
Instruction of use
ASDET U&I
Disposable FACE MASK
3 Layers pleated design · Earloop
Easily breathable · Hypoallergenic
ZHEJIANG LILY UNDERWEAR CO., LTD.
358 Wenxi Street, Wucheng District, Jinhua City, Zhejiang, China
50 MASKS
MADE IN CHINA
Premium Elite
GB/T32610-2016
non-medical use

统一社会信用代码

91330700755914679 2 (1/1)

营业执照

(副本)

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息

名　　称　浙江丽莱内衣有限公司

类　　型　有限责任公司(台港澳与境内合资)

法定代表人　黄栩潇

经营范围　一般项目：高档内衣、服装、内衣辅料制造、销售；第二类医疗器械批发；第二类医疗器械零售；日用口罩（非医用）生产；日用口罩（非医用）销售(除依法须经批准的项目外，凭营业执照依法自主开展经营活动)。许可项目：第二类医疗器械生产(依法须经批准的项目，经相关部门批准后方可开展经营活动，具体经营项目以审批结果为准)。

注册资本　贰佰壹拾万美元

成立日期　2003 年 12 月 09 日

营业期限　2003 年 12 月 09 日 至 2053 年 12 月 08 日

住　　所　浙江省金华市婺城区秋滨街道文溪街 358 号

登记机关　金华市市场监督管理局

2020 年02 月25 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年 1 月 1 日至 6 月 30 日通过国家信用公示系统报送公示年度报告。

国家市场监督管理总局监制

医疗器械生产许可证

许可证编号：浙食药监械生产许 20200100 号

企业名称：浙江丽莱内衣有限公司

生产地址：浙江省金华市婺城区秋滨街道文溪街 358 号三号厂房第三层

法定代表人：黄栩潇

生产范围：II 类:14-14-医护人员防护用品

企业负责人：杨榕

住　　所：浙江省金华市婺城区秋滨街道文溪街 358 号

发证部门：浙江省药品监督管理局

有效期限：至 2020 年 10 月 2 日

发证日期：2020 年 4 月 8 日

国家食品药品监督管理总局制

中华人民共和国医疗器械注册证

注册证编号：浙械注准20202141154

注册人名称	浙江丽莱内衣有限公司
注册人住所	浙江省金华市婺城区秋滨街道文溪街358号
生产地址	浙江省金华市婺城区秋滨街道文溪街358号
代理人名称	不适用
代理人住所	不适用
产品名称	一次性使用医用口罩
型号、规格	型号：非无菌型；规格：175mm×95mm。
结构及组成	产品由口罩体、鼻夹、口罩带组成，为耳带式结构。
适用范围	用于普通环境下的一次性卫生护理。不作外科手术时特殊防护用。
附 件	本产品执行YY/T 0969-2013《一次性使用医用口罩》标准（除4.7.2无菌（不适用）、4.8环氧乙烷残留量（不适用）、4.9生物学评价外）。
其他内容	/
备 注	本产品为防控新型冠状病毒感染的肺炎疫情应急审批产品，注册证有效期为6个月，产品标签和说明书上应醒目标注“仅供防控疫情应急使用”。

审批部门：浙江省药品监督管理局

批准日期：2020年04月02日

有效期至：2020年10月02日

浙江省药品监督管理局 医疗器械注册专用 3301050140714

MedPath

EC-Registration Certificate

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

No. R A002 15/A Rev. 01

Manufacturer: ZHEJIANG LILY UNDERWEAR CO.,LTD.

358 Wenxi Street, Wucheng District, Jinhua City,

Zhejiang, 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, 2020-04-07 MedPath GmbH

MedPath

Appendix A: Product Category(ies)

Name	Classifi-cation	UMDNS Code	Form No.	Registration No.
Disposable Medical Face Mask	I	12-447	00300970	to be issued

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
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CE

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00300970

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 S 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 S 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 **ZHEJIANG LILY UNDERWEAR CO.,LTD.**		
	Staat / State **CN**		
	Ort / City **Jinhua City**		Postleitzahl / Postal code **321025**
	Straße, Haus-Nr. / Street, house no. **358 Wenxi Street, Wucheng District**		
	Telefon / Phone **+86-579-82208612**		Telefax / Fax
	E-Mail / E-mail **TINA_PU@ASSET.COM.CN**		

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		
	S Erstanzeige / Initial notification £ Änderungsanzeige / Notification of change		

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

Klasse / Class

S 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 S nein / no

Nummer(n) der Bescheinigung(en) / Certificate number(s)

Handelsname des Produktes / Trade name of the device
Disposable 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 **2020-03-31**

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	**ZHEJIANG LILY UNDERWEAR CO.,LTD**
CLIENT ADDRESS	358 Wenxi Street, Wucheng District, Jinhua City, Zhejiang, China
TEST PERIOD	31-Mar-2020~10-Apr-2020

Prepared By	**Authorized By**
(Bella Xu) Report Drafter	(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:
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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	:	Surgical mask
Sample Quantity	:	40 pieces
Lot Number/Batch Code	:	/
Specification	:	/
Size	:	17.5*9.5*3
Type of Mask	:	Type IIR
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Standard	Judgement
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
2	Differential Pressure Test	EN 14683:2019+AC:2019(E) Annex C	Pass
3	Synthetic Blood Penetration Test	ISO 22609:2004	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	Pass

Note: Pass = Meet customer requirements;

Fail = Fail customer requirements;

= No comment;

N.D. = Not detected.

Photo of Samples

Restults

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.9% Specimen 2#: 99.8% Specimen 3#: 99.7% Specimen 4#: 99.8% Specimen 5#: 99.9%
2	Differential Pressure Test	33.0 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~13#: None seen
4	Microbial Cleanliness Test	Specimen 1#: 1 CFU/g Specimen 2#: 2 CFU/g Specimen 3#: <1 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 : Surgical mask
Specification : /
Lot Number : /
Sample Receiving Date : 2020-03-31

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.

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	21	33	0	0	0	0	0	0
2	38	32	0	0	0	0	0	0
3	63	98	0	0	0	0	0	0
4	127	157	0	0	0	1	0	0
5	1219	1476	0	0	3	5	3	2
6	362	374	0	1	1	1	2	1
Total (*T*), CFU	1830	2170	<1	1	4	7	5	3
Average (C), CFU	$2.0x10^3 = (P_A+P_B) / 2$							
BFE ,%				99.9	99.8	99.7	99.8	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 : Surgical mask
Specification : /
Lot Number : /
Sample Receiving Date : 2020-03-31

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#	31.8	33.0	< 60	Pass
2#	30.6			
3#	35.2			
4#	30.1			
5#	37.4			

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
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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

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	:	Surgical mask
Specification	:	/
Lot Number	:	/
Sample Receiving Date	:	2020-03-31

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 13 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4h at (21±5)°C and (85±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).

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 at 0.5 s) / (g at 1.5 s - g at 0.5 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.

Results:

Specimen	Test Results*	Requirements	Judgement
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

Chemical/Microbiology Laboratory:
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Phone : +86 (21) 6037 6375
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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

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 : Surgical mask

Specification : /

Lot Number : /

Sample Receiving Date : 2020-03-31

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#	0	1	1	According to EN ISO 11737-1:2018 the microbial cleanliness of the mask shall be ≤30 CFU/g tested.	Pass
2#	2	0	2		
3#	0	0	<1		
4#	0	1	1		
5#	1	0	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-

Chemical/Microbiology Laboratory:
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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:
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No.151 Heng Tong Road Shanghai
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180011112242

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国际互认
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TESTING
CNAS L6780

检 验 报 告

TEST REPORT

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Scan checks for authenticity

W202005874E

浙江省轻工业品质量检验研究院

Zhejiang Light Industrial Products Inspection and Research Institute

国家纺织服装产品质量监督检验中心（浙江）

National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

Zhejiang Light Industrial Products Inspection and Research Institute
National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

Test report

Number: W202005874E

Name of Customer	ZHEJIANG LILY UNDERWEAR CO.,LTD	Address	358 Wenxi Street, Wucheng District, Jinhua City, Zhejiang, China
Manufacturer	ZHEJIANG LILY UNDERWEAR CO.,LTD	Address	358 Wenxi Street, Wucheng District, Jinhua City, Zhejiang, China
Sample information	Name of sample: KN95 MASK Characteristics of sample: White Trademark of sample: --- Specification/model: --- Level: KN95 Category of safety specification: --- Art. No.: --- ----------		
Above-mentioned information by Customer-supplied			
The sent way of sample	Courier	Sample quantity	30 pieces
Receiving Date of Sample	2020/04/13	Test Category	Entrusted inspection
Date of Testing	2020-04-13- 2020-04-14		
Rating Requirements	GB 2626-2006		

Test Summary:

See the attached page for the results.

Test Seal

Date of Approval: 2020-04-17

Remarks	The sample is not pretreated and the result is for reference.

Approved by: 曹丽勤

Test report

Number:W202005874E

ITEM	STANDARD (KN95)	RESULT	RATING
1. FILTER EFFICIENCY(SALT MEDIUM) (GB 2626-2006)(%)			
-	≥95.0	99.7	PASS
2. RESPIRATORY RESISTANCE (GB 2626-2006)(Pa)			
-INSPIRATORY RESISTANCE	≤350	107	PASS
-EXPIRATORY RESISTANCE	≤250	89	PASS

Test report

Picture(s) of sample

—End of report—

DECLARATION

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6. If there is any dissent of the report, the entrusting party shall notify our organization timely. For the mandatory inspection given by governmental administration departments, and dissent about the sample being tested or test results on the report should be dealt with in accordance with national regulations.

浙江省轻工业品质量检验研究院及附设的检验中心
The Affiliated Inspection Centers

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检 验 报 告

TEST REPORT

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报 告 编 号
REPORT NO.　国纺委字第 YJ202001741 号

产 品 名 称
NAME OF SAMPLE　民用口罩

委 托 单 位
CUSTOMER　浙江丽莱内衣有限公司

检 验 类 别
TEST CATEGORY　委托检验

浙江省轻工业品质量检验研究院

（浙江省纺织测试研究院）

Zhejiang Light Industrial Products Inspection and Research Institute

国家纺织服装产品质量监督检验中心（浙江）

National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

浙江省轻工业品质量检验研究院
国家纺织服装产品质量监督检验中心（浙江）

检验报告

国纺委字第 YJ202001741 号

委托单位名称 Name of Customer	浙江丽莱内衣有限公司	地 址 Address	---
生产单位 Manufacturer	---	地 址 Address	---
样品信息 Sample information	样品名称 Name of sample：民用口罩 样品特性 Characteristics：蓝色 商标 Trademark：--- 规格/号型 Specification/model：--- 等 级 Level：--- 安全技术类别 Category of safety specification：--- 样品款号/货号 Art. No.：--- ----------		
以上为客供信息（Above-mentioned information by Customer-supplied）			
来样方式 The sent way of sample	快递	样品数量 Sample quantity	1 包
送检日期 Receiving Date of Sample	2020-03-07	检测类别 Test Category	委托检验
判定依据 RatingRequirements	GB/T 32610-2016		

检测结论/Test Summary：

实测结果详见附页。

[签章]

(检验报告专用章)Test Seal

批准日期/ Date of Approval：2020-03-07

备 注 Remarks	1、样品标识未标注防护效果级别，按最低标准要求 D 级判定。 2、样品未经预处理。

签 发：
Approved by

检验报告

国纺委字第 YJ202001741 号

序号	检测项目		检测方法	单位	标准要求（D 级）	实测值	单项评价	结果备注
1	呼吸阻力	吸气阻力	GB/T 32610-2016	Pa	≤175	88.2	符合	---
		呼气阻力		Pa	≤145	68.3		
2	过滤效率		GB/T 32610-2016 附录 A	%	≥90	96.2	符合	---
3	防护效果		GB/T 32610-2016 附录 B	%	≥65	69.1	符合	---

检验报告

样品照片

—以下空白—

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DECLARATION

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（2018）国认监认字（244）号

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检 验 报 告

TEST REPORT

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报 告 编 号
REPORT NO.　国纺委字第 W202004460 号

产 品 名 称
NAME OF SAMPLE　儿童款一次性防护口罩

委 托 单 位
CUSTOMER　浙江丽莱内衣有限公司

检 验 类 别
TEST CATEGORY　委托检验

浙江省轻工业品质量检验研究院

（浙江省纺织测试研究院）

Zhejiang Light Industrial Products Inspection and Research Institute

国家纺织服装产品质量监督检验中心（浙江）

National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

浙江省轻工业品质量检验研究院
国家纺织服装产品质量监督检验中心（浙江）

检验报告

国纺委字第 W202004460 号

委托单位名称 Name of Customer	浙江丽莱内衣有限公司	地 址 Address	---
生产单位 Manufacturer	浙江丽莱内衣有限公司	地 址 Address	---
样品信息 Sample information	样品名称 Name of sample：儿童款一次性防护口罩 样品特性 Characteristics：白色 商标 Trademark：--- 规格/号型 Specification/model：--- 等 级 Level：--- 安全技术类别 Category of safety specification：--- 样品款号/货号 Art. No.：--- ----------		
以上为客供信息（Above-mentioned information by Customer-supplied）			
来样方式 The sent way of sample	快递	样品数量 Sample quantity	1 盒
送检日期 Receiving Date of Sample	2020-04-07	检测类别 Test Category	委托检验
判定依据 RatingRequirements	GB 2626-2006		

检测结论/Test Summary：

实测结果详见附页。

[签章]

(检验报告专用章)Test Seal

批准日期/ Date of Approval：2020-04-09

备 注 Remarks	1、样品标识未标注滤料级别，按最低标准要求 KN90 判定。 2、样品未经预处理，数据供参考。

签 发：
Approved by

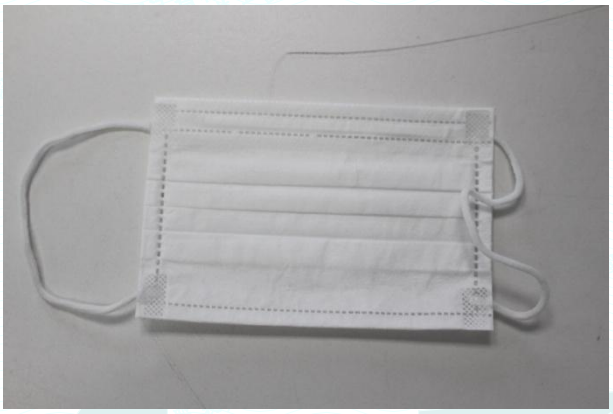
检验报告

国纺委字第 W202004460 号

序号	检测项目		检测方法	单位	标准要求（KN90）	实测值	单项评价	结果备注
1	过滤效率（盐性介质）		GB 2626-2006 6.3	%	≥90.0	91.0	符合	---
2	呼吸阻力	吸气阻力	GB 2626-2006 6.5 6.6	Pa	≤350	58	符合	---
		呼气阻力		Pa	≤250	41		

检验报告

样品照片



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检 验 报 告

TEST REPORT

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报 告 编 号 REPORT NO.	国纺委字第 W202004461 号
产 品 名 称 NAME OF SAMPLE	学生款一次性防护口罩
委 托 单 位 CUSTOMER	浙江丽莱内衣有限公司
检 验 类 别 TEST CATEGORY	委托检验

浙江省轻工业品质量检验研究院

（浙江省纺织测试研究院）

Zhejiang Light Industrial Products Inspection and Research Institute

国家纺织服装产品质量监督检验中心（浙江）

National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

浙江省轻工业品质量检验研究院
国家纺织服装产品质量监督检验中心（浙江）

检验报告

国纺委字第 W202004461 号

委托单位名称 Name of Customer	浙江丽莱内衣有限公司	地 址 Address	---
生产单位 Manufacturer	浙江丽莱内衣有限公司	地 址 Address	---
样品信息 Sample information	样品名称 Name of sample：学生款一次性防护口罩 样品特性 Characteristics：白色 商标 Trademark：--- 规格/号型 Specification/model：--- 等 级 Level：--- 安全技术类别 Category of safety specification：--- 样品款号/货号 Art. No.：--- ----------		
以上为客供信息（Above-mentioned information by Customer-supplied）			
来样方式 The sent way of sample	快递	样品数量 Sample quantity	1 盒
送检日期 Receiving Date of Sample	2020-04-07	检测类别 Test Category	委托检验
判定依据 RatingRequirements	GB 2626-2006		

检测结论/Test Summary：

实测结果详见附页。

[签章]

(检验报告专用章)Test Seal

批准日期/ Date of Approval：2020-04-08

备 注 Remarks	1、样品标识未标注滤料级别，按最低标准要求 KN90 判定。 2、样品未经预处理，数据供参考。

签 发：
Approved by

检验报告

国纺委字第 W202004461 号

序号	检测项目		检测方法	单位	标准要求（KN90）	实测值	单项评价	结果备注
1	过滤效率（盐性介质）		GB 2626-2006 6.3	%	≥90.0	94.1	符合	---
2	呼吸阻力	吸气阻力	GB 2626-2006 6.5 6.6	Pa	≤350	79	符合	---
		呼气阻力		Pa	≤250	57		

检验报告

样品照片

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DECLARATION

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2. The test report will be deemed invalid without signatures of the inspector/reviewer and authorized personnel, and the red special inspection stamp of our organization.
3. The test report will be invalid if it is altered. Copies of the report are invalid without the red special inspection stamp of our organization.
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浙江省轻工业品质量检验研究院及附设的检验中心
The Affiliated Inspection Centers

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Zhejiang Center of Quality Test for Sports Products　　E-Mail：wujtest@126.com
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浙江省杭州市余杭区良渚街道经一路 1 号良渚大学科技园 3 号楼
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国家锁具产品质量监督检验中心（浙江）　　联系电话：0571-85027738
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Address：No. 24 Tangmiao Rd., Hangzhou, Zhejiang

180011112242

（2018）国认监认字（244）号

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国际互认
检测
TESTING
CNAS L6780

检 验 报 告

TEST REPORT

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报 告 编 号 REPORT NO.	国纺委字第 W202005874 号
产 品 名 称 NAME OF SAMPLE	KN95 口罩
委 托 单 位 CUSTOMER	浙江丽莱内衣有限公司
检 验 类 别 TEST CATEGORY	委托检验

浙江省轻工业品质量检验研究院

（浙江省纺织测试研究院）

Zhejiang Light Industrial Products Inspection and Research Institute

国家纺织服装产品质量监督检验中心（浙江）

National Textiles and Garment Quality Supervision Inspection Center(Zhejiang)

浙江省轻工业品质量检验研究院
国家纺织服装产品质量监督检验中心（浙江）

检验报告

国纺委字第 W202005874 号

委托单位名称 Name of Customer	浙江丽莱内衣有限公司	地 址 Address	---
生产单位 Manufacturer	浙江丽莱内衣有限公司	地 址 Address	---
样品信息 Sample information	样品名称 Name of sample：KN95 口罩 样品特性 Characteristics：白色 商标 Trademark：--- 规格/号型 Specification/model：--- 等 级 Level：KN95 安全技术类别 Category of safety specification：--- 样品款号/货号 Art. No.：--- ----------		
以上为客供信息（Above-mentioned information by Customer-supplied）			
来样方式 The sent way of sample	快递	样品数量 Sample quantity	30 只
送检日期 Receiving Date of Sample	2020-04-13	检测类别 Test Category	委托检验
判定依据 RatingRequirements	GB 2626-2006		

检测结论/Test Summary：

实测结果详见附页。

[签章]

(检验报告专用章)Test Seal

批准日期/ Date of Approval：2020-04-14

备 注 Remarks	样品未经预处理，数据供参考。

签 发：
Approved by

检验报告

国纺委字第 W202005874 号

序号	检测项目		检测方法	单位	标准要求（KN95）	实测值	单项评价	结果备注
1	过滤效率（盐性介质）		GB 2626-2006 6.3	%	≥95.0	99.7	符合	---
2	呼吸阻力	吸气阻力	GB 2626-2006 6.5 6.6	Pa	≤350	107	符合	---
		呼气阻力		Pa	≤250	89		

检验报告

样品图片

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171021110579

检验检测报告

TEST REPORT

STFWT20205393

产品名称 Product Name	一次性使用医用口罩
委托单位 Trust Unit	浙江丽莱内衣有限公司
生产单位 Manufacturer	浙江丽莱内衣有限公司
检验检测类别 Test Category	委托送样检验

江苏省特种安全防护产品质量监督检验中心
JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS

检 验 检 测 报 告

Test Report

防伪查询

STFWT20205393

产品名称 Product Name	一次性使用医用口罩	规格型号 Specification Type	型号：非灭菌型，规格：175mm×95mm
		商 标 Trademark	——
委托单位 Trust Unit	浙江丽莱内衣有限公司	电 话 Tel	0579-82208599
生产单位 Manufacturer	浙江丽莱内衣有限公司	样品等级 Sample Grade	——
样品数量 Sample Quantity	50 只（1 只/包）	送样日期 Sample Receiving Date	2020-03-18
检验检测类别 Test Category	委托送样检验	批号/货号 Serial Number	生产批号：20200302，生产日期：2020.03.14
样品状态 Samples Conditions	符合检测要求		
检验检测及判定依据 Document and Decide Accordance	YY/T 0969-2013 《一次性使用医用口罩》		
检验检测结论 Test Conclusion	样品经检验，所检项目符合 YY/T0969-2013 标准规定的要求。 签发日期：2020-03-25 SignatuimDate		
备 注 Remarks	本报告检验结论仅对所检项目得出，不代表未经检验的项目或功能符合要求。 本报告仅对来样负责。		

批 准：陈敏 Approver　　审 核：吴高高 Examiner　　主 检：蔡燕文 Majortester

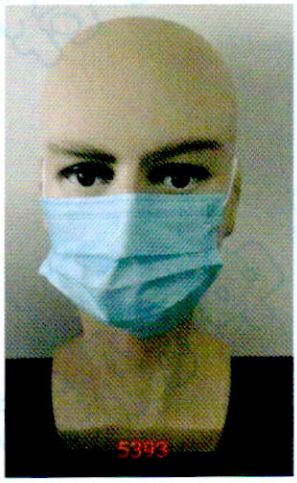
检 验 检 测 结 果
Testing Results

STFWT20205393

序号 Serial	检验检测项目 Test Items		单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment
1	外观		——	口罩外观应整洁，形状完好，表面不得有破损、污渍。	口罩外观整洁，形状完好，表面未有破损、污渍。	合 格
2	结构与尺寸		——	口罩佩戴好后，应能罩住佩戴者的鼻、口至下颌。 长：175mm±9mm 宽：95mm±5mm	口罩佩戴好后，能罩住佩戴者的鼻、口至下颌。 长：175mm 宽：95mm	合 格
3	鼻夹		——	1、口罩上应配有鼻夹，鼻夹由可塑性材料制成。 2、鼻夹长度应不小于8.0cm。	1、口罩上配有鼻夹，鼻夹由可塑性材料制成。 2、鼻夹长度： 9.5cm、9.5cm、9.5cm。	合 格
4	口罩带		——	1、口罩带应戴取方便。 2、每根口罩带与口罩体连接点处的断裂强力应不小于10N。	1、口罩带戴取方便。 1#：试样断裂强力不小于10N 2#：试样断裂强力不小于10N 3#：试样断裂强力不小于10N	合 格
5	细菌过滤效率/%（BFE）		——	≥95	99.6	合 格
6	通气阻力		Pa/cm^2	口罩两侧面进行气体交换的通气阻力应不大于49 Pa/cm^2	4#：26 5#：25 6#：26	合 格
7	环氧乙烷残留量		μg/g	≤10	未标注经环氧乙烷处理，不测此项。	——
8	微生物指标	细菌菌落总数	CFU/g	≤100	80	合 格
		大肠菌群	——	不得检出	未检出	
		金黄色葡萄球菌	——	不得检出	未检出	
		绿脓杆菌	——	不得检出	未检出	
		溶血性链球菌	——	不得检出	未检出	
		真菌	——	不得检出	未检出	

检 验 检 测 结 果
Testing Results

样 品 图 片



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The Institute Complain Tel:0523-86989901
检验检测机构业务电话：0523-86989959
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业务受理微信号

SPC

特防检测

中心官方微信公众号

CERTIFICATE OF FDA

Facility Registration and Device Listing of Medical Device

ZHEJIANG LILY UNDERWEAR CO., LTD

Owner/Operator Number: 10067835

Registration/FEI Number: Active, Waiting for Registration Number Assignment

Address: No 358 Wenxi Street, Wucheng District, Jinhua, Zhejiang, 321025, CHINA

has completed the Facility Registration and Device Listing with the US FDA, through

HUMISS INC.

Listing Number	Premarket Submission	Product Code(s)	Device Name(s)	Activities	Models
D387038	Exempt	MSH	Respirator, surgical	Manufacturer	Disposal protective face mask (Adult: 17.5X9.5CM, Student mask: 14.5X9.5CM, 12.5X8CM), KN95 mask, N95 mask, 3D mask

HUMISS INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of calendar year stated above, unless said registration is terminated after issuance of this certificate. HUMISS INC. makes no other representations or warranties, nor does this certificate make any representation 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 product(s) or establishment by the U.S Food and Drug Administration. HUMISS INC. assumes no liability to any person or entity in connection with foregoing.

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Issue date: Apr. 7, 2020

Expire date: Dec. 31, 2020

Certificate №: HU-M-200407024

HUMISS INC.
4845 Pearl East Cir Ste 118, Boulder, CO, 80301, USA
001-720-759-5888

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. 4G200407F.ZLU0S82

Certificate's Holder:	ZHEJIANG LILY UNDERWEAR CO.,LTD No358 Wenxi Street, Wucheng District, Jinhua City, Zhejiang, China
Certification ECM Mark:	ENTE CERTIFICAZIONE MACCHINE – European Conformity – SAFETY COMPLIANCE MARK – Type Approved
Product:	Disposal Protective Face Mask
Model(s):	Adult: 17.5X9.5cm, Children Mask: 14.5X9.5CM , 12.5X8CM
Verification to:	Standard: EN 149:2001+A1:2009 related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

CE

The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 07 April 2020

Expiry date: 06 April 2025

Reviewer
Technical expert
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Approver
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Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. 4G200407F.ZLU0S84

Certificate's Holder:	ZHEJIANG LILY UNDERWEAR CO.,LTD No358 Wenxi Street, Wucheng District, Jinhua City, Zhejiang, China
Certification ECM Mark:	ENTE CERTIFICAZIONE MACCHINE – European Conformity – SAFETY COMPLIANCE MARK – Type Approved
Product:	Personal Protective Face Mask
Model(s):	KN95 Mask, N95 Mask, 3D MASK
Verification to:	Standard: EN 149:2001+A1:2009 related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

CE

The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 07 April 2020

Expiry date: 06 April 2025

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