TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Anhui Tiankang Medical Technology Co., Ltd.
No. 228 Weiyi Road
Economic Development Zone
Tianchang City
239300 Anhui
China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-09-17
Certificate Registration No.:	SX 60131062 0001
An audit was performed. Report No.:	15096003 004
This Certificate is valid until:	2021-09-16

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-09-17

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

1.0 EC Declaration of Conformity

Manufacturer:	Name: Anhui Tiankang Medical Technology Co., Ltd. Add: No. 228 Weiyi Road, Economic Development Zone, Tianchang City, 239300 Anhui, China
European Representative:	Name: MedPath GmbH Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
Product Name:	Single-use Medical Face Mask (Type I,Type II,Type IIR)
Object of the declaration:	Types/Sizes: With earloop or with earloop(flat earloop) or with earloop(folded earloop) or with tie coverall: 12.5cm x 9cm,14.5cm x 9cm,16.5cm x 9cm,17cm x8cm,17cm x 9cm,17cm x 9.5cm,17cm x 10cm,17.5cm x 8cm,17.5cm x 9cm,17.5cm x 9.5cm,17.5cm x 10cm,18cm x 8cm,18cm x 9cm,18cm x9 .5cm,18cm x 10cm,19.5cm x 8cm,19.5cm x 9cm,19.5cm x 9.5cm,19.5cm x 10cm
UMDNS Code:	12-447
Classification (MDD, Annex IX):	Ⅰ, rule 1
Conformity Assessment Route:	Annex Ⅶ

We herewith declare in sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards such as EN 14683:2019+AC:2019 etc. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Start of CE Marking:	2020-03-25
Place of Issue:	Tianchang,CHINA
Date of Issue:	2020-04-23

Signature: Bai baodong

Mr. Baodong Bai

Position: General Manager

2020.4.23

MedPath

EC-Registration Certificate

Directive 93/42/EEC on Medical Devices (MDD), Article 14

No. R A001 29 Rev. 01

Manufacturer: Anhui Tiankang Medical Technology Co., Ltd.

No. 228 Weiyi Road, Economic Development Zone,
Tianchang City, 239300 Anhui, China

Product Category(ies): See Appendix A

CE

This is to certify that, in accordance of the Medical Device Directive 93/42/EEC (amended by 2007/47/EC), MedPath GmbH agrees to perform all duties and responsibilities as the Authorized Representative for the aforementioned manufacturer as stipulated and demanded by the aforementioned Directive. The German Competent Authority is notified of the manufacturer's medical device(s) and has allocated registration numbers shown in Appendix A. The manufacturer has provided MedPath GmbH with the appropriate Declaration(s) of Conformity confirming that the medical device(s) fulfills/fulfill the applicable requirements of the aforementioned Directive.

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
Tel.089-189174474 · Fax 089-54858884

Date, 2020-03-28 MedPath GmbH

MedPath

Appendix A: Product Category(ies)

No.	Name	Class	UMDNS Code	Form No.	Registration No.
1	Single-use Medical Face Mask	I	12-447	00297923	to be issued
2	Non-woven Coveralls	I	15-223	00297925	to be issued
3	Non-woven Isolation Gowns	I	15-037	00297927	to be issued

echnology Co., Ltd

MedPath GmbH
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CE

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/CA61**		
	Bezeichnung / Name **Regierung von Oberbayern**		
	Staat / State **Deutschland**		Land / Federal state **Bayern**
	Ort / City **München**		Postleitzahl / Postal code **80534**
	Straße, Haus-Nr. / Street, house no. **Maximilianstraße 39**		
	Telefon / Phone **+49-89-21760**		Telefax / Fax **+49-89-21762914**
	E-Mail / E-mail **medizinprodukteanzeigeverfahren@reg-ob.bayern.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority		Registriernummer / Registration number
	Typ der Anzeige / Notification type ☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change ☐ 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 ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ 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 ☐ 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 ☐ 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/0000047823**		
	Bezeichnung / Name **MedPath GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Bayern**
	Ort / City **München**		Postleitzahl / Postal code **80807**
	Straße, Haus-Nr. / Street, house no. **Mies-van-der-Rohe-Strasse 8**		
	Telefon / Phone **089 189174474**		Telefax / Fax
	E-Mail / E-mail **info@medpath.pro**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Anhui Tiankang Medical Technology Co., Ltd.**		
	Staat / State **CN**		
	Ort / City **Tianchang City**		Postleitzahl / Postal code **239300**
	Straße, Haus-Nr. / Street, house no. **No. 228 Weiyi Road, Economic Development Zone**		
	Telefon / Phone **+86 13705505106**		Telefax / Fax
	E-Mail / E-mail **zy@tkmedical.com**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Zheng Mei c/o MedPath GmbH**		
	Staat / State **Deutschland**		Land / Federal state **Bayern**
	Ort / City **München**		Postleitzahl / Postal code **80807**
	Straße, Haus-Nr. / Street, house no. **Mies-van-der-Rohe-Strasse 8**		
	Telefon / Phone **089 189174474**		Telefax / Fax **089 5485 8884**
	E-Mail / E-mail **info@medpath.pro**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change		

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
	Klasse / Class ☒ I ☐ I - steril / sterile ☐ I - mit Messfunktion / with measuring function ☐ I - steril und mit Messfunktion / sterile and with measuring function ☐ IIa ☐ IIb ☐ III ☐ 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 ☐ Aktives implantierbares Medizinprodukt / Active implantable medical device ☐ 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
	App (Software auf mobilen Endgeräten) ☐ ja / yes ☒ nein / no
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	Handelsname des Produktes / Trade name of the device **Single-use Medical Face Mask**
	Produktbezeichnung / Name of device
	Nomenklaturcode / Nomenclature code **12-447**
	Nomenklaturbezeichnung / Nomenclature term **Maske**
	Kategoriecode / Category code **10**
	Kategorie / Category **Produkte zum Einmalgebrauch**
	Kurzbeschreibung deutsch / German short description
	Kurzbeschreibung englisch / English short description

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
	☐ Semikritische Medizinprodukte / Semicritical medical devices ☐ Gruppe A / Group A ☐ Gruppe B / Group B
	☐ Kritische Medizinprodukte / Critical medical devices ☐ Gruppe A / Group A ☐ Gruppe B / Group B ☐ Gruppe C / Group C Nummer der Bescheinigung / Certificate number
	Sterilisationsverfahren / Sterilisation procedures ☐ Dampfsterilisation / Steam sterilisation ☐ Gassterilisation / Gas sterilisation ☐ Strahlensterilisation / Radiation sterilisation ☐ 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 **München**

Datum
Date **2020-03-28**

Name **Song Wang**

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

SUBJECT	**Physical & Microbiological Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Anhui Tiankang Medical Technology Co.,Ltd**
CLIENT ADDRESS	No.228 WeiyiRoad Economic Development Zone Tianchang City 239300 Anhui China
TEST PERIOD	01-May-2020~12-May-2020

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By

(Leo Liu)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

TEST REPORT

Sample Description	:	Single-use Medical Face Mask
Sample Quantity	:	50 pieces
Lot Number/Batch Code	:	200416
Specification	:	With earloop
Size	:	/
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Method	Test Standard Type Ⅰ	Judgement
1	Bacterial Filtration Efficiency Test (BFE), %	EN 14683:2019+AC:2019(E) Annex B	≥ 95	Pass
2	Differential Pressure Test (Pa/cm^2)	EN 14683:2019+AC:2019(E) Annex C	< 40	Pass
3	Microbial Cleanliness Test (CFU/g)	EN 14683:2019+AC:2019(E) Annex D	≤ 30	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
# = No comment;
N.D. = Not detected.

Photo of Samples

Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.7% Specimen 2#: 99.6% Specimen 3#: 99.7% Specimen 4#: 99.7% Specimen 5#: 99.6%
2	Differential Pressure Test	27.3 Pa/cm^2
3	Microbial Cleanliness Test	Specimen 1#: 6 CFU/g Specimen 2#: 6 CFU/g Specimen 3#: 4 CFU/g Specimen 4#: 3 CFU/g Specimen 5#: 3 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of mask.

2. Sample description was given by client

Sample description : Single-use Medical Face Mask
Specification : With earloop
Lot Number : 200416
Sample Receiving Date : 2020-05-01

3. Test Method

EN 14683:2019+AC:2019(E) Annex B

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538.
4.2 Peptone water.
4.3 Tryptic Soy Broth(TSB).
4.4 Tryptic Soy Agar(TSA).
4.5 Bacterial filtration efficiency test apparatus.
4.6 Six-stage viable particle Anderson sampler.
4.7 Flow meters.

5. Test specimen

5.1 As requested by client, take a total of 5 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

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200 070 P.R.China

6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
6.4 Perform a positive control run without a test specime to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
  6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
  6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
  6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
  6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: 77cm^2).
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control after completion of the sample set.
6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
6.9 Incubate agar plates at (37±2)°C for (20 to 52) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$BFE=(C-T) / C \times 100$$

T is the total plate count for the test specimen.

C is the mean of the total plate counts for the two positive controls.

8. Test results*

P Value / Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	32	37	0	0	0	0	0	0
2	97	83	0	0	0	0	0	0
3	185	160	0	0	0	0	0	0
4	409	352	0	1	1	0	0	0
5	1314	1518	0	5	6	4	4	5
6	513	499	0	2	3	4	3	5
Total (*T*), CFU	2550	2649	<1	8	10	8	7	10
Average (C), CFU	2.6 x10^3= (P_A+P_B) / 2							
BFE ,%				99.7	99.6	99.7	99.7	99.6
Requirements	≥ 95							
Remarks	*P* is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. *T* is the total of *P* value for the test specimen. *C* is the mean of the total of *P* value of the two positive controls.							

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
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No.151 Heng Tong Road Shanghai
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Differential pressure Test

1.Purpose

The purpose of the test was to measure the differential pressure of masks.

2.Sample description was given by client

Sample description : Single-use Medical Face Mask
Specification : With earloop
Lot Number : 200416
Sample Receiving Date : 2020-05-01

3.Test Method

EN 14683:2019+AC:2019(E) Annex C

4. Apparatus and materials

Differential pressure testing instrument

5.Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5) °C and (85±5)% relative humidity.

6. Procedure

6.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min.
6.2 The pretreated specimen is placed across the orifice (total area 4.9cm^2, test area diameter 25mm) and clamped into place so as to minimize air leaks.
6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.
6.4 The differential pressure is read directly.
6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results* (Pa/cm^2)	Average （Pa/cm^2）	Requirements	Judgement
1#	29.0	27.3	< 40	Pass
2#	27.6			
3#	24.7			
4#	25.4			
5#	29.7			

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Microbial Cleanliness Test

1. Purpose

The purpose of the test was to measure microbial cleanliness of mask.

2. Sample description was given by client

Sample description : Single-use Medical Face Mask
Specification : With earloop
Lot Number : 200416
Sample Receiving Date : 2020-05-01

3. Test Method

According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D

4. Apparatus and materials

4.1 Orbital shaker.
4.2 0.45 um filter.
4.3 Tryptic Soy Agar (TSA).
4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
4.6 Extraction apparatus.

5. Test specimen

5.1 As requested by client, take a total of 5 mask samples.
5.2 Mask samples for testing are provided in the original primary packaging.
5.3 Condition at (18 to 26)℃ and (45 to 65)% relative humidity during testing.

6. Procedure

6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 mL aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDA for fungi enumeration.
6.5 The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.
6.6 Calculate the colonies of each agar plate.

7. Calculation

For each test specimen calculate the microbial cleanliness as follows by counting the total colonies of the TSA and SDA plates.

Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	6	0	6	EN14683:2019+AC:2019(E) Annex D EN ISO 11737-1:2018 ≤ 30 CFU/g	Pass
2#	6	0	6		
3#	4	0	4		
4#	3	0	3		
5#	3	0	3		

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
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Regional Head Office:
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Tkmd®

Test report

Report number: 200327

Product name: Single-use medical face mask

Production lot number: 200327

Report date: 20200329

Anhui Tiankang Medical Technology Co., Ltd.

Test report

Quality table-208 A/0

Report No.:200327

Product name	Single-use medical face mask		
Production lot number	200327	Specification	17.5cm*9.5cm
Sampling quantity	100pcs	Lot quantity	2,000pcs
Test date	2020.3.22-3.29	Report date	2020.3.29
Inspection basis	EN 14683：2019+AC：2019		

Inspection item	Technical requirements	Inspection result	Conclusion
Appearance	The appearance of the mask should be clean, the shape is intact, the surface must not be damaged, stains.	Meet the requirement	Pass
Construction and dimension	The construction and dimensions shall meet the requirements specified in the following table.	Meet the requirement	Pass

Specification	A±5%	B±5%
17cm×8cm	17	8
17cm×9.5cm	17	9.5
17.5cm×8cm	17.5	8
17.5cm×9.5cm	17.5	9.5
18cm×8cm	18	8
18cm×9.5cm	18	9.5
19.5cm×8cm	19.5	8
19.5cm×9.5cm	19.5	9.5
12.5×9cm	12.5	9
16.5cm×9cm	16.5	9
17cm×9cm	17	9
17cm×10cm	17	10
17.5cm×9cm	17.5	9
17.5cm×10cm	17.5	10
18cm×9cm	18	9
18cm×10cm	18	10
19.5cm×9cm	19.5	9
19.5cm×10cm	19.5	10
14.5cm×9cm	14.5	9

	After wearing the mask, it should cover the wearer's mouth, nose and jaw		
Nose clip	Masks should be fitted with nose clips made of plastic materials. Nose clip length should not be less than 8.0cm.	Meet the requirement	Pass
Mask strap	Mask straps should be adjusted easily. The breaking force at the connection point between each mask belt and the mask body should be no less than 10N.	Meet the requirement	Pass
Bacterial filtration efficiency (BFE), (%)	≥ 95%。	Meet the requirement	Pass
Differential pressure (Pa/cm^2)	< 40 Pa/cm^2	Meet the requirement	Pass
Microbial cleanliness (cfu/g)	≤ 30 cfu / g	Meet the requirement	Pass
Conclusion	Comply with the **provisions of** EN 14683：2019+AC：2019		

Seal

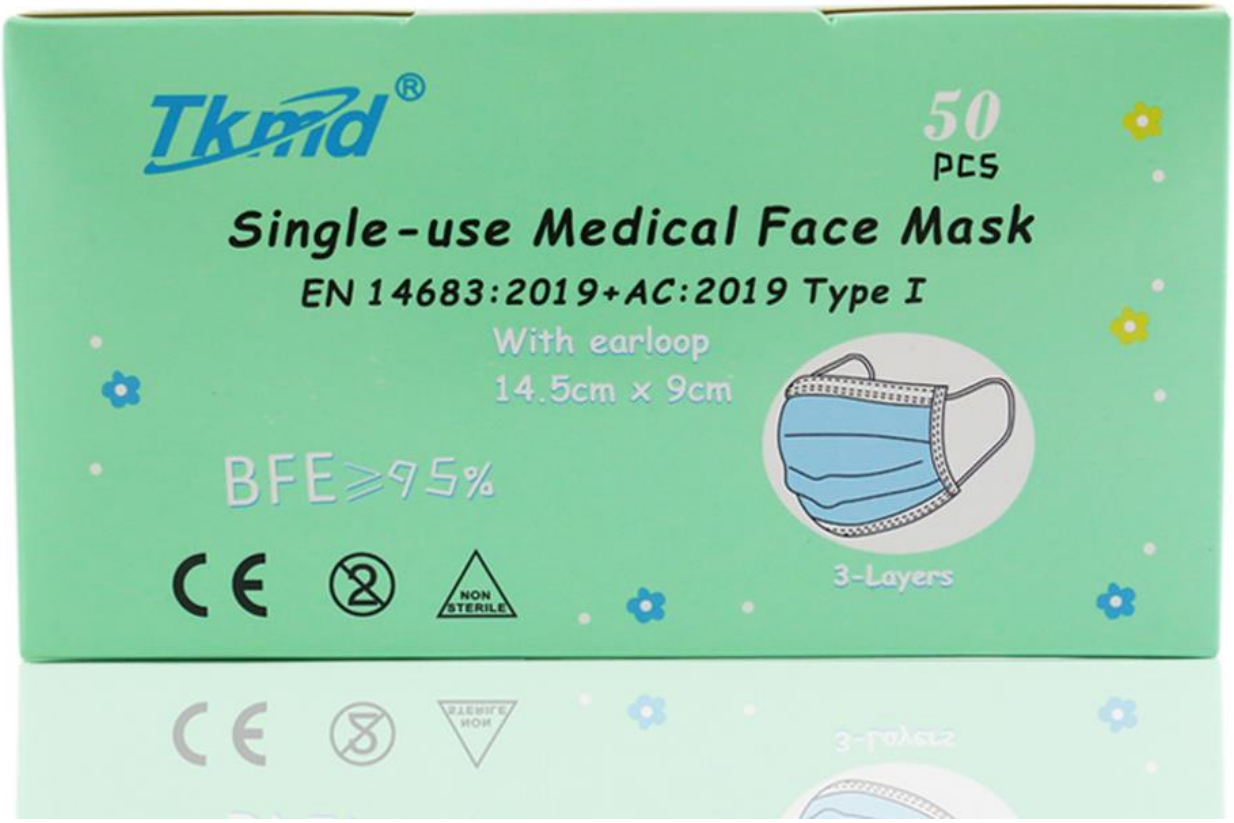
Date: March 29, 2020

Approval:　　Reviewer:　　Tester:

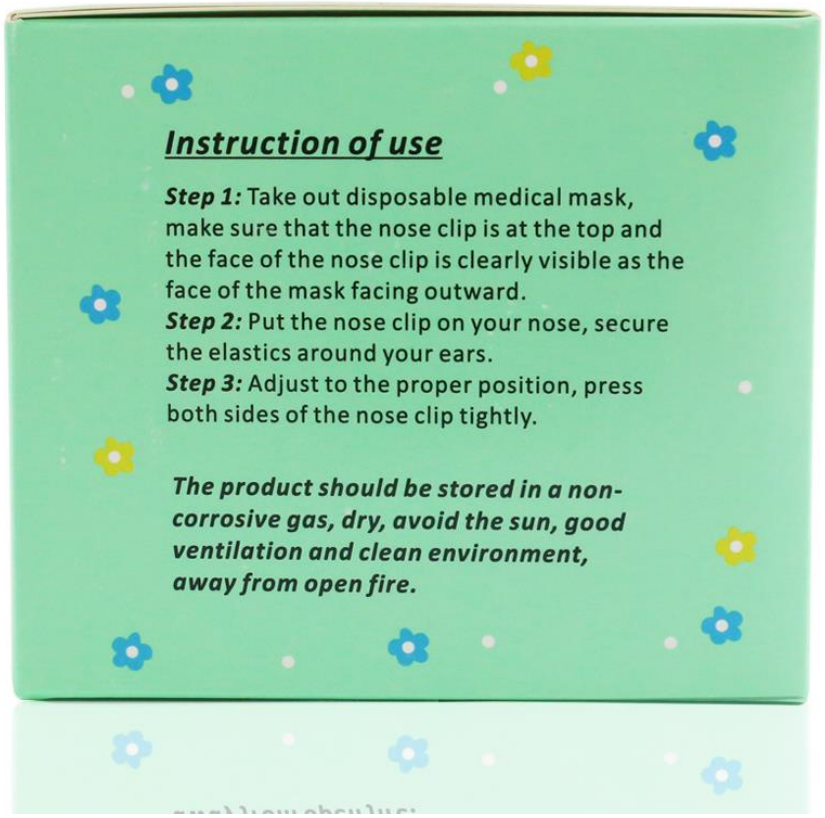
Note: This form is in duplicate, one to the sales department and the other to the quality department.

Kindermasken Typ I nach EN14683

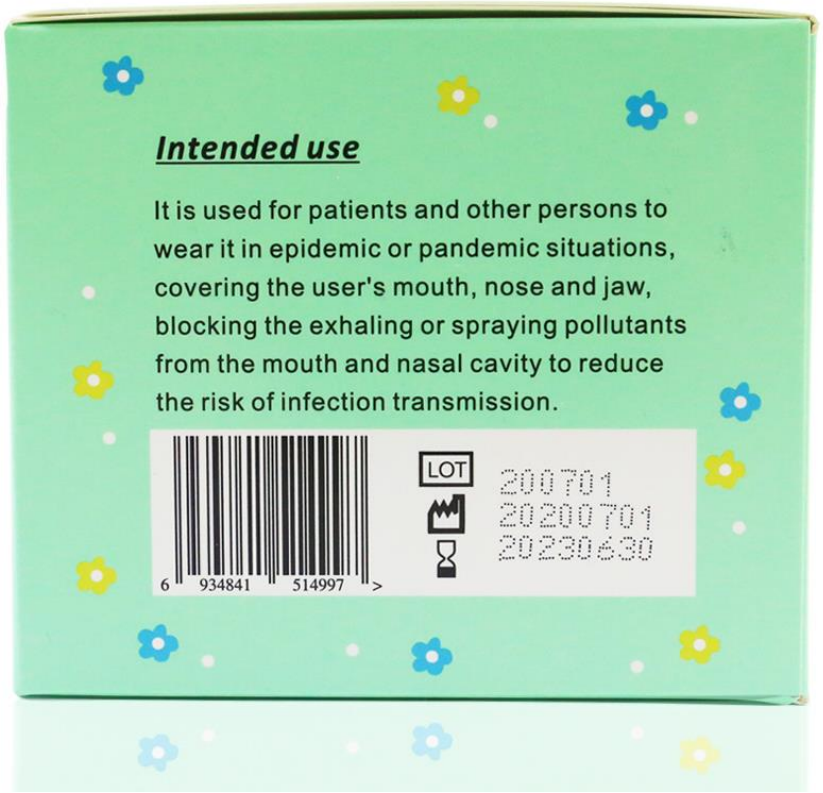
Vorderansicht



Seitenansicht von links



Seitenansicht von rechts



Draufsicht

Ansicht von hinten