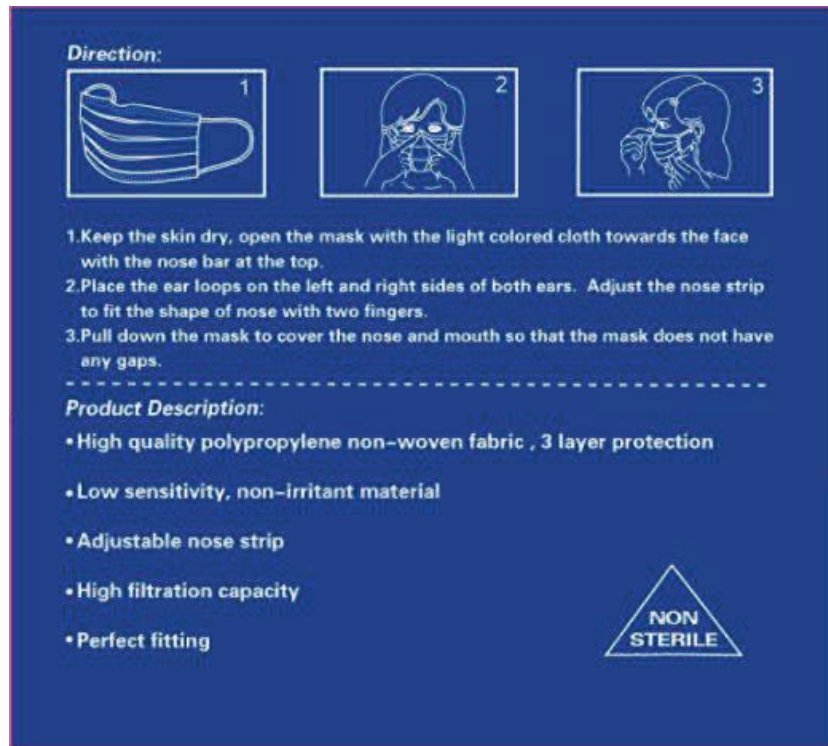


Figure 3 Side view of packaging box

Product: disposable medical mask (non-sterile)

Type Designation: (non-sterile flat ear-hanging)



Figure 4 Front view of packaging box



Figure 5 General view of packaging bag

Product: disposable medical mask (non-sterile)

Type Designation: (non-sterile flat ear-hanging)



Figure 6 General view of packaging bag

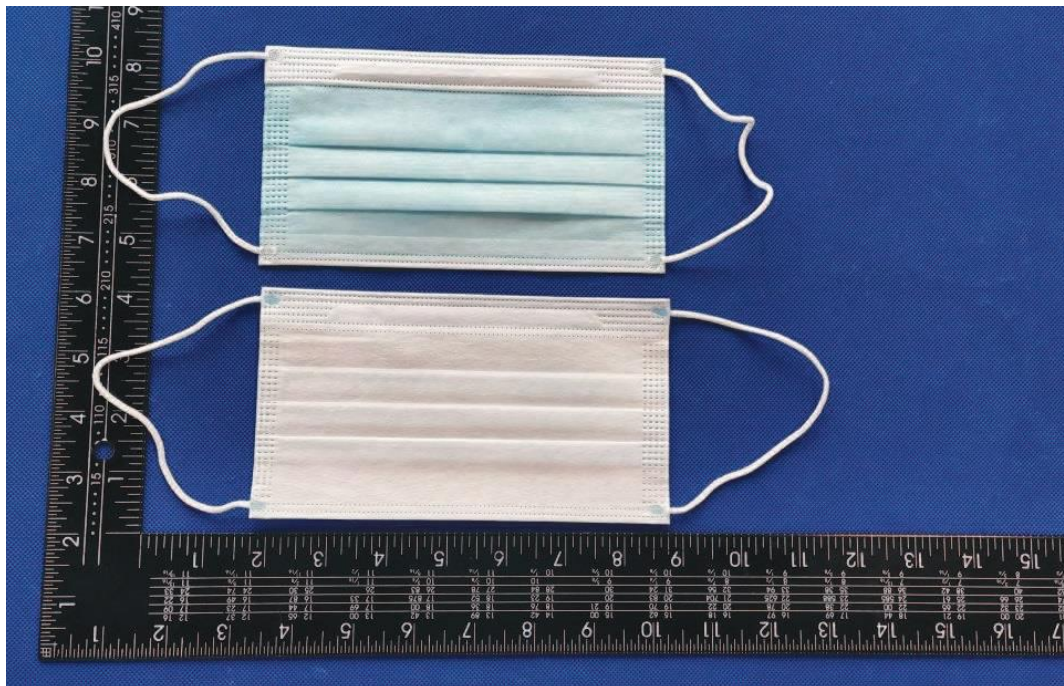


Figure 7 View of medical mask

Product: disposable medical mask (non-sterile)

Type Designation: (non-sterile flat ear-hanging)

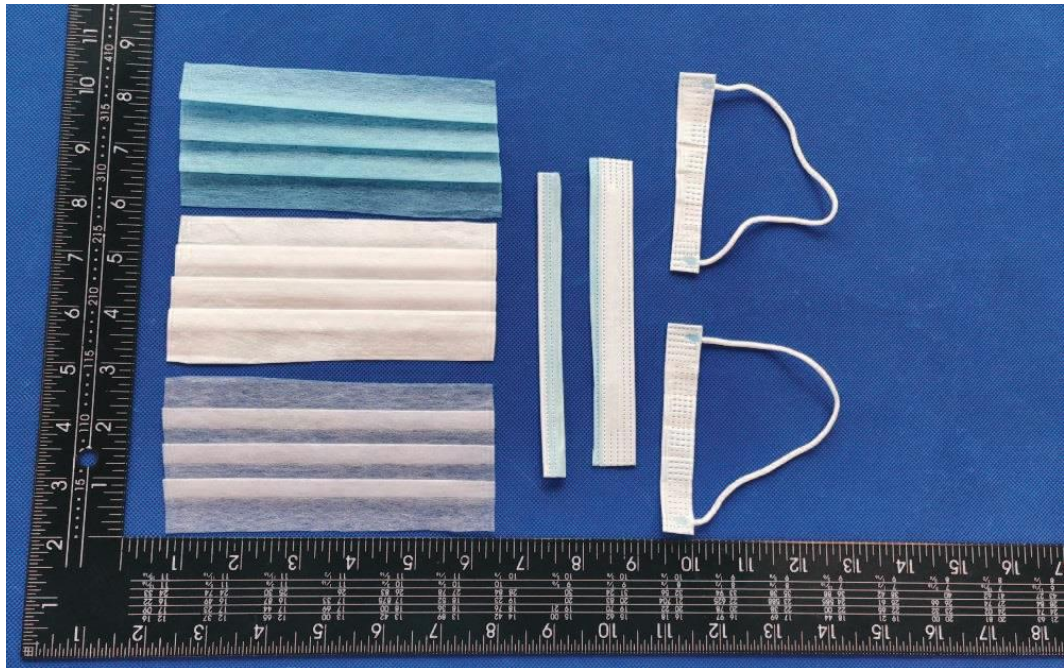


Figure 8 View of mask (3-ply)

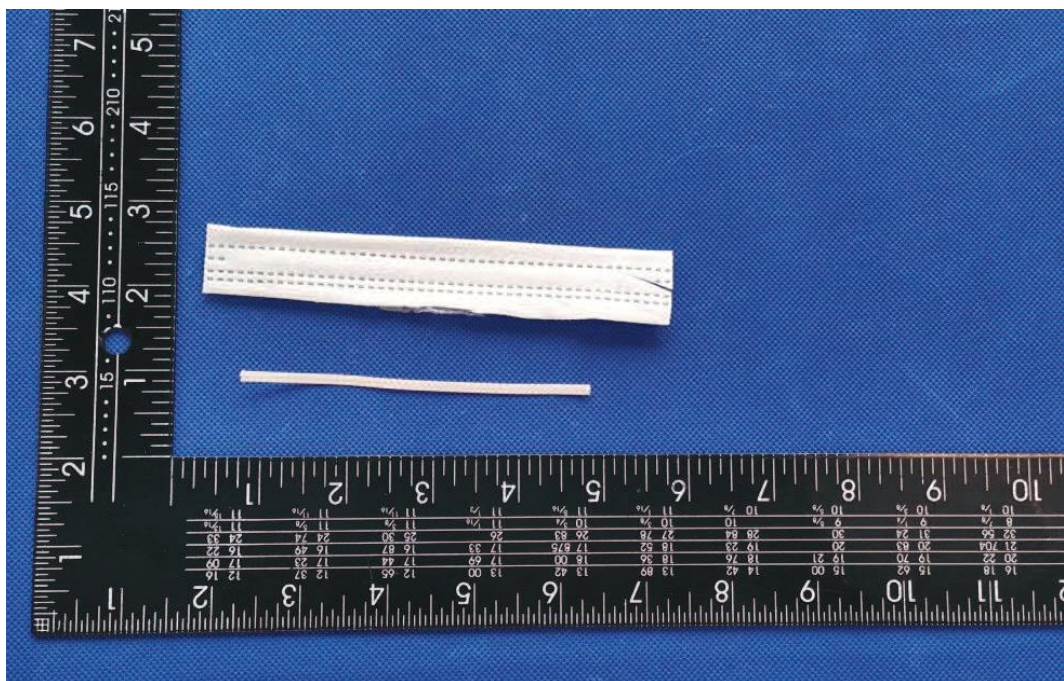


Figure 9 View of nose clip

END OF THE PHOTO DOCUMENTATION