International Certification Registrar International Certification Registrar International Certification Registrar

Attestation of Conformity

No. ICR Polska/M63

CE

Name and address of Registered Manufacturer:

Product name:	Medical Face Mask
Product type/model:	Flat Shape, Arch Shape, Folding Type, Binding Belt Type, Ear Hanging Type
Trade mark:	n/a

This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.

Relevant EC Directive:	Medical Device Directive 93/42/EEC
Conformity assessment procedure:	EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)
Classification:	Class I according Rule 1 of Annex IX of Directive 93/42/EEC
Applied normative documents:	EN 14(:2019
Applied Quality Management System	n/a

This AoC will remain valid only if Quality Management System Certificate remains valid.
The assessment process has been carried out in accordance with the program PC-P-07-07.
Evaluation has been carried out in accordance with test report made by:

- SHENZHEN CTO TECHNOLOGY CO., LTD

No. of test report:	CTO200316:
Issue date:	24.03.2020
Expiration date:	23.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3125.

This Attestation applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standard.

INTERNATIONAL CERTIFICATION REGISTAR ★ ICR ★ REGISTERED FIRM ★ JEDNOSTKA NOTYFIKOWANA Nr 2703

Director: Rafał Kalinowski

Warsaw, 24. 03. 2020.

ICR Polska Co. Ltd.
ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com

APPLICATION FOR TEST REPORT

On Behalf of

Prepared For

Product Name	:	Medical Face Mask
Model	:	Flat Shape, Arch Shape, Folding Type, Binding Belt Type, Ear Hanging Type
Prepared By	:	SHENZHEN CTO TECHNOLOGY CO., LTD 9/F, block B, SME incubation center, Tangtou Avenue, Shiyan Town, Bao'an District, Shenzhen City, Guangdong Province, China
Test Date	:	Feb. 26, 2020 –Mar. 16, 2020
Date of Report	:	Mar. 16, 2020
Report No.	:	

MDD TEST REPORT
EN 14683: 2019
Surgical masks - Requirements and test methods

Report Reference No.....:	
Compiled by (+ signature).....:	Laurent Wu
Approved by (+ signature).....:	Mike Wang
Date of issue.....:	Mar. 16, 2020
Testing Laboratory.....:	SHENZHEN CTO TECHNOLOGY CO., LTD
Address.....:	9/F, block B, SME incubation center, Tangtou Avenue, Shiyan Town, Bao'an District, Shenzhen City, Guangdong Province, China
Applicant's name.....:	
Address.....:	
Test specification:	
Standard.....:	EN 14683: 2019
Non-standard test method.....:	N/A
Test item description.....:	Medical Face Mask
Trade Mark.....:	N/A
Manufacturer.....:	
Address.....:	
Model/Type reference.....:	Flat Shape, Arch Shape, Folding Type, Binding Belt Type, Ear Hanging Type
Classification	Type II

Possible test case verdicts:

- test case does not apply to the test object ... N (Not apply)

- test object does meet the requirement ..... P (Pass)

- test object does not meet the requirement... F (Fail)

Testing .....

Date of receipt of test item ..... Feb. 26, 2020

Date(s) of performance of tests ..... Feb. 26, 2020 –Mar. 16, 2020

General remarks:

The test results presented in this report relate only to the object tested.

This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

"(See Enclosure #)" refers to additional information appended to the report.

"(See appended table)" refers to a table appended to the report.

General product information:

The all models are same except their model number, and all tests are based on Flat Shape

Copy of marking plate:

Medical Face Mask
Model: Flat Shape
Classification: Type II
Standard: EN 14683:2019

CE

Made in China

EN 14683			
Clause	Requirement – Test	Result - Remark	Verdict
4	Classification		--
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant, The 'R' signifies splash resistance.	Type II	P
5	Requirements		--
5.1	General		P
5.1.1	Materials and construction		P
5.1.2	Design		P
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides		P
	Medical face mask may have different shapes and constructions as well as additional features such as a face shield(to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	Type II; to enhance fit by conforming to the nose contours	P
5.2	Performance requirements		P
5.2.1	General		P
	All tests shall be carried out on finished products or samples cut from finished products.		P
5.2.2	Bacterial filtration efficiency (BFE)	Sample 1: 98.6% Sample 2: 98.8% Sample 3: 98.8% Sample 4: 99.2% Sample 5: 99.3% Sample 6: 99.2%	P
5.2.3	Breathability	Sample 1: 28.4Pa/cm^2 Sample 2: 28.0Pa/cm^2 Sample 3: 27.8Pa/cm^2 Sample 4: 27.5Pa/cm^2 Sample 5: 26.1Pa/cm^2 Sample 6: 27.8Pa/cm^2	P
5.2.4	Splash resistance	Not required	P
5.2.5	Microbial cleanliness (Bioburden)	Sample 1: 17cfu/g Sample 2: 21cfu/g Sample 3: 21cfu/g Sample 4: 21cfu/g Sample 5: 20cfu/g Sample 6: 18cfu/g	P
5.2.6	Biocompatibility	classification in EN ISO 10993-1,	P
5.2.7	Summary of performance requirements		P
6	Marking, labelling and packaging		--

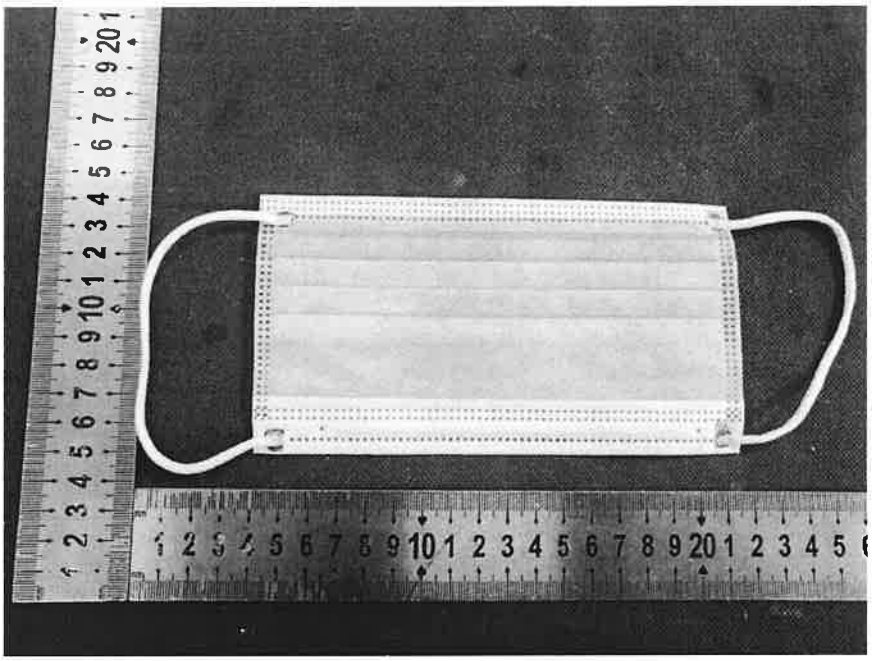
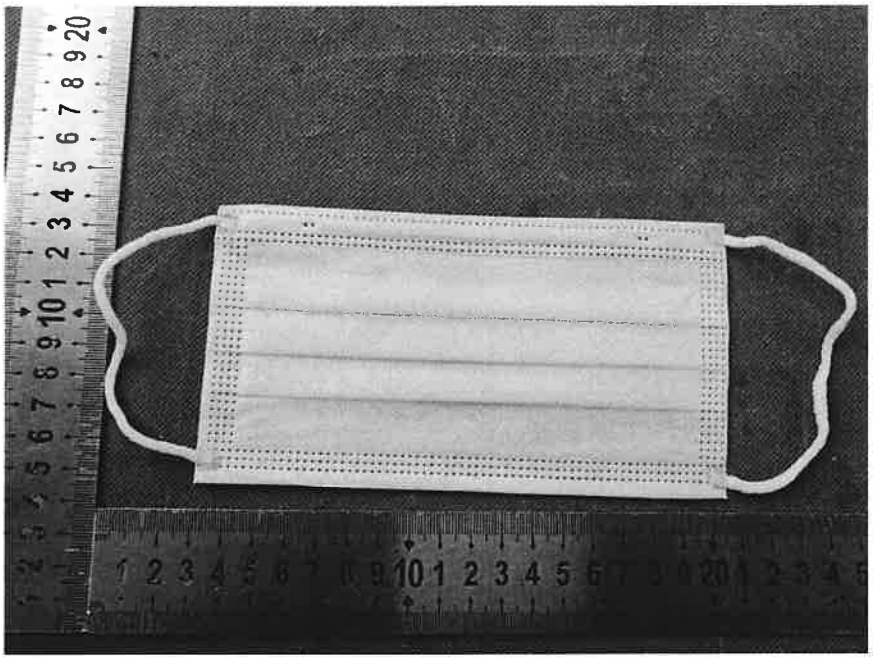
EN 14683			
Clause	Requirement – Test	Result - Remark	Verdict
	Annex I, § 13, of the medical Devices Directive (93/42/EEC) or Annex I § 23, of the Medical Device Regulation(EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied.	See packaging	P
	The following information shall be supplied:		P
	a) number of this European Standard;	EN14683:2019	P
	b) type of mask(as indicated in Table1).	Type II	P
	ENISO 15223-1: 2016 and EN1041: 2008+A1: 2013 should be considered.		P

Table 1 — Performance requirements for medical face masks

Test	Type I [a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm^2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

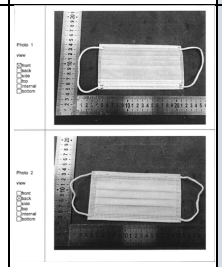
[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

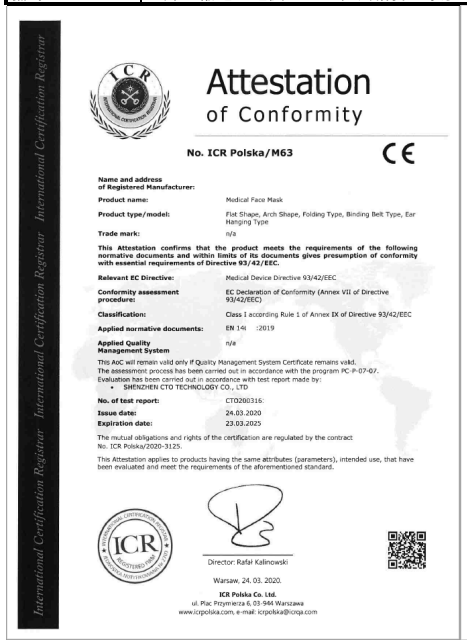
ANNEX A: Photo-documentation

Photo 1 view ☒front ☐back ☐side ☐top ☐internal ☐bottom	
Photo 2 view ☐front ☒back ☐side ☐top ☐internal ☐bottom	

------ End of Report ------

Quotations From Shelly(19/04/2020)

商品名	素材	認証	色	サイズ/cm	梱包	枚数/ケース	L	W	H	グロスウェイト	画像	最小発注数	ケース量	M3	CIF東京 100,000	CIF東京 300,000	CIF東京 500,000	納期
Medical Face Mask Testing BFE≥ 95% 別途資料あり	25gsm PP + 25gsm MB + 25GSM PP	CE	blue or white	17.5*9.5	50 pcs/bag 1 bags/box (size: 200x100x100mm)	2000pcs	53.0cm	42.0cm	34.0cm	9.2kg		50,000	50CTNS	3.78m³	¥45/1枚	¥43/1枚	¥40/1枚	入金後 20～25日
お支払い条件	発注時50%前金、工場出荷時50%、※国内送料は別途																	
有効期限	**安定した為替レートと原材料価格（2%未満の変動）に基づいて、見積もり送付時から7日間**有効																	
備考	※海上輸送・通関処理・社会情勢の状況により、納入時期が前後する可能性が有ります。※商品の発送へ向けた手配は着金後翌日からとなります。※国内送料は別途																	



International Certification Registrar International Certification Registrar International Certification Registrar

Attestation of Conformity

No. ICR Polska/M63

CE

Name and address of Registered Manufacturer:

Product name: Medical Face Mask

Product type/model: Flat Shape, Arch Shape, Folding Type, Binding Belt Type, Ear Hanging Type

Trade mark: n/a

This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.

Relevant EC Directive: Medical Device Directive 93/42/EEC

Conformity assessment procedure: EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)

Classification: Class I according Rule 1 of Annex IX of Directive 93/42/EEC

Applied normative documents: EN 14l :2019

Applied Quality Management System n/a

This AoC will remain valid only if Quality Management System Certificate remains valid.
The assessment process has been carried out in accordance with the program PC-P-07-07.
Evaluation has been carried out in accordance with test report made by:

- SHENZHEN CTO TECHNOLOGY CO., LTD

No. of test report: CTO200316:

Issue date: 24.03.2020

Expiration date: 23.03.2025

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Director: Rafał Kalinowski

Warsaw, 24. 03. 2020.

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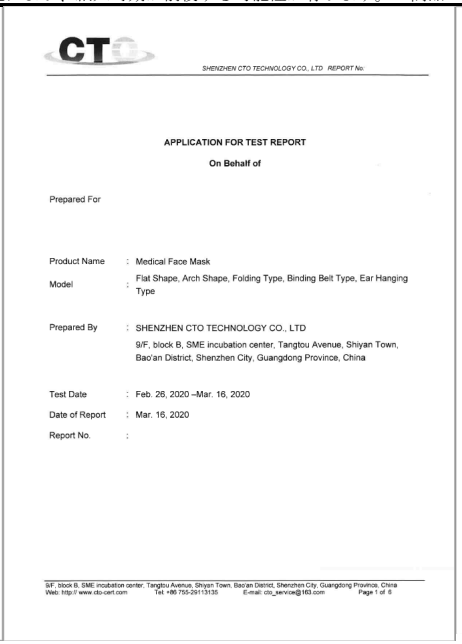


CT

SHENZHEN CTO TECHNOLOGY CO., LTD REPORT No:

APPLICATION FOR TEST REPORT

On Behalf of

Prepared For

Product Name : Medical Face Mask

Model : Flat Shape, Arch Shape, Folding Type, Binding Belt Type, Ear Hanging Type

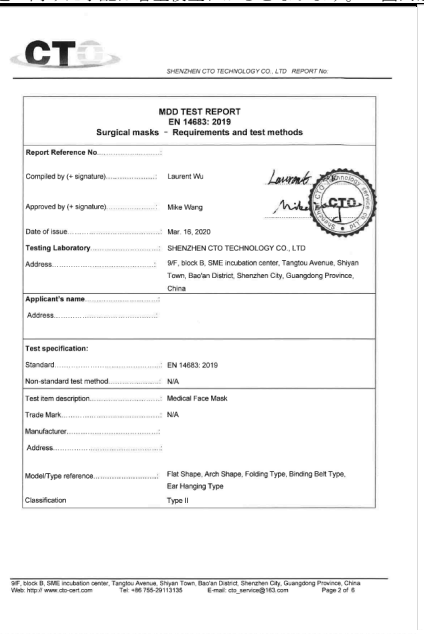
Prepared By : SHENZHEN CTO TECHNOLOGY CO., LTD
9/F, block B, SME incubation center, Tangtou Avenue, Shiyan Town, Bao'an District, Shenzhen City, Guangdong Province, China

Test Date : Feb. 26, 2020 –Mar. 16, 2020

Date of Report : Mar. 16, 2020

Report No. :

9/F, block B, SME incubation center, Tangtou Avenue, Shiyan Town, Bao'an District, Shenzhen City, Guangdong Province, China
Web: http:// www.cto-cert.com Tel: +86 755-29113135 E-mail: cto_service@163.com Page 1 of 6



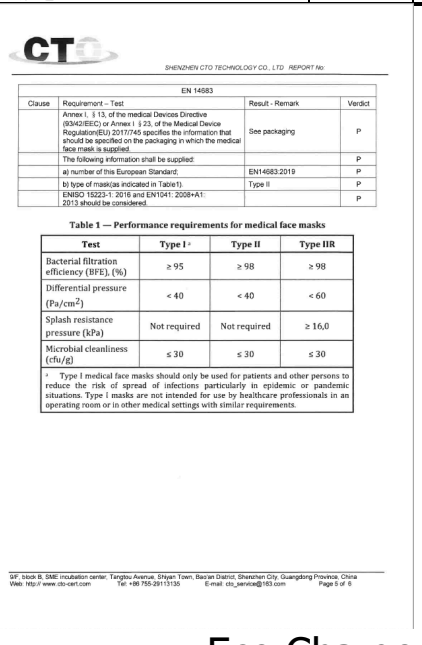
CT

SHENZHEN CTO TECHNOLOGY CO., LTD REPORT No:

MDD TEST REPORT
EN 14683: 2019
Surgical masks - Requirements and test methods

Report Reference No.	
Compiled by (+ signature)	Laurent Wu
Approved by (+ signature)	Mike Wang
Date of issue	Mar. 16, 2020
Testing Laboratory	SHENZHEN CTO TECHNOLOGY CO., LTD
Address	9/F, block B, SME incubation center, Tangtou Avenue, Shiyan Town, Bao'an District, Shenzhen City, Guangdong Province, China
Applicant's name	
Address	
Test specification:	
Standard	EN 14683: 2019
Non-standard test method	N/A
Test item description	Medical Face Mask
Trade Mark	N/A
Manufacturer	
Address	
Model/Type reference	Flat Shape, Arch Shape, Folding Type, Binding Belt Type, Ear Hanging Type
Classification	Type II

9/F, block B, SME incubation center, Tangtou Avenue, Shiyan Town, Bao'an District, Shenzhen City, Guangdong Province, China
Web: http:// www.cto-cert.com Tel: +86 755-29113135 E-mail: cto_service@163.com Page 2 of 6



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EN 14683			
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Eco Charge Japane Co.,LTD