



## EC DECLARATION OF CONFORMITY

### Manufacturer:

ELDO CARE CORPORATION LIMITED  
Rm.1902, Easey comm. Bldg., 253-261 Hennessy Road, Wanchai, Hongkong

### European Authorized Representative

Company: Lotus NL B.V.  
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Declares that the MDD described hereafter

Product name and model:

ELFM3600 - Non-Woven Face Mask, Ear-loop, 3-ply, non-sterile

Meet the provisions of the Council Directive 93/42/EEC & 2007/47/CE which apply to them.

*Harmonized standards or normative documents :*  
*EN 14683:2019+AC:2019 TYPE IIR BFE  $\geq$ 98%*

The medical device has been assigned to class I according to Annex VII of the Directive 2007/47/CE. It bears the mark:



CONFORMITY ASSESSMENT ROUTE: Annex VII

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of:  
ELDO CARE CORPORATION LIMITED

Place , date  
Shanghai, China  
Sep. 9<sup>th</sup>, 2020

Legally binding signature, Function  
Co-founder & CEO  
Ellen Wang

EC Declaration of Conformity

For and on behalf of  
ELDO CARE CO., LIMITED  
  
Authorized Signature(s)

ELDO CODE	GIMA CODE	PRODUCT DESCRIPTION	PACKING
ELFM3600	20670	GISAFE – color: light blue Surgical mask 3ply - Type IIR non-woven - earloop- non sterile – singly packed	box 50pcs
ELFM3600	20700	GISAFE – color: light blue Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	box 50pcs
ELFM3600	20695	GISAFE – color: light blue Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20697	GISAFE – color: pink Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	box 50pcs
ELFM3600	20694	GISAFE – color: pink Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20698	GISAFE – color: white Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	box 50pcs
ELFM3600	20699	GISAFE – color: light green Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	box 50pcs
ELFM3600	20685	GISAFE – fantasy: cartoon Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20686	GISAFE – fantasy: peace Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20687	GISAFE – fantasy: stars Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20680	GISAFE – color: light blue Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20682	GISAFE – fantasy: cartoon Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20696	GISAFE – color: light blue Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	box 2000pcs (200 flowpack of 10 pcs)
ELFM3600	20701	GISAFE – color: black Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	box 50pcs
ELFM3600	20688	GISAFE – fantasy: colours Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20689	GISAFE – fantasy: macarones Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20690	GISAFE – fantasy: skulls Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs
ELFM3600	20691	GISAFE – fantasy: military Surgical mask 3ply - Type IIR non-woven - earloop- non sterile	flowpack 10pcs



# GIMA

## **GISAFE MASCHERINA CHIRURGICA FILTRANTE 98% 3 VELI tipo IIR con elastici - adulti - teschi - flowpack**

**Codice:** 20690  
**Categoria:** Mascherine  
**Unità di vendita:** conf. 10 pz.  
**Quantitativi minimi:** 1  
**Dispositivo:** Dispositivo medico  
**Classe:** I  
**NSIS:** 2043900  
**CND:** T020601  
**EAN13:** 8023279206906



**Descrizione:** MASCHERINE FILTRANTI 98% A 3 VELI - TIPO IIR con elastici

- Modello per adulti
- Flowpack da 10
- Fantasia: skulls

Mascherine chirurgiche leggere e confortevoli adatte per ospedali, studi dentistici e ambulatori.

- vasta gamma: mascherine adulti in 5 colori o 7 fantasie; mascherine pediatriche in 1 colore o 1 fantasia
- disponibili in scatola da 50 o flowpack da 10
- nasello modellabile da adattare alla forma anatomica del viso
- senza fibra di vetro, efficienza di filtrazione BFE =98%
- materiale non tessuto, senza lattice
- 1° velo esterno 28 gsm non tessuto
- 2° velo 25 gsm filtro meltblown
- 3° velo interno 25 gsm non tessuto

Scatola multilingue: GB, FR, IT, ES, PT, DE, SE, GR, RO, Arabo.

**Caratteristiche tecniche:** BFE% = 98  
Pressione differenziale (Pa/cm<sup>2</sup>) < 60  
CfU/g < 30  
Dimensioni: 17,5 x 9,5 cm (adulti)  
Conforme a EN 14683:2019 + AC:2019; DDM 93/42/CEE Classe I

ELDO CARE CORPORATION LIMITED  
RM.1902, EASEY COMM. BLDG., 253-261 HENNESSY ROAD, WANCHAI, HONGKONG

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A)GIMA BRANDED 20690 - 3 PLY SURGICAL MASK-DISPOSABLE-  
EARLOOP - FANTASY: SKULLS

Composition : (A)67% non-woven, 33% melt-blown

Sample Color : (A)FANTASY: SKULLS

Style No. : ELFM3600

Model No. : ELFM3600

Lot No. : Not provided

Manufacturer : ELDO CARE CORPORATION LIMITED

Country of Origin : China

Type/ Level : IIR

Sample Dimension : 17.5X9.5CM

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Dec 30, 2020

Testing Period : Dec 30, 2020 - Jan 13, 2021

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the  
sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

*Helen Xuan*

Helen Xuan (Authorized Signatory)

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**Test Result**

**EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods**

**Clause 5.2 Performance Requirement**

**Clause 5.2.2 Bacterial Filtration Efficiency (BFE)**

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

Sample: A  
 Test Side : Inside  
 Test Area : Approximately 60 cm<sup>2</sup>  
 Flow Rate : 28.3 L/min  
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.  
 Dimensions of test specimen : ~170mm x 162mm  
 Positive Control Average : 2325.5 CFU  
 Negative Monitor Count : < 1 CFU  
 Mean Particle Size : 3.0 ±0.3µm  
 Test bacteria : Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE)	1	99.9%
	2	99.9%
	3	99.9%
	4	99.9%
	5	99.9%

**Remark:**

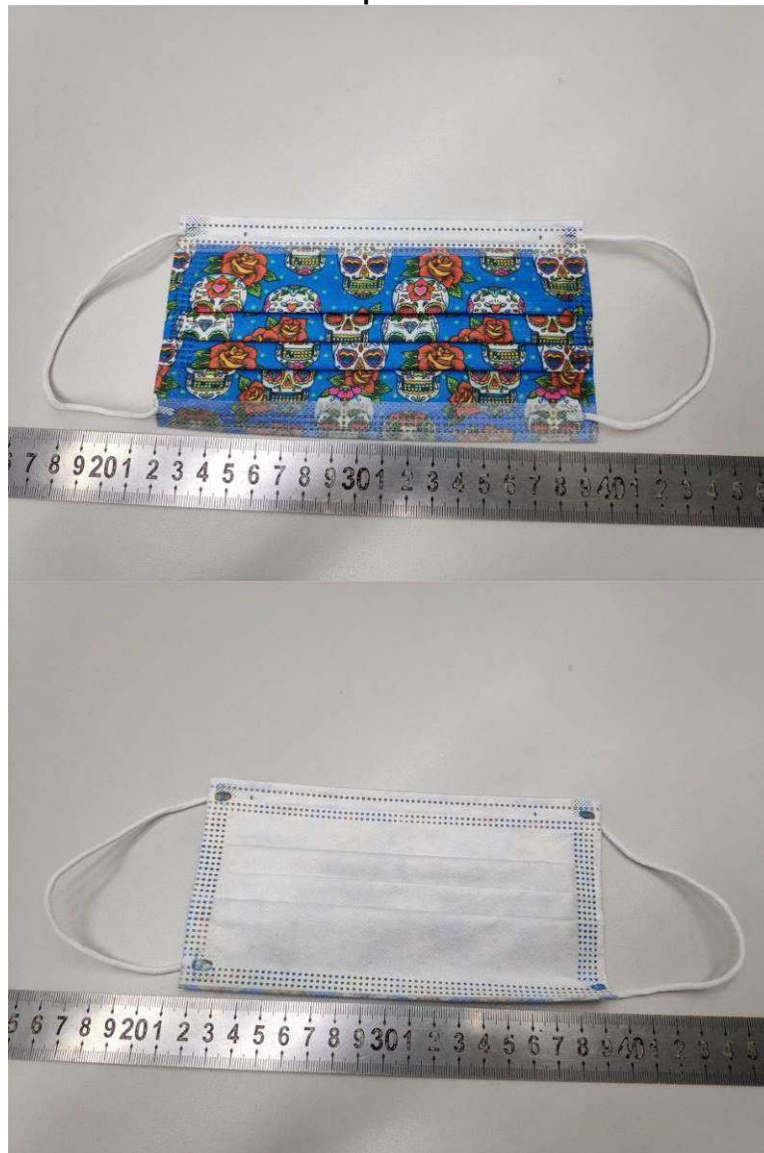
- 1) Performance Requirement: Type I ≥95%, Type II ≥98%, Type IIR ≥98%
- 2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.



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### Sample Photo



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ELDO CARE CORPORATION LIMITED  
RM.1902, EASEY COMM. BLDG., 253-261 HENNESSY ROAD, WANCHAI, HONGKONG

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A)GIMA BRANDED 20690 - 3 PLY SURGICAL MASK-DISPOSABLE-  
EARLOOP - FANTASY: SKULLS

Composition : (A)67% non-woven, 33% melt-blown

Sample Color : (A)FANTASY: SKULLS

Style No. : ELFM3600

Model No. : ELFM3600

Lot No. : Not provided

Manufacturer : ELDO CARE CORPORATION LIMITED

Country of Origin : China

Type/ Level : IIR

Sample Dimension : 17.5X9.5CM

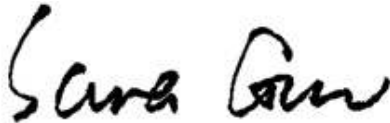
Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Dec 30, 2020

Testing Period : Dec 30, 2020 - Jan 13, 2021

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the  
sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of  
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Sara Guo (Account Executive)

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Test Result

**EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods**

**Clause 5.2 Performance Requirement**

**Clause 5.2.3 Breathability**

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

Sample: A

- Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks
- Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
- Test Area : 4.9 cm<sup>2</sup>
- Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm <sup>2</sup> )	The average value for each test specimen (Pa/cm <sup>2</sup> )
1	1-1	38.5	39
	1-2	39.6	
	1-3	37.4	
	1-4	38.7	
	1-5	38.7	
2	2-1	38.5	39
	2-2	39.6	
	2-3	37.8	
	2-4	39.2	
	2-5	38.5	
3	3-1	37.9	38
	3-2	39.5	
	3-3	34.2	
	3-4	38.9	
	3-5	39.3	
4	4-1	37.6	38
	4-2	38.7	
	4-3	39.5	
	4-4	35.9	
	4-5	36.3	
5	5-1	37.7	38
	5-2	35.6	
	5-3	39.8	
	5-4	39.2	
	5-5	37.5	

Remark:

- 1) Performance Requirement: Type I<40 Pa/cm<sup>2</sup>, Type II<40 Pa/cm<sup>2</sup>, Type IIR<60 Pa/cm<sup>2</sup>
- 2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.



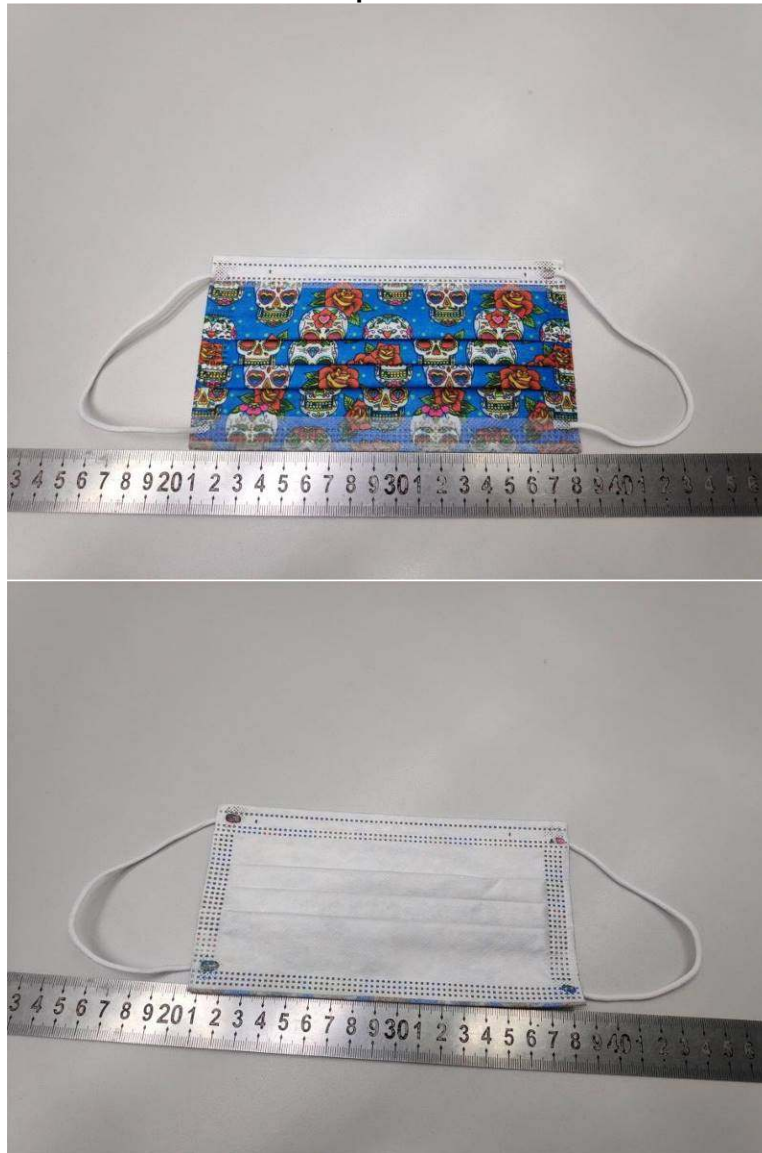
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### Sample Photo



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Test Report

SL52045325931301TX

Date: January 13, 2021

Page 1 of 3

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Sample Color : (A)FANTASY: SKULLS

Style No. : ELFM3600

Model No. : ELFM3600

Lot No. : Not provided

Manufacturer : ELDO CARE CORPORATION LIMITED

Country of Origin : China

Type/ Level : IIR

Sample Dimension : 17.5X9.5CM

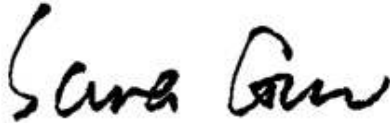
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Test Result

**EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods**

**Clause 5.2 Performance Requirement**

**Clause 5.2.4 Splash Resistance**

(ISO 22609 :2004)

Sample: A

Test Blood Pressure : 16.0kPa  
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.  
 Distance of the mask to the tip of cannula : 300±10mm

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:			32		
Overall result:			Acceptable		

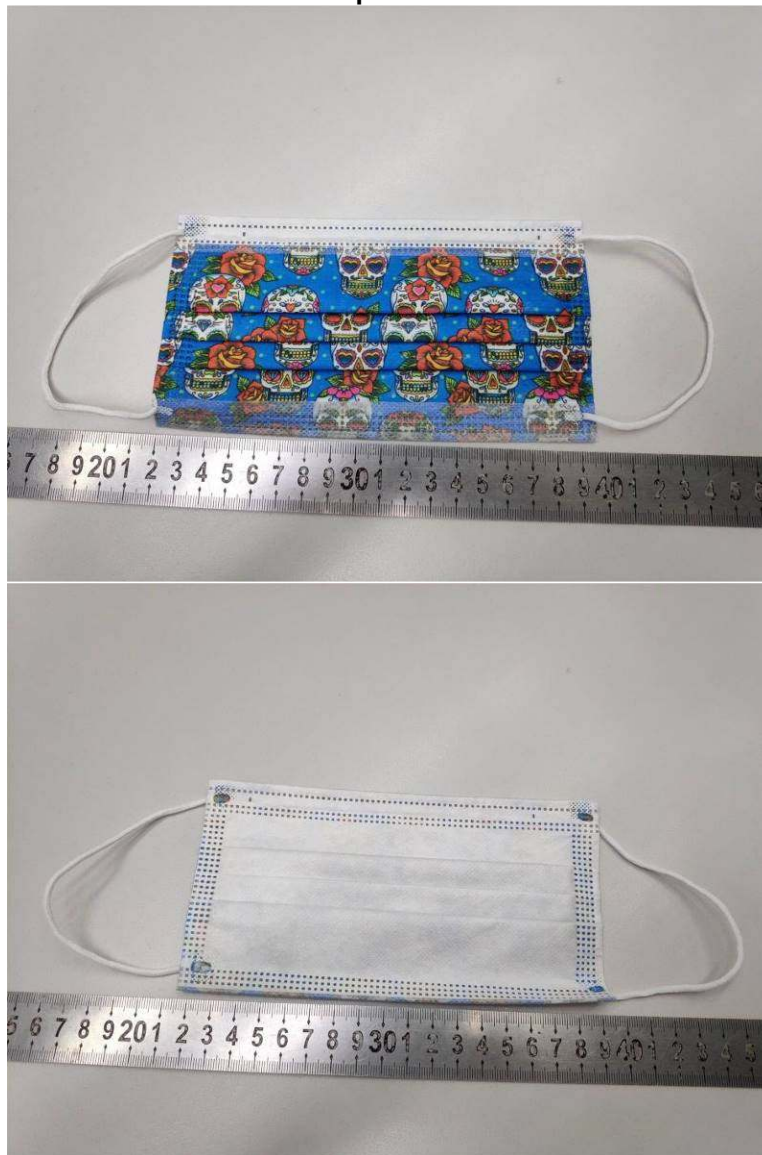
Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
- 2) Test was conducted within 60s after removal from conditioning chamber.
- 3) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.



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 中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e [sgs.china@sgs.com](mailto:sgs.china@sgs.com)

Sample Photo



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Test Report

SL52045325935101TX

Date: January 13, 2021

Page 1 of 3

ELDO CARE CORPORATION LIMITED  
RM.1902, EASEY COMM. BLDG., 253-261 HENNESSY ROAD, WANCHAI, HONGKONG

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A)GIMA BRANDED 20690 - 3 PLY SURGICAL MASK-DISPOSABLE-  
EARLOOP - FANTASY: SKULLS

Composition : (A)67% non-woven, 33% melt-blown

Sample Color : (A)FANTASY: SKULLS

Style No. : ELFM3600

Model No. : ELFM3600

Lot No. : Not provided

Manufacturer : ELDO CARE CORPORATION LIMITED

Country of Origin : China

Type/ Level : IIR

Sample Dimension : 17.5X9.5CM

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Dec 30, 2020

Testing Period : Dec 30, 2020 - Jan 13, 2021

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the  
sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center



Sara Guo (Account Executive)



Dongjing Liu (Authorized Signatory)



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Test Result

**EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods**

**Clause 5.2 Performance Requirement**

**Clause 5.2.5 Microbial Cleanliness**

(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	3.74	30	8.02
2#	3.73	<3	<0.8
3#	3.76	33	8.78
4#	3.75	33	8.80
5#	3.74	48	12.83

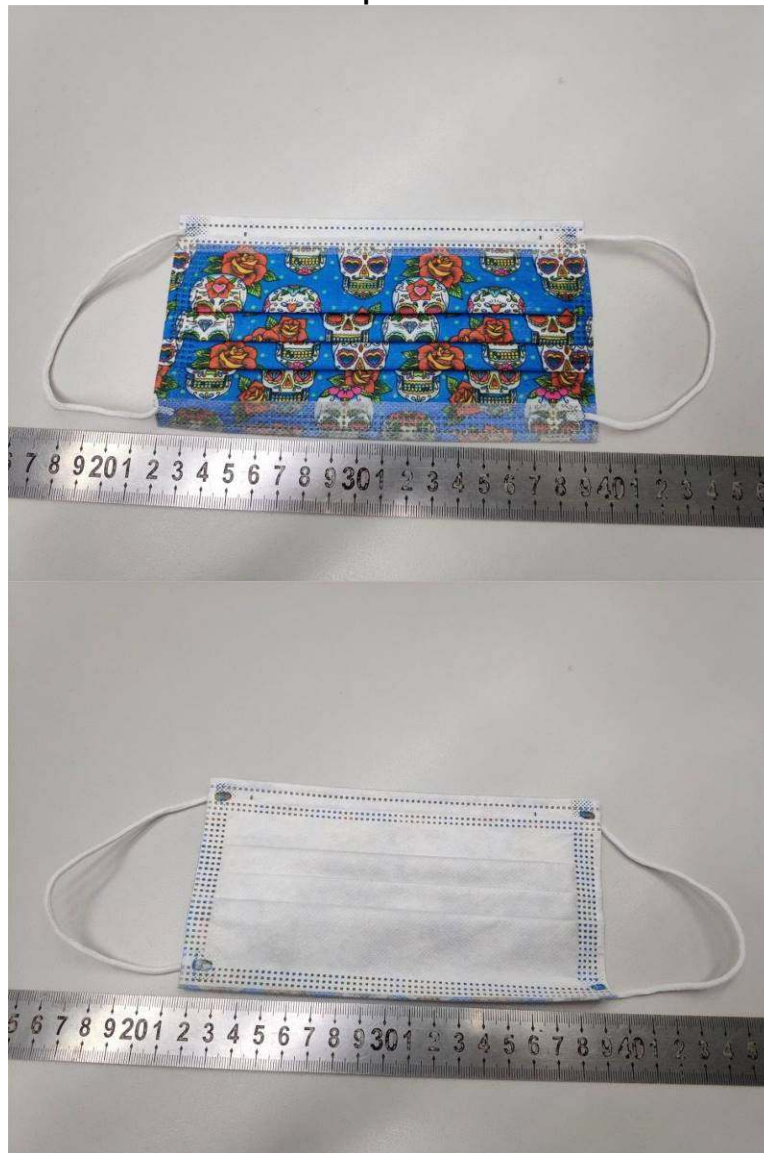
Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g



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### Sample Photo



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