Manufacturer:

Name: Ningbo Green Textile Co., Ltd.

Add: No.498,3rd Xingci Road, Hangzhou Bay New Zone, Ningbo, Zhejiang, China 315336

Zip Code: 315300

Tel: 0574-63529560

Fax: 0574-63529560

European Representative:

CMC Medical Devices & Drugs S.L

C/Horacio Lengo Nº 18

CP 29006, Málaga-Spain

Tel: +34951214054

Fax: +34952330100

email - info@cmcmedicaldevices.com

Product Name: Disposable Face Mask

Model/size:

Model	Size
NB GREEN2020-12	175mm*95mm (±5mm)

Classification and relevant Rule of MDD: class I, MDD 93/42/EEC Annex IX, Rule 1

Different models depend on the customer's specific requirements and no clinical manifestation difference.

The UMDNS code: 12458

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the prmises of the manufacturer. Ningbo Green Textile Co., Ltd. is exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES (MDD 93/42/EEC)

CE

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

produced devices.

The above mention declaration of conformity is exclusively under the responsibility of

Company: Ningbo Green Textile Co., Ltd.

Address: No.498,3rd Xingci Road, Hangzhou Bay New Zone, Ningbo, Zhejiang, China 315336

Ningbo 2020-05-16

Place, date

Zurong Gu 宁 极

Legally binding signature, Function

NINGBO GREEN TEXTILE CO., LTD 绿色纺织品有限公司 3302820209765

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/19052020.9

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Ningbo Green Textile Co., Ltd.
No.498,3rd Xingci Road, Hangzhou Bay New Zone, Ningbo, Zhejiang, China

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/903/2020**

CE

Issued on: 19/05/2020

Valid until: 18/05/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE

ANNEX I Medical Device Products

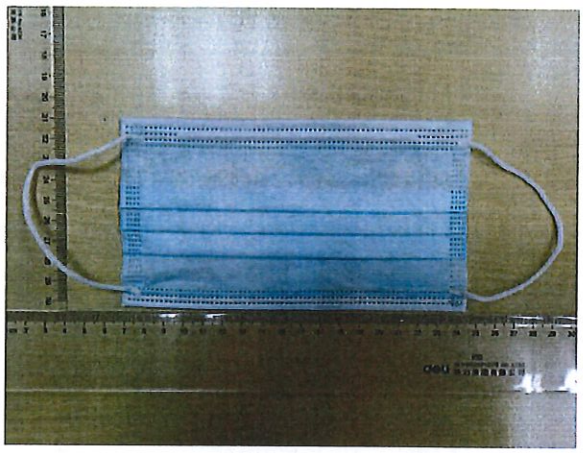
Surgical mask

Disposable Face Mask

CE

Prüfbericht-Nr.: *Test Report No.:*	**60370782 001**	**Auftrags-Nr.:** *Order No.:*	**244235774**	Seite 1 von 14 *Page 1 of 14*
Kunden-Referenz-Nr.: *Client Reference No.:*	**2254343**	**Auftragsdatum:** *Order date:*	**08.05.2020**	
Auftraggeber: *Client:*	**Ningbo Green Textile Co., Ltd** No. 498, 3rd Xingci Road, Hangzhou Bay New Zone, Ningbo, Zhejiang, China			
Prüfgegenstand: *Test item:*	**Disposable Medical Face Mask**			
Bezeichnung / Typ-Nr.: *Identification / Type No.:*	**Green2020-12**			
Auftrags-Inhalt: *Order content:*	**Type test**			
Prüfgrundlage: *Test specification:*	**EN 14683:2019+AC:2019 (except for Clause 5.2.6 Biocompatibility)**			

Wareneingangsdatum: *Date of receipt:*	09.05.2020
Prüfmuster-Nr.: *Test sample No.:*	A002819135-001
Prüfzeitraum: *Testing period:*	11.05.2020 to 26.05.2020
Ort der Prüfung: *Place of testing:*	See page 3
Prüflaboratorium: *Testing laboratory:*	TÜV Rheinland (Shanghai) Co., Ltd.
Prüfergebnis*: *Test result*:*	Pass



geprüft von / *tested by:*

16.06.2020 Rainbow Pan/PE

Datum *Date*	Name/Stellung *Name/Position*	Unterschrift *Signature*

kontrolliert von / *reviewed by:*

16.06.2020 Xiaojun Ding/Reviewer Xiaojun Ding

Datum *Date*	Name/Stellung *Name/Position*	Unterschrift *Signature*

Sonstiges / *Other:*

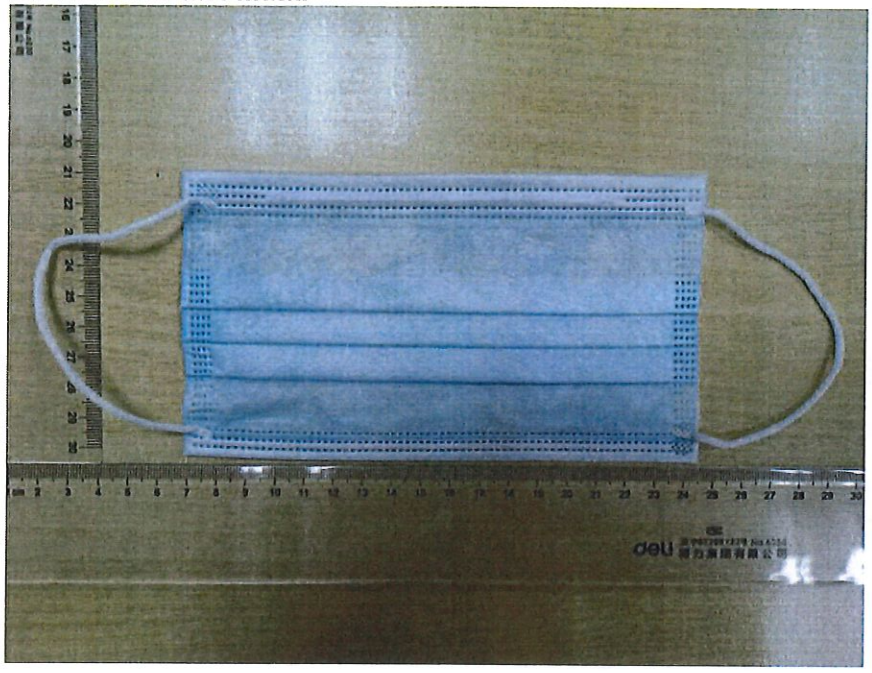
The test report consists of EN 14683 test report including this cover page (14 pages).
Clause 5.2.6 Biocompatibility is not evaluated in this report.

Zustand des Prüfgegenstandes bei Anlieferung: Prüfmuster vollständig und unbeschädigt
Condition of the test item at delivery: *Test item complete and undamaged*

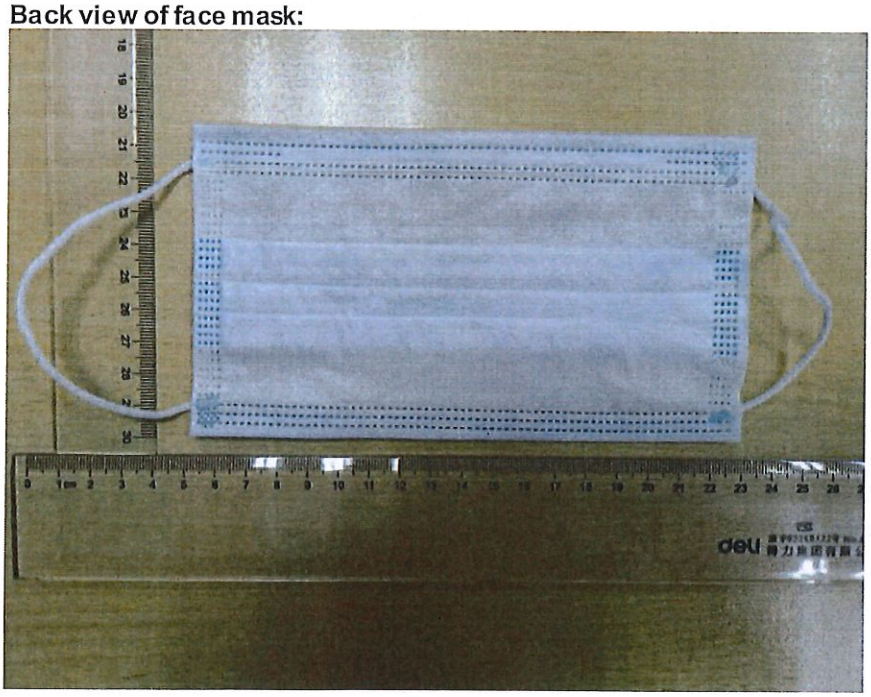
* Legende:	1 = sehr gut	2 = gut	3 = befriedigend	4 = ausreichend	5 = mangelhaft
	P(ass) = entspricht o.g. Prüfgrundlage(n)		F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	N/A = nicht anwendbar	N/T = nicht getestet
Legend:	*1 = very good*	*2 = good*	*3 = satisfactory*	*4 = sufficient*	*5 = poor*
	P(ass) = passed a.m test specification(s)		*F(ail) = failed a.m test specification(s)*	*N/A = not applicable*	*N/T = not tested*

EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods	
Report Reference No. ..... :	See cover page
Date of issue ..... :	See cover page
Total number of pages ..... :	See cover page
Testing Laboratory ..... :	**TÜV Rheinland (Shanghai) Co., Ltd.**
Address ..... :	No.177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China
Applicant's name ..... :	**Ningbo Green Textile Co., Ltd**
Address ..... :	No. 498, 3rd Xingci Road, Hangzhou Bay New Zone, Ningbo, Zhejiang, China
Test specification:	
Standard ..... :	EN 14683:2019+AC:2019
Test procedure ..... :	Type test
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	EN 14683:2019+AC:2019_A
Test Report Form Originator ..... :	TÜV Rh (SZ)
Master TRF ..... :	2020-03
Test item description ..... :	Disposable Medical Face Mask
Trade Mark ..... :	N/A
Manufacturer ..... :	Same as applicant
Model/Type reference ..... :	Green2020-12
Classification ..... :	Type II

Front view of face mask:

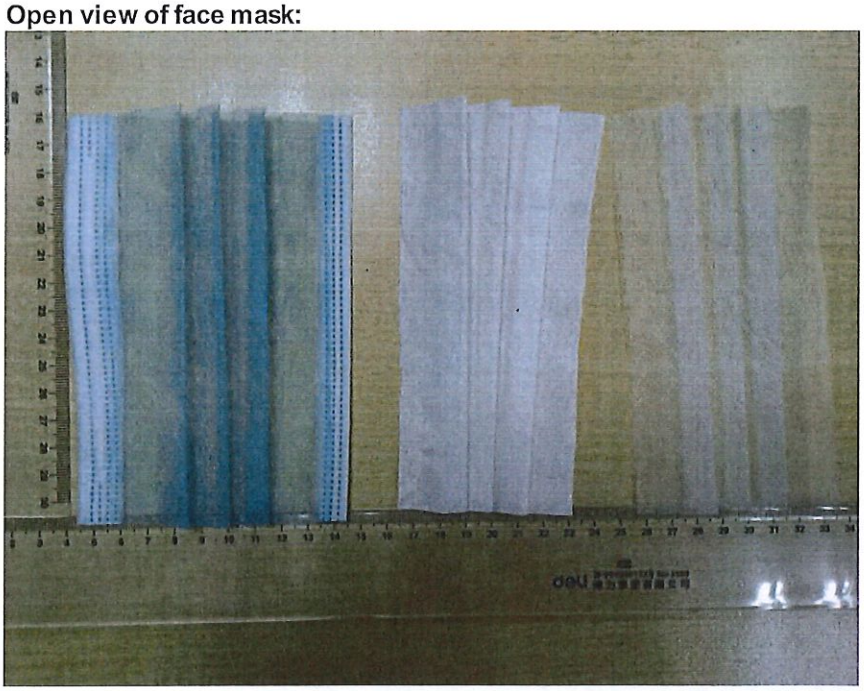


Back view of face mask:



Open view of face mask:

Open view of face mask:



Testing

Date of receipt of test item(s).....: See cover page

Dates of tests performed.....: See cover page

Possible test case verdicts:

- test case does not apply to the test object ..... : N/A
- test object does meet the requirement..... : P (Pass)
- test object was not evaluated for the requirement ... : N/E (collateral standards only)
- test object does not meet the requirement..... : F (Fail)

General remarks:

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests 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 testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Name and address of factory (ies).....: Same as applicant

General product information:

The submitted samples are type II, non-sterile disposable medical mask which is intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

Clause 5.2.6 Biocompatibility is not evaluated in this test report.

The test results are for reference only. Relevant certification may be needed if the mask is intended to be sold in Europe.

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
4	**Classification**		P
	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**		P
5.1	**General**		P
5.1.1	**Materials and construction**		P
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	Composed of a filter layer between layers of fabric	P
	The medical face mask shall not disintegrate, split or tear during intended use.	Complied	P
	In the selection of the filter and layer materials, attention shall be paid to cleanliness.	Considered	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.	Fitted closely over nose	P
	Medical face masks 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).	With a nose bridge	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.	Complied	P
5.2.2	**Bacterial filtration efficiency (BFE)**		P
	When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	See appended table 5.2.2	P
	For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE.	Not thick and rigid mask	N/A

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually.	No such condition	**N/A**
	The lowest performing panel or area shall determine the BFE value of the complete mask		**N/A**
5.2.3	**Breathability**		**P**
	When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.	See appended table 5.2.3	**P**
	If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).	No such respiratory protective device	**N/A**
5.2.4	**Splash resistance**		**N/A**
	When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.	Not Type IIR	**N/A**
5.2.5	**Microbial cleanliness (Bioburden)**		**P**
	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be $\leqslant$ 30 CFU/g tested (see Table 1).	See appended table 5.2.5	**P**
5.2.6	**Biocompatibility**		**N/E**
	According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact.		**N/E**
	The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime.		**N/E**
	The results of testing should be documented according to the applicable parts of the EN ISO 10993 series.		**N/E**
	The test results shall be available upon request.		**N/E**
6	**Marking, labelling and packaging**		**P**
	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.	Checked and complied	**P**
	The following information shall be supplied:		**P**
	a) number of this European Standard;	Marked on the label	**P**

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	b) type of mask (as indicated in Table 1).	Marked on the label	P
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.	Considered	P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

5.2.2	TABLE: Bacterial filtration efficiency (BFE)							P
Batch/ lot no.:	**Test Speci -men no.:**	**Dimension of the test specimen L x W (mm x mm)**	**test area (cm^2)**	**Flow rate (l/min)**	**Mean of the total plate counts of the two positive controls**	**Mean plate count of the negative controls**	**BFE for each test specimen (%)**	**Remarks**
A00281 9135-001	1	175×95	Φ11cm	28.3	1022	0	99.0	P
	2	175×95	Φ11cm	28.3	1022	0	99.4	P
	3	175×95	Φ11cm	28.3	1022	0	99.3	P
	4	175×95	Φ11cm	28.3	1022	0	99.4	P
	5	175×95	Φ11cm	28.3	1022	0	99.3	P

Supplementary information:
1, Each specimen was conditioned at _21±5_ °C and _85±5_ % relative humidity for _4_ h to bring them into equilibrium with atmosphere prior to testing.
2, The side of the test specimen was facing towards the challenge aerosol:__face_
3, The plate count collected by the cascade impactor.

Remark:
Limit value: Type I ≥95%; Type II≥98%; Type IIR ≥98%.

5.2.3	TABLE: Breathability (Differential pressure)				P
Batch/ lot no.:	**Test Specimen number-Test area number**	**Differential pressure for each test area (Pa/cm^2)**	**The averaged differential pressure for each test specimen (Pa/cm^2)**	**Flow rate (l/min)**	**Remarks**
A0028 19135-001	1-1	20.7	20.7	8.0	P
	1-2	21.7		8.0	P
	1-3	20.3		8.0	P
	1-4	21.2		8.0	P
	1-5	19.4		8.0	P
	2-1	22.0	22.5	8.0	P
	2-2	23.3		8.0	P
	2-3	23.8		8.0	P
	2-4	22.1		8.0	P

EN 14683:2019+AC:2019					
Clause	Requirement + Test			Result - Remark	Verdict
	2-5	21.5		8.0	P
	3-1	20.1	20.3	8.0	P
	3-2	20.6		8.0	P
	3-3	21.6		8.0	P
	3-4	20.2		8.0	P
	3-5	19.1		8.0	P
	4-1	24.3	25.2	8.0	P
	4-2	23.8		8.0	P
	4-3	25.8		8.0	P
	4-4	26.0		8.0	P
	4-5	25.9		8.0	P
	5-1	20.7	19.6	8.0	P
	5-2	18.7		8.0	P
	5-3	19.5		8.0	P
	5-4	20.3		8.0	P
	5-5	19.0		8.0	P

Supplementary information:

Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with atmosphere prior to testing.

Remark:

Limit value: Type I <40; Type II <40; Type IIR <60.

5.2.4	TABLE: Splash resistance			N/A
Batch/ lot no.:	**Test mask no.:**	**The material of tested mask**	**Test result (Pass/fail)**	**Remarks**
	1	--	--	--
	2	--	--	--
	3	--	--	--
	4	--	--	--
	5	--	--	--
	6	--	--	--
	7	--	--	--
	8	--	--	--

EN 14683:2019+AC:2019				
Clause	Requirement + Test		Result - Remark	Verdict
	9	--	--	--
	10	--	--	--
	11	--	--	--
	12	--	--	--
	13	--	--	--
	14	--	--	--
	15	--	--	--
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	28	--	--	--
	29	--	--	--
	30	--	--	--
	31	--	--	--
	32	--	--	--

Supplementary information:

1, Each specimen was conditioned at_°C and __ % relative humidity for __h to bring them into equilibrium with atmosphere prior to testing.
2, The description of target area tested:
3, Any technique used to enhance visual detection of synthetic blood:
4, The temperature and relative humidity for testing: _°C and _ %
5, Description of any pre-treatment techniques used:____

Remark:

Limit value: not required for Type I and Type II;
Type IIR face mask should have splash resistance when splash resistance pressure ≥16,0 performed.

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

5.2.5	TABLE: Microbial cleanliness (Bioburden)				P
Batch/ lot no.:	**Mask(under test) no.:**	**Weight of each mask (g)**	**Total bioburden per individual mask (CFU/g)**	**Remarks**	
A002819135-001	**1**	**2.91**	**<1**	**P**	
	2	**2.90**	**<1**	**P**	
	3	**2.94**	**<1**	**P**	
	4	**2.93**	**<1**	**P**	
	5	**2.88**	**<1**	**P**	
Supplementary information: **Remark:** Limit value: Type I ≤30; Type II ≤30; Type IIR ≤30.					

End of test report

CIFRA

C/ Sofía, 3-5
Pol. Ind. Cabezo Beaza
C.P. 30353 CARTAGENA (Spain)
CIF. B30668420

DOCUMENTAZIONE AGGIUNTIVA

TEST REPORT Num.:200271319
DI VERIFICA E CONTROLLO QUALITÀ
REALIZZATO DAL NOSTRO UFFICIO DI GUANGZHOU (CINA)
COMMISSIONATO A GTTC, Nº1 ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P. R. CHINA.

广检集团 GTTC

CMA 170000113982

ilac-MRA CNAS TESTING CNAS L10314

Questo organismo di verifica è riconosciuto a livello internazionale e approvato dal CNAS, l'ente di accreditamento del Governo.

MALGRADO NON SIA OBBLIGATORIO, LA NOSTRA AZIENDA EFFETTUA RIPETUTE VERIFICHE PER GARANTIRE L'AUTENTICITÁ DELLA MERCE E IL RISPETTO SCRUPOLOSO DELLE NORME EUROPEE.

广检集团 —GTTC—

CMA 170000113982 Jac MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L10314

TEST REPORT (Electronic version)

扫码下载报告

VERIFICATION WEBSITE: www.gttc.net.cn

VERIFICATION CODE: DKER-4700-34

No:200271319

ISSUE DATE:2020-09-05

APPLICANT: CIFRA GUANGZHOU OFFICE
ADDRESS: ROOM 2001, NORTH TOWER, TIMES NEW WORLD CENTER, 2193 GUANGYUAN EAST ROAD, TIANHE DISTRICT, GUANGZHOU

INFORMATION CONFIRMED BY APPLICANT:

DISPOSABLE MEDICAL MASK(NON-STERILE)

QUANTITY: 10 PIECES

MODEL: CV-43

DATE RECEIVED/DATE TEST STARTED: 2020-08-29

CONCLUSION:

BACTERIAL FILTRATION EFFICIENCY	M

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT
"---" -NO COMMENT

REMARK:
ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).
COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.
THE EXPERIMENT WAS CARRIED OUT AT No.1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P.R.CHINA.

APPROVED BY: 郭子山

ZiShan Guo SENIOR ENGINEER

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

总部:广州市番禺区珠江路1号
花都实验室:广州市花都区狮岭镇旗岭河滨西路1号

电话:020-61994598/61994599
电话:020-37721161/66348638

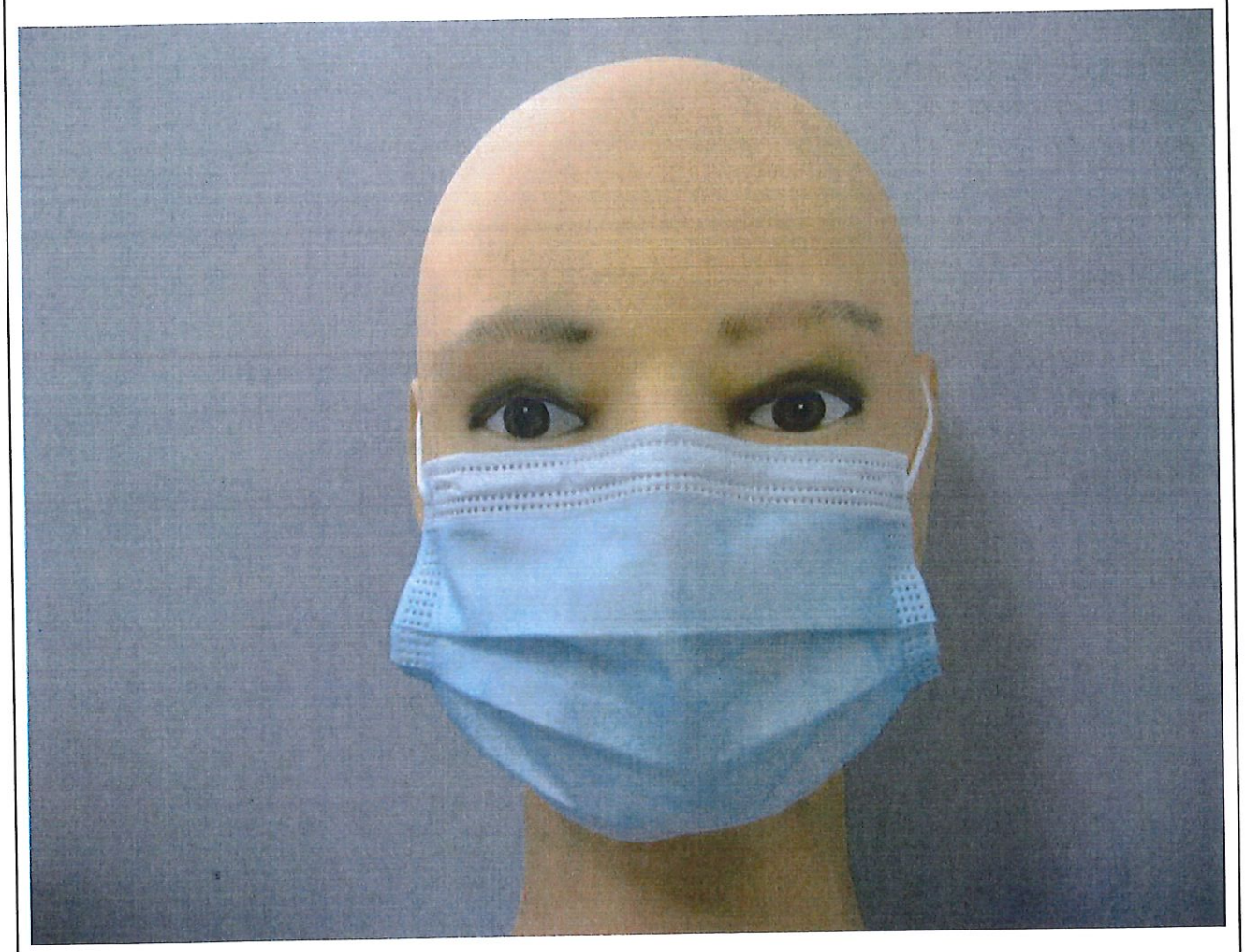
广检集团
GTTC

170000113982

TEST REPORT

(Electronic version)

No:200271319



PAGE 2 OF 3

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

总部:广州市番禺区珠江路1号
花都实验室:广州市花都区狮岭镇旗岭河滨西路1号

电话:020-61994598/61994599
电话:020-37721161/66348638

TEST REPORT

(Electronic version)

No:200271319

BACTERIAL FILTRATION EFFICIENCY(%)

(YY 0469-2011 ANNEX B, TEST BACTERIA: STAPHYLOCOCCUS AUREUS ATCC 6538, TEST AREA: 49cm^2, FLOW RATE: 28.3L/min, MEAN PARTICLE SIZE: 3.0μm, RESULT OF THE POSITIVE CONTROL: 1.9×10^3 CFU, RESULT OF THE NEGATIVE CONTROL: <1CFU)

		REQUIREMENT
BFE_1	99.7	≥95
BFE_2	99.6	(YY/T 0969-2013)
BFE_3	99.3	

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

———End of Report———

总部:广州市番禺区珠江路1号
花都实验室:广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161/66348638