

# **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 ≥98%

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



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

**EC Declaration of Conformity** 

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

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

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#### Eldo Care Corporation Limited

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## GISAFE MASCHERINA CHIRURGICA FILTRANTE 98% 3 VELI tipo IIR con elastici - pediatrica - azzurra - flowpack

Codice:	20680
Categoria:	Mascherine
Unità di vendita:	conf 10 pz.
Quantitativi minimi:	1
Dispositivo:	Dispositivo medico
Classe:	Ι
NSIS:	1946919
CND:	T020601
EAN13:	8023279206807
Descrizione:	MASCHERINE FILTRANTI 98% A 3 VELI - TIPO IIR con elastici
	• Modello pediatrico • Flowpack da 10 • Colore: azzurro
	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
Caratteristiche tecnic	Scatola multilingue: GB, FR, IT, ES, PT, DE, SE, GR, RO, Arabo. he: BFE% = 98 Pressione differenziale (Pa/cm2) < 60 CfU/g < 30 Dimensioni: 14 x 9 cm (pediatrica) Conforme a EN 14683:2019 + AC:2019; DDM 93/42/CEE Classe I





SL52045300702301TX

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 20680 - 3 PLY SURGICAL MASK PEDIATRIC - DISPOSABLE - EARLOOP-LIGHT BLUE
Composition Sample Color Style No. Lot No. Manufacturer	::	(A)67% non-woven, 33% melt-blown (A)LIGHT BLUE ELFM3600 Not provided ELDO CARE CO., LIMITED
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date Testing Period Test Result(s)	: : :	Oct 19, 2020 Oct 21, 2020 - Oct 30, 2020 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 Juan

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 Test Area Flow Rate Pre-Conditioning Dimensions of test specimen Positive Control Average Negative Monitor Count Mean Particle Size	: :	Inside Approximately 60 cm <sup>2</sup> 28.3 L/min Minimum of 4 hours at 21±5°C and 85±5% R.H. ~140mm x 150mm 2450 CFU < 1 CFU 3.0 ±0.3µm
Test bacteria	:	Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
	1	99.9%
Bacterial Filtration Efficiency (BFE)	2	99.7%
	3	99.7%
	4	99.9%
	5	99.8%

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%.

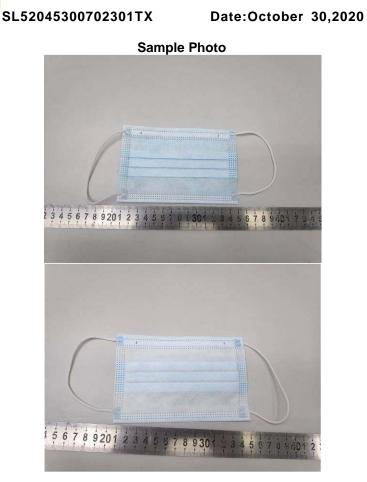


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**Test Report** 





SL52045312151601TX

Date:November 23,2020

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 20680 - 3 PLY SURGICAL MASK PEDIATRIC- DISPOSABLE- EARLOOP-LIGHT BLUE
Composition Sample Color Style No. Lot No. Manufacturer	:	(A)67% non-woven,33% melt-blown (A)LIGHT BLUE ELFM3600 Not provided ELDO CARE CO., LIMITED
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date Testing Period Test Result(s)	:	Nov 09, 2020 Nov 11, 2020 - Nov 23, 2020 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)



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SL52045312151601TX

**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

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	52.5	
	1-2	56.3	
1	1-3	53.5	54
	1-4	48.9	
	1-5	57.6	
	2-1	58.2	
	2-2	58.7	
2	2-3	54.9	57
	2-4	57.1	
	2-5	57.6	
	3-1	48.9	
	3-2	53.6	
3	3-3	57.5	51
	3-4	46.2	
	3-5	47.8	
	4-1	49.5	
	4-2	46.1	
4	4-3	53.1	48
	4-4	44.8	
	4-5	46.7	
-	5-1	48.5	
	5-2	46.7	
5	5-3	48.2	50
	5-4	53.2	
	5-5	51.5	]

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>

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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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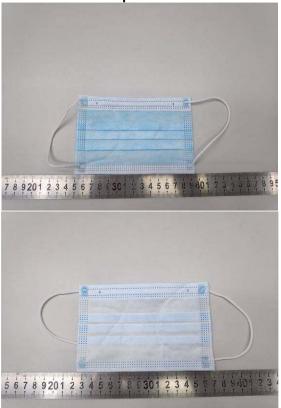




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Date:November 23,2020





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Composition Sample Color Style No. Lot No. Manufacturer	: : : :	(A)67% non-woven, 33% melt-blown (A)LIGHT BLUE ELFM3600 Not provided ELDO CARE CO., LIMITED	
Test Performed	:	Selected test(s) as requested by applicant	
Sample Receiving Date Testing Period Test Result(s)	:	Oct 19, 2020 Oct 20, 2020 - Oct 30, 2020 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).	

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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 5.2.4 Splash Resistance

(ISO 22609 :2004)

Sample: A Test Blood Pressure Pre-Conditioning Distance of the mask to the tip of cannula

16.0kPa Minimum of 4 hours at 21±5°C and 85±5% R.H. 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:			Acce	ptable	

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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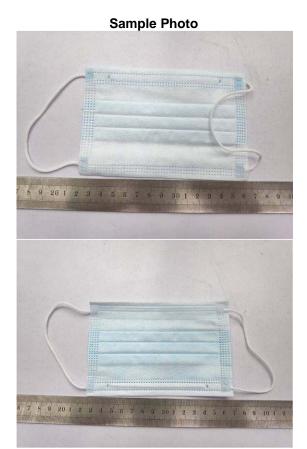
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Date:October 30,2020



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\*\*\*End of Report\*\*\*



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SL52045312270801TX

Date:November 20,2020

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 20680 - 3 PLY SURGICAL MASK PEDIATRIC- DISPOSABLE - EARLOOP-LIGHT BLUE
Composition Sample Color Style No.	:	(A)67% non-woven, 33% melt-blown (A)LIGHT BLUE ELFM3600
Lot No. Manufacturer	:	Not provided ELDO CARE CO., LIMITED
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date Testing Period Test Result(s)	:	Nov 10, 2020 Nov 11, 2020 - Nov 20, 2020 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)

longing li

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#	2.38	36	15.13
2#	2.42	36	14.88
3#	2.44	45	18.44
4#	2.43	51	20.99
5#	2.42	18	7.44

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



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The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

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