

EC 符合性声明

Declaration of Conformity

 European Commission

EC Declaration of Conformity

Manufacturer: Hunan Wondo Medical Supplies Co., Ltd
Address: Building 12th, Advanced Energy Storage and Energy Saving of Creative Industrial Park, No. 169, 2nd, Area East Renmin Road, Changsha Economic and Technological Development Zone, Hunan, Province, China

EU Authorised Representative:
Company: Osmunda Medical Technology Service GmbH
Address: Von Oppen-Weg 15, 14476 Potsdam, Germany
DIMDI code: DE/0000047267

Product name: Medical protective mask **Model:** Foldable type
UMDN code: 12-458
Classification: Class I
Rule: According to Rule 1, Annex VIII, Chapter III of (EU) MDR 2017/745
Conformity assessment route: ANNEX II + ANNEX III + Article 19 of (EU) MDR 2017/745
Intended use: The medical protective mask is suitable for the protection of the healthcare personnel and related personnel against airborne respiratory infections. It should not be used for isolation of intensive care unit (rooms) and other places with strict control of microbial indicators.

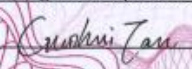
We hereby declare that the above mentioned product meets the provision of the Medical Device Regulation (EU) MDR 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

CE

Standard Applied:

EN ISO 13485:2016	EN ISO 14971:2012	EN 14683:2019 +AC: 2019	BS EN ISO 15223-1:2016
EN ISO 10993-1:2009/AC:2010	EN ISO 10993-5:2009	ISO 10993-10:2010	EN 1041:2008

Place, Date of Issue:
Changsha, 24th April 2020

Represented by Management Representative:
Name: Guohui Tan
Function: Management Representative
Signature: 

The signature is signed on behalf of Hunan Wondo Medical Supplies Co., Ltd.

TÜV检测报告

TÜV Test Report

Test Report No.: 721654638-3
Report Date: 18 May 2020



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 Hunan Wondo Medical Supplies Co., Ltd

CLIENT ADDRESS Building 12th, advanced energy storage and energy saving of creative industrial park, No.169, 2nd Area East Renmin Road, Changsha economic and technological development zone, Hunan Province, China

TEST PERIOD 30-Apr-2020~10-May-2020

Prepared By

Bella Xu
(Bella Xu)
Report Drafter

Authorized By



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:
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Regional Head Office:
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(China) Co., Ltd.
No.151 Heng Tong Road Shanghai
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TÜV®

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Test Report No.: 721654638-3
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TEST REPORT

Sample Description : Medical protective mask
Sample Quantity : 90 pieces
Lot Number/Batch Code : 20200312
Specification : Foldable type
Size : /
Brand Name : /

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Standard	Test Standard Type II R	Judgement
1	Bacterial Filtration Efficiency Test (BFE), %	EN 14683:2019+AC:2019(E) Annex B	≥ 98	Pass
2	Differential Pressure Test (Pa/cm ²)	EN 14683:2019+AC:2019(E) Annex C	< 60	Pass
3	Synthetic Blood Penetration Test (kPa)	ISO 22609:2004	≥ 16.0	Pass
4	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



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Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.9% Specimen 2#: 99.9% Specimen 3#: 99.9% Specimen 4#: 99.9% Specimen 5#: 99.9%
2	Differential Pressure Test	50.5 Pa/cm ²
3	Synthetic Blood Penetration Test	Specimen 1#~32#: None seen
4	Microbial Cleanliness Test	Specimen 1#: 2 CFU/g Specimen 2#: 1 CFU/g Specimen 3#: 3 CFU/g Specimen 4#: 1 CFU/g Specimen 5#: 1 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 : Medical protective mask
Specification : Foldable type
Lot Number : 20200312
Sample Receiving Date : 2020-04-30

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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6. Procedure

- 6.1 Preparation of the bacterial challenge: Dilute the culture 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 specimen 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. Immediately 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 run, 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: 77cm²).
- 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.

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8. Test results*

Stage Number \ P Value	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	150	122	0	0	0	0	0	0
2	153	147	0	0	0	0	0	0
3	156	205	0	0	0	0	0	0
4	177	232	0	0	0	0	0	0
5	1619	1681	0	0	0	0	0	0
6	390	308	0	0	0	0	0	0
Total (T), CFU	2645	2693	<1	<1	<1	<1	<1	<1
Average (C), CFU	$2.7 \times 10^3 = (P_A + P_B) / 2$							
BFE, %	99.9							
Requirements	≥ 98							
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.							

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 : Medical protective mask
Specification : Foldable type
Lot Number : 20200312
Sample Receiving Date : 2020-04-30

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 $(21 \pm 5)^\circ\text{C}$ and $(85 \pm 5)\%$ 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 4.9cm², 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#	50.9	50.5	< 60	Pass
2#	51.5			
3#	47.9			
4#	50.1			
5#	52.3			

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Synthetic Blood Penetration Test

1. Purpose

For evaluation of resistance of masks to penetration by a fixed volume of synthetic blood at a high velocity.

2. Sample description was given by client

Sample description : Medical protective mask
Specification : Foldable type
Lot Number : 20200312
Sample Receiving Date : 2020-04-30

3. Test Method

ISO 22609:2004

4. Apparatus and materials

- 4.1 Synthetic blood.
- 4.2 Tensiometer.
- 4.3 Synthetic blood penetration test apparatus;
- 4.4 Targeting plate.
- 4.5 Air pressure source.
- 4.6 Ruler.
- 4.7 Balance.
- 4.8 Controlled temperature and humidity chamber.

5. Test specimen

- 5.1 As requested by client, take a total of 32 test specimens.
- 5.2 Prior to testing, condition all test specimens for a minimum of 4h at $(21 \pm 5)^{\circ}\text{C}$ and $(85 \pm 5)\%$ relative humidity.

6. Procedure

- 6.1 Prepare the synthetic blood (40~44 mN/m) for the test.
- 6.2 Determine the density of the synthetic blood.
- 6.3 Fill the reservoir with new synthetic blood.
- 6.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.
- 6.5 Set the reservoir pressure to the approximate pressure.
- 6.6 Place the targeting plate approximately 1 cm away from the mask.
- 6.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

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- 6.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).
- 6.9 Calculate the difference in weight of the two spurts. For a test fluid with a density of 1.003, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.

Table 1 Target weight difference

Fluid Pressure (mmHg)	Weight difference for 1s difference in spurt duration (g)		
	Min.	Target	Max.
120	3.002	3.063	3.124

- 6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.
- 6.11 Record the weight difference for the spurts exiting the nozzle.
- 6.12 Record the pressure in the reservoir.
- 6.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.
- 6.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.
- 6.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2 % ~ -5 % of the difference in weight from the nozzle.
- 6.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.
- 6.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 6.7 to 6.11).
- 6.18 For standard synthetic blood, the timer duration can be estimated using the formula:
(p is the density of the test fluid.) $t = 0.5 + (2 \times p - g \text{ at } 0.5 \text{ s}) / (g \text{ at } 1.5 \text{ s} - g \text{ at } 0.5 \text{ s})$.
- 6.19 Record the timer setting to use as the starting point for subsequent testing.
- 6.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.
- 6.21 Squirt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.
- 6.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.
- 6.23 Report the results (none / penetration) for each test specimen at the test pressure.

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Results:

1#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	Pass
2#	None Seen		Pass
3#	None Seen		Pass
4#	None Seen		Pass
5#	None Seen		Pass
6#	None Seen		Pass
7#	None Seen		Pass
8#	None Seen		Pass
9#	None Seen		Pass
10#	None Seen		Pass
11#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass
14#	None Seen		Pass
15#	None Seen		Pass
16#	None Seen		Pass
17#	None Seen		Pass
18#	None Seen		Pass
19#	None Seen		Pass
20#	None Seen		Pass
21#	None Seen		Pass
22#	None Seen		Pass
23#	None Seen		Pass
24#	None Seen		Pass
25#	None Seen		Pass
26#	None Seen		Pass
27#	None Seen		Pass
28#	None Seen		Pass
29#	None Seen		Pass
30#	None Seen		Pass
31#	None Seen		Pass
32#	None Seen		Pass

TUV SUD 认证公司

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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 : Medical protective mask
Specification : Foldable type
Lot Number : 20200312
Sample Receiving Date : 2020-04-30

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 Agar (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) °C 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*:

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

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-



11/05/2020

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CE 备案凭证

CE Filing Certificate

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMD/IV)
Formularnummer 00305838

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/CA76	
Bezeichnung / Name Landesamt für Arbeitsschutz, Verbraucherschutz und Gesundheit, Abteilung Gesundheit, Dezernat G4	
Staat / State Deutschland	Land / Federal state Brandenburg
Ort / City Zossen	Postleitzahl / Postal code 15806
Straße, Haus-Nr. / Street, house no. Wünsdorfer Platz 3	
Telefon / Phone +49-331-8683852	Telefax / Fax +49-331-8683865
E-Mail / E-mail medizinprodukte@lavg.brandenburg.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/0000047267
Bezeichnung / Name	Osmunda Medical Technology Service GmbH
Staat / State	Land / Federal state
Deutschland	Brandenburg
Ort / City	Postleitzahl / Postal code
Potsdam	14476
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Von Oppen-Weg, 15	
Telefon / Phone	Telefax / Fax
030 50590627	
E-Mail / E-mail	
eu@osmundacn.com	

Hersteller / Manufacturer	
Bezeichnung / Name	Hunan Wondo Medical Supplies Co., Ltd
Staat / State	CN
Ort / City	Postleitzahl / Postal code
Changsha, Hunan	410000
Straße, Haus-Nr. / Street, house no.	
Building 12th, Advanced Energy Storage and Energy Saving of Creative Industrial Park, No. 169, 2nd, Area East Renmin Road, Changsha Economic and Techn	
Telefon / Phone	Telefax / Fax
0086-731-86910566	
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	Min Yang
Staat / State	Land / Federal state
Deutschland	Berlin
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Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00305838

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	Medical Protective Mask (Non-Sterile)
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	Medical protective mask (non-sterile) is suitable for the basic protection of medical staff and related workers under the environment with the risk of airborne respiratory infections. It can filter the particulate matter in the air and block the droplet, the blood, the body fluid, and the secretions and so on. The medical protective mask cannot use in the isolation intensive care unit (room) and other places with strict control of microbial indicators. Model: Foldable type

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	Berlin	Datum Date	2020-05-14
		Name	Min Yang
			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

包装信息

Packaging Information



Bag: 21x17cm
5 PCs/Bag



Box: 20.5x17x17.5cm
10 Bags/Box



Carton: 20 Boxes/Carton
Measure: 64cmx43cmx36cm
QTY/Bag: 5 PCs
QTY/Box: 50PCs
QTY of Boxes/Carton: 20 Boxes
QTY/Carton: 1000PCs
G.W: 7.6KG N.W: 4.3KG