Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

Jinhua Xinfeng Packaging Material Co. Ltd
2/F, building 12, 297 Donsheng Road, Jindong District, Jinhua City, Zhejiang Province, P.R. China

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Shenzhen CCT Testing Technology Co., Ltd.

Owner/Operator Number: 10070913

Registration Number: 3012307300

Device Listing#:

Listing No	Code	Device Name	Activities
878.4040	QKR	Medical Face Mask	Manufacturer

CCT will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. CCT makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. CCT assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, CCT is not affiliated with the U.S. Food and Drug Administration.

Chief engineer
Issued: Feb 12, 2020
Expiration Date: Feb 11, 2021

SHENZHEN CCT TESTING TECHNOLOGY CO.,LTD CCT Testing Service

Shenzhen CCT Testing Technology Co., Ltd
Web: www.cct-prc.com www.fda-test.com
Tel: 86 755 33157675 fda@fda-test.com

CE认证

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CE Technical Documentation Review Report

Applicant:	Jinhua Xinfeng Packaging Material Co., Ltd 2/F, Building 12, 297 Donsheng Road, Jindong District, Jinhua City, Zhejiang Province, P.R.C
Report Number:	60355567-001
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of REGULATION (EU) 2017/745, Annex II
Product(s):	Medical Face Masks
Type(s)/Model(s):	Type I
Classification:	Class I (according to manufacturer's declaration)
Examination period:	Mar.27.2020
Date of expiry:	Mar.26.2025
Review result:	During the examination of the provided Technical Documentation (No.: YKY-CE-01, Version A/0, Dated 2020-Mar-16), no Non-compliance according to the requirements of REGULATION (EU) 2017/745, Annex II was detected.

Yuhong CHEN
Vice General Manager Medical Greater China
TÜV Rheinland (China) Ltd.

Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd Ring Road,
Chaoyang District, Beijing, 100022, P.R.China

CE认证

Produkte
Products

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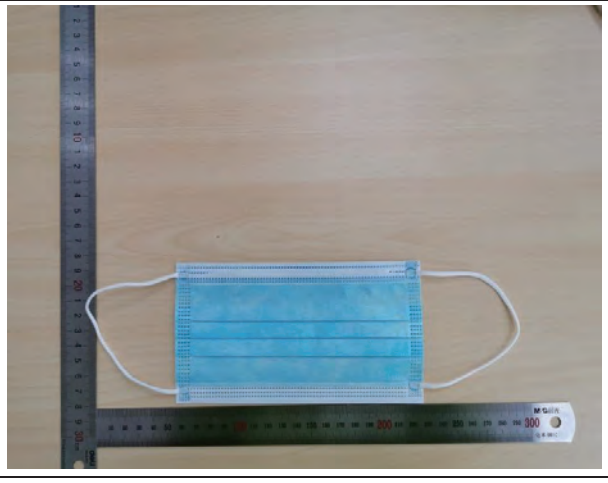
Prüfbericht-Nr.: *Test Report No.*:	**60361105 001**	**Auftrags-Nr.:** *Order No.*:	**190104843**	Seite 1 von 12 *Page 1 of 12*
Kunden-Referenz-Nr.: *Client Reference No.*:	**N/A**	**Auftragsdatum:** *Order date*:	**2019-09-27**	

Auftraggeber: *Client*: **Jinghua xinfeng Packaging Material Co. Ltd**
2/F building 12, 297 donsheng road, Jindong District, Jinhua City, Zhejiang Province ,P.R. C

Prüfgegenstand: *Test item*:	**Medical Face Masks**
Bezeichnung / Typ-Nr.: *Identification / Type No.*:	**Flat Pleated Ear Loops**
Auftrags-Inhalt: *Order content*:	**Type test**
Prüfgrundlage: *Test specification*:	**EN 14683:2019+AC:2019**
Wareneingangsdatum: *Date of receipt*:	**2020-02-14**
Prüfmuster-Nr.: *Test sample No.*:	**Engineering sample**
Prüfzeitraum: *Testing period*:	**2020-02-14 to 2020-03-24**
Ort der Prüfung: *Place of testing*:	**TÜV Rheinland (China) Ltd.**
Prüflaboratorium: *Testing laboratory*:	**TÜV Rheinland (China) Ltd.**
Prüfergebnis*: *Test result**:	**Pass**



geprüft von / *tested by*:

2020-04-13	Su Meng / Project Engineer	
Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

kontrolliert von / *reviewed by*:

2020-04-13	Han Dong / Reviewer	
Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

Sonstiges / *Other*:

- Attachment 1. Photographic Documentation (2 pages)

Zustand des Prüfgegenstandes bei Anlieferung: *Condition of the test item at delivery*: Prüfmuster vollständig und unbeschädigt *Test item complete and undamaged*

* 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*

TUV Rheinland(China) Ltd. Room 303,1st Area Chuang Xin Building No.B,No.12,Hong Da Road (north) Economic Technological Development Area Beijing 100176 P.R.China

EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods	
Report Reference No. ..... :	**60361105 001**
Date of issue..... :	See cover page
Total number of pages ..... :	See cover page
Testing Laboratory ..... :	**TÜV Rheinland (China) Ltd.**
Address..... :	Unit 707, AVIC Building, No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing 100022, P,R, China
Applicant's name ..... :	**Jinghua xinfeng Packaging Material Co. Ltdd**
Address..... :	2/F building 12, 297 donsheng road, Jindong District, Jinhua City, Zhejiang Province ,P.R. C
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..... :	**Medical Face Masks**
Trade Mark..... :	N/A
Manufacturer ..... :	**Jinghua xinfeng Packaging Material Co. Ltd** 2/F building 12, 297 donsheng road, Jindong District, Jinhua City, Zhejiang Province ,P.R. C
Model/Type reference..... :	**Flat Pleated Ear Loops**
Classification..... :	Type I

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 5.2.5: 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 **Flat Pleated Ear Loops**

Testing

Date of receipt of test item(s).....: 2020-02-14

Dates of tests performed .....: 2020-02-14 to 2020-03-24

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 ☐ comma / ☒ point is used as the decimal separator.

Name and address of factory (ies) ..... : Jinghua xinfeng Packaging Material Co. Ltd,

2/F building 12, 297 donsheng road, Jindong District, Jinhua City, Zhejiang Province ,P.R. C

General product information:

Intended use：
The Medical Face Masks are intended to be worn by patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations.

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.	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
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.	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
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 1.1 1.2.	The Bacterial Filtration Efficiency ≥ 95% 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
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 2.1 2.2.	The differential pressure <40Pa/cm^2 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
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.	Not such masks	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 3.1 3.2).	The bioburden of the medical mask was ≤30 CFU/g See appended Table 5.2.5	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 biocompatibility of mask was evaluated in following report: CSTBR20030057 CSTBR20030058 CSTBR20030059	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: CSTBR20030057 CSTBR20030058 CSTBR20030059	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: CSTBR20030057 CSTBR20030058 CSTBR20030059	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: CSTBR20030057 CSTBR20030058 CSTBR20030059	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.	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 I	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^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**
Flat Pleated Ear Loops	**1**	100×100	100	28.3	2490	0	97.0	≥95
	2	100×100	100	28.3	2489	0	98.0	≥95
	3	100×100	100	28.3	2385	0	97.0	≥95
	4	100×100	100	28.3	2357	0	97.0	≥95
	5	100×100	100	28.3	2524	0	97.0	≥95

Supplementary information:
1, 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.
2, The side of the test specimen was facing towards the challenge aerosol:out side of mask

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/cm²)	The averaged differential pressure for each test specimen (Pa/cm²)	Flow rate (l/min)	Remarks
Flat Pleated Ear Loops	1-1	31.0	30.9	8	<40
	1-2	30.7		8	<40
	1-3	31.2		8	<40
	1-4	30.9		8	<40
	1-5	30.7		8	<40
	2-1	37.6	37.1	8	<40
	2-2	37.0		8	<40
	2-3	36.7		8	<40
	2-4	37.2		8	<40
	2-5	37.0		8	<40
	3-1	39.2	38.9	8	<40
	3-2	39.0		8	<40
	3-3	38.6		8	<40
	3-4	39.0		8	<40
	3-5	38.7		8	<40
	4-1	39.1	38.5	8	<40
	4-2	39.0		8	<40
	4-3	38.5		8	<40
	4-4	37.9		8	<40
	4-5	38.0		8	<40
	5-1	37.2	36.8	8	<40
	5-2	36.7		8	<40
	5-3	36.8		8	<40
	5-4	36.3		8	<40
	5-5	37.0		8	<40

Supplementary information:

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

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	-	-	-
	29	-	-	-

EN 14683:2019+AC:2019				
Clause	Requirement + Test		Result - Remark	Verdict
	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**	
Flat Pleated Ear Loops	**1**	**3.1**	**13.9**	**≤30**	
	2	**3.1**	**13.5**	**≤30**	
	3	**3.1**	**13.9**	**≤30**	
	4	**3.0**	**13.0**	**≤30**	
	5	**3.0**	**13.7**	**≤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

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

	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**
Flat Pleated Ear Loops	**1**	**3.1**	**13.9**	**≤30**
	2	**3.1**	**13.5**	**≤30**
	3	**3.1**	**13.9**	**≤30**
	4	**3.0**	**13.0**	**≤30**
	5	**3.0**	**13.7**	**≤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

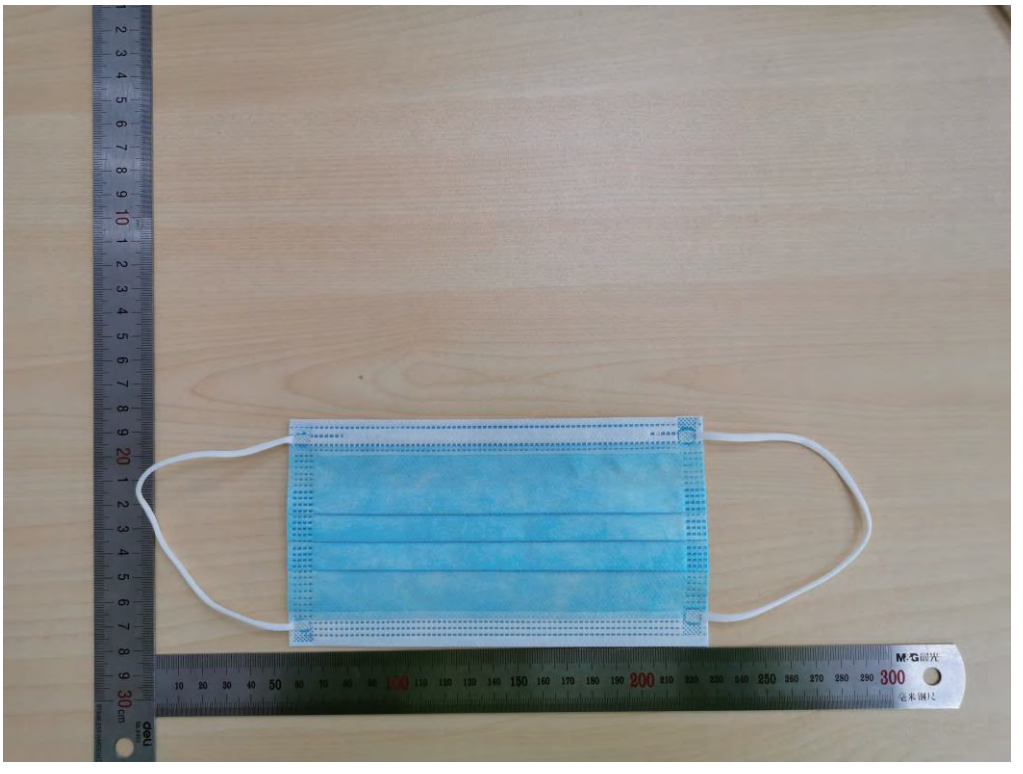
Medical Face Masks
Flat Pleated Ear Loops
Jinhua Xinfeng Packaging Material Co. Ltd

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

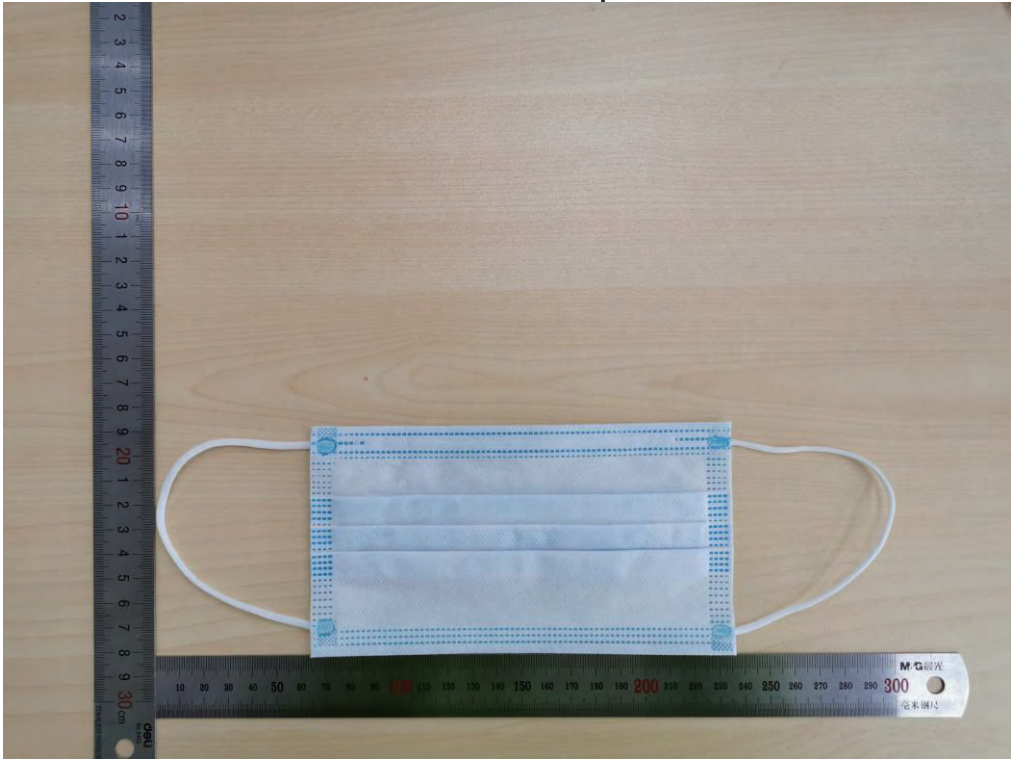
Report Number: **60361105 001** Attachment 1

Model: Flat Pleated Ear Loops

Pic.1: The obverse side view of **Flat Pleated Ear Loops**



Pic.2: The reverse side view of **Flat Pleated Ear Loops**



Pic.3: Marking, labelling and packaging of **Flat Pleated Ear Loops**

CE认证

TÜVRheinland®

CE Technical Documentation Review Report

Applicant:	Guangxi Guigang Bairui Medical Equipment Co. Ltd Standard Factory Building B2, Shika Industrial Park, Qintang District, Guigang, Guangxi , China
Report Number:	60355567-001
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of REGULATION (EU) 2017/745, Annex II
Product(s):	Medical Face Masks
Type(s)/Model(s):	Type I
Classification:	Class I (according to manufacturer's declaration)
Examination period:	Mar.27.2020
Date of expiry:	Mar.26.2025
Review result:	During the examination of the provided Technical Documentation (No.: YKY-CE-01, Version A/0, Dated 2020-Mar-16), no Non-compliance according to the requirements of REGULATION (EU) 2017/745, Annex II was detected.

Yuhong CHEN
Vice General Manager Medical Greater China
TÜV Rheinland (China) Ltd.

Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd Ring Road,
Chaoyang District, Beijing, 100022, P.R.China

CE认证

Produkte
Products

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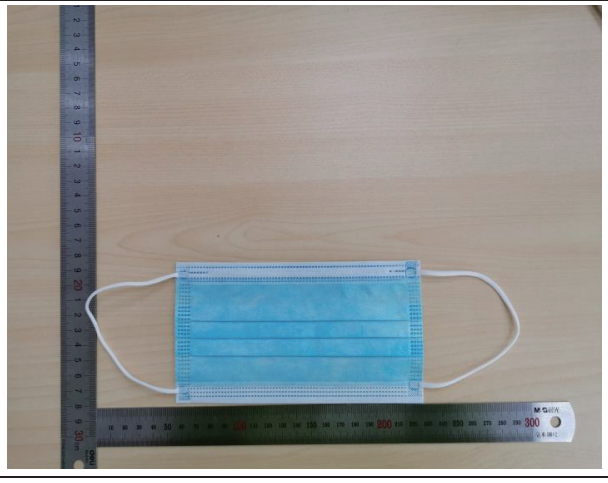
Prüfbericht-Nr.: *Test Report No.:*	**60361105 001**	**Auftrags-Nr.:** *Order No.:*	**190104843**	Seite 1 von 12 *Page 1 of 12*
Kunden-Referenz-Nr.: *Client Reference No.:*	**N/A**	**Auftragsdatum:** *Order date:*	**2019-09-27**	

Auftraggeber: *Client:* **Guangxi Guigang Bairui Medical Equipment Co. Ltd**
Standard Factory Building B2, Shika Industrial Park, Qintang District, Guigang, Guangxi P.R. C

Prüfgegenstand: *Test item:*	**Medical Face Masks**
Bezeichnung / Typ-Nr.: *Identification / Type No.:*	**Flat Pleated Ear Loops**
Auftrags-Inhalt: *Order content:*	**Type test**
Prüfgrundlage: *Test specification:*	**EN 14683:2019+AC:2019**
Wareneingangsdatum: *Date of receipt:*	**2020-02-14**
Prüfmuster-Nr.: *Test sample No.:*	**Engineering sample**
Prüfzeitraum: *Testing period:*	**2020-02-14 to 2020-03-24**
Ort der Prüfung: *Place of testing:*	**TÜV Rheinland (China) Ltd.**
Prüflaboratorium: *Testing laboratory:*	**TÜV Rheinland (China) Ltd.**
Prüfergebnis*: *Test result*:*	**Pass**



geprüft von / *tested by*:

2020-04-13	Su Meng / Project Engineer	
Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

kontrolliert von / *reviewed by*:

2020-04-13	Han Dong / Reviewer	
Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

Sonstiges / *Other*:

- Attachment 1. Photographic Documentation (2 pages)

Zustand des Prüfgegenstandes bei Anlieferung: *Condition of the test item at delivery:* Prüfmuster vollständig und unbeschädigt *Test item complete and undamaged*

* Legende:	1 = sehr gut	2 = gut	3 = befriedigend	4 = ausreichend	5 = mangelhaft
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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.

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.

TUV Rheinland(China) Ltd. Room 303,1st Area Chuang Xin Building No.B,No.12,Hong Da Road (north) Economic Technological Development Area Beijing 100176 P.R.China

EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods	
Report Reference No. ..... :	**60361105 001**
Date of issue..... :	See cover page
Total number of pages ..... :	See cover page
Testing Laboratory ..... :	**TÜV Rheinland (China) Ltd.**
Address..... :	Unit 707, AVIC Building, No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing 100022, P,R, China
Applicant's name ..... :	**Guangxi Guigang Bairui Medical Equipment Co. Ltd**
Address..... :	Standard Factory Building B2, Shika Industrial Park, Qintang District, Guigang, Guangxi P.R. C
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..... :	**Medical Face Masks**
Trade Mark..... :	Bairuijian
Manufacturer ..... :	**Guangxi Guigang Bairui Medical Equipment Co. Ltd Standard Factory Building B2, Shika Industrial Park, Qintang District, Guigang, Guangxi P.R. C.**
Model/Type reference..... :	**Flat Pleated Ear Loops**
Classification..... :	Type I

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 5.2.5: 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 **Flat Pleated Ear Loops**

Testing

Date of receipt of test item(s).....: 2020-02-14

Dates of tests performed .....: 2020-02-14 to 2020-03-24

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 ☐ comma / ☒ point is used as the decimal separator.

Name and address of factory (ies) ..... : Guangxi Guigang Bairui Medical Equipment Co. Ltd

Standard Factory Building B2, Shika Industrial Park, Qintang District, Guigang, Guangxi P.R. C.

General product information:

Intended use：
The Medical Face Masks are intended to be worn by patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations.

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.	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
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.	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
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 1.1 1.2.	The Bacterial Filtration Efficiency ≥ 95% 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
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 2.1 2.2.	The differential pressure <40Pa/cm^2 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
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.	Not such masks	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 3.1 3.2).	The bioburden of the medical mask was ≤30 CFU/g See appended Table 5.2.5	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 biocompatibility of mask was evaluated in following report: CSTBR20030057 CSTBR20030058 CSTBR20030059	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: CSTBR20030057 CSTBR20030058 CSTBR20030059	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: CSTBR20030057 CSTBR20030058 CSTBR20030059	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: CSTBR20030057 CSTBR20030058 CSTBR20030059	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.	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 I	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^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**
Flat Pleated Ear Loops	**1**	100×100	100	28.3	2490	0	97.0	≥95
	2	100×100	100	28.3	2489	0	98.0	≥95
	3	100×100	100	28.3	2385	0	97.0	≥95
	4	100×100	100	28.3	2357	0	97.0	≥95
	5	100×100	100	28.3	2524	0	97.0	≥95

Supplementary information:
1, 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.
2, The side of the test specimen was facing towards the challenge aerosol:out side of mask

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**
Flat Pleated Ear Loops	**1-1**	**31.0**	**30.9**	**8**	**<40**
	1-2	**30.7**		**8**	**<40**
	1-3	**31.2**		**8**	**<40**
	1-4	**30.9**		**8**	**<40**
	1-5	**30.7**		**8**	**<40**
	2-1	**37.6**	**37.1**	**8**	**<40**
	2-2	**37.0**		**8**	**<40**
	2-3	**36.7**		**8**	**<40**
	2-4	**37.2**		**8**	**<40**
	2-5	**37.0**		**8**	**<40**
	3-1	**39.2**	**38.9**	**8**	**<40**
	3-2	**39.0**		**8**	**<40**
	3-3	**38.6**		**8**	**<40**
	3-4	**39.0**		**8**	**<40**
	3-5	**38.7**		**8**	**<40**
	4-1	**39.1**	**38.5**	**8**	**<40**
	4-2	**39.0**		**8**	**<40**
	4-3	**38.5**		**8**	**<40**
	4-4	**37.9**		**8**	**<40**
	4-5	**38.0**		**8**	**<40**
	5-1	**37.2**	**36.8**	**8**	**<40**
	5-2	**36.7**		**8**	**<40**
	5-3	**36.8**		**8**	**<40**
	5-4	**36.3**		**8**	**<40**
	5-5	**37.0**		**8**	**<40**

Supplementary information:

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

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	-	-	-
	29	-	-	-

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

	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**
Flat Pleated Ear Loops	**1**	**3.1**	**13.9**	**≤30**
	2	**3.1**	**13.5**	**≤30**
	3	**3.1**	**13.9**	**≤30**
	4	**3.0**	**13.0**	**≤30**
	5	**3.0**	**13.7**	**≤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

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

	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**
Flat Pleated Ear Loops	**1**	**3.1**	**13.9**	**≤30**
	2	**3.1**	**13.5**	**≤30**
	3	**3.1**	**13.9**	**≤30**
	4	**3.0**	**13.0**	**≤30**
	5	**3.0**	**13.7**	**≤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

TÜVRheinland®

PHOTO DOCUMENTATION

for

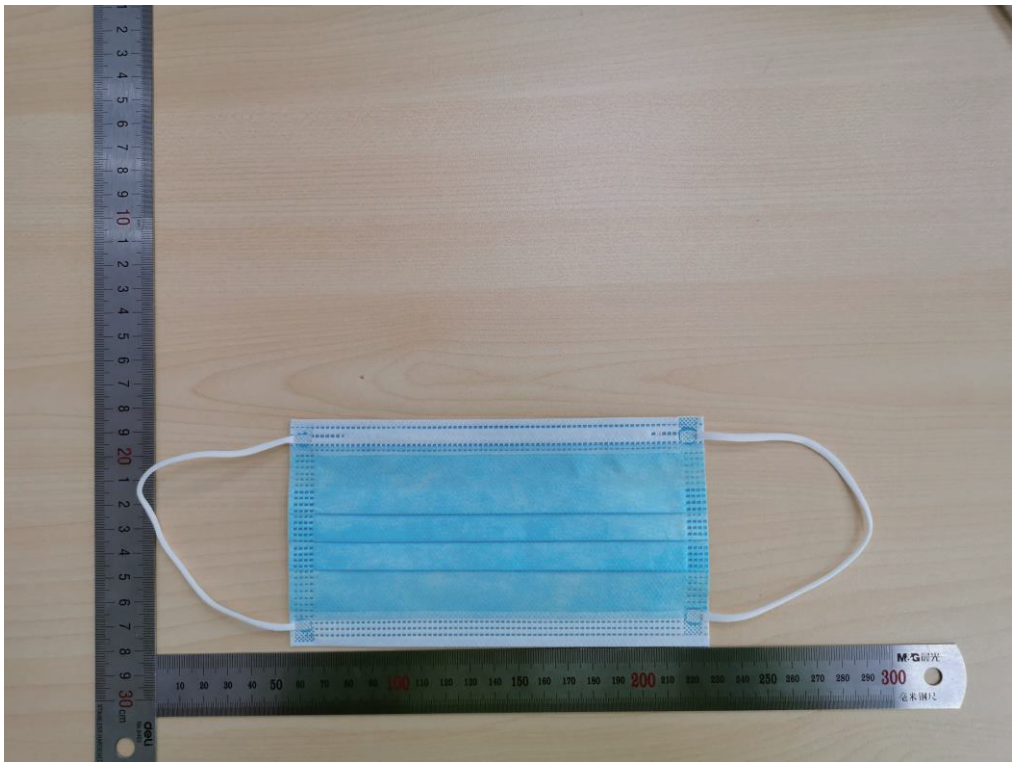
Medical Face Masks
Flat Pleated Ear Loops
Guangxi Guigang Bairui Medical Equipment Co. Ltd

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

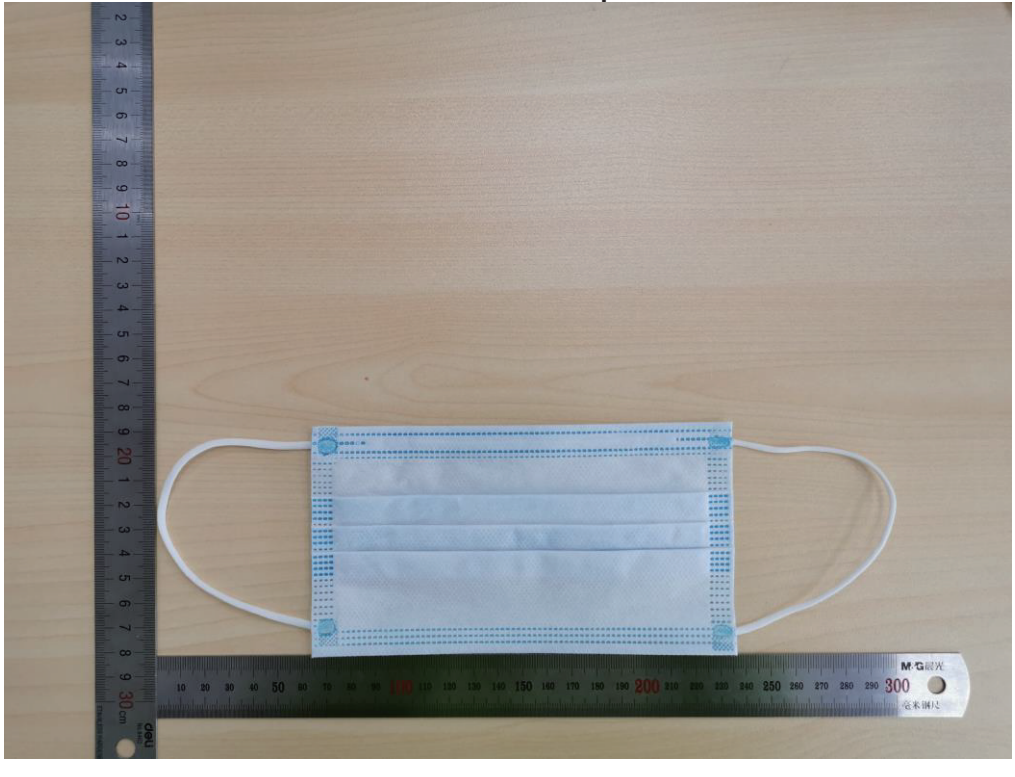
Report Number: **60361105 001** Attachment 1

Model: Flat Pleated Ear Loops

Pic.1: The obverse side view of **Flat Pleated Ear Loops**



Pic.2: The reverse side view of **Flat Pleated Ear Loops**



Pic.3: Marking, labelling and packaging of **Flat Pleated Ear Loops**