EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/28102020.2

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

Baoji Taidakang Medical Technology Co., Ltd
No.2 Workshop, Tianwang Town, Baoji High-Tech Development Zone,
Shanxi Province, 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/2476/2020**

CE

Issued on: 28/10/2020 Valid until: 27/10/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE

ANNEX I Medical Device Products

Protective Face Mask for Medical Use

Surgical Mask

Single-Use Medical Face Mask

CE

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: BAOJI TAIDAKANG MEDICAL TECHNOLOGY CO., LTD
No.2 workshop in the courty of Shaanxi Taihua Logistics Industry Co., Ltd.
Tianwang Town
Baoji High-tech Development Zone
Shaanxi
721305
China

宝鸡泰达康医疗科技有限公司
中国
陕西省
宝鸡市
高新开发区
天王镇
陕西泰华物流产业有限公司院内2号厂房
邮编：721305

Holds Certificate No: **MD 730516**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The manufacture and distribution of Protective Face Mask For Medical Use, Surgical Mask and Single-Use Medical Face Mask.
医用防护口罩、外科口罩和一次性使用医用口罩的制造和分销。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-09-11
Latest Revision Date: 2020-09-11

Effective Date: 2020-09-11
Expiry Date: 2023-09-10

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EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 730518 R000

Manufacturer: BAOJI TAIDAKANG MEDICAL TECHNOLOGY CO., LTD

Address:
No.2 workshop in the courty
of Shaanxi Taihua Logistics
Industry Co., Ltd.
Tianwang Town
Baoji High-tech Development Zone
Shaanxi
721305
China

Single Registration Number: Not Available

EU Authorised Representative: CMC Medical Devices & Drugs S.L.

Address:
C/ Horacio Lengo Nº18
CP 29006
Málaga
Spain

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-10-01** Date: **2020-10-01** Expiry Date: **2025-09-30**

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EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 730518 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Protective Face Mask For Medical Use	Class Is
Surgical Mask	Class Is
Single-Use Medical Face Mask	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

First Issued: **2020-10-01** Date: **2020-10-01** Expiry Date: **2025-09-30**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 730518 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
Current	3222026	First Issue.

First Issued: **2020-10-01** Date: **2020-10-01** Expiry Date: **2025-09-30**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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中国认可
国际互认
检测
TESTING
CNAS L0599

BAOJI TAIDAKANG MEDICAL TECHNOLOGY CO.,LTD.
NO.2 WORKSHOP, TIANWANG TOWN, BAOJI HI-TECH DEVELOPMENT ZONE, SHAANXI PROVINCE, CHINA

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

Sample Description	:	(A)Protective Face Mask For Medical Use
Sample Color	:	(A)White
Lot No.	:	T20200926
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Oct 29, 2020
Testing Period	:	Nov 02, 2020 - Nov 12, 2020
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 / Hailian Xuan (Authorized Signatory)

检验检测专用章
Inspection & Testing Services
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.
Testing Center

3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
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

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^2
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	:	~189mm x 155mm
Positive Control Average	:	2451CFU
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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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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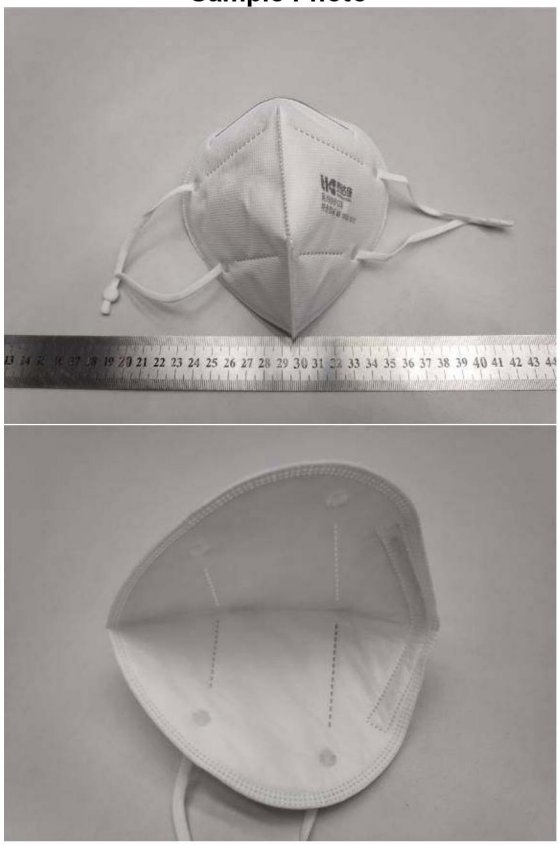
Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	6.51	3	0.46
2#	6.51	21	3.23
3#	6.39	21	3.29
4#	6.41	6	0.94
5#	6.47	21	3.25

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

Sample Photo



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.

End of Report

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Prüfbericht-Nr.: *Test Report No.*:	**60373866 001**	**Auftrags-Nr.** *Order No.*:	**168264851**	Seite 1 von 12 *Page 1 of 12*
Kunden-Referenz-Nr.: *Client Reference No.*:	N/A	**Auftragsdatum:** *Order date*:	May 14, 2020	
Auftraggeber: *Client*:	BAOJI TAIDAKANG MEDICAL TECHNOLOGY CO., LTD. NO. 2 WORKSHOP, TANWANG TOWN, BAOJI HIGH-TECH DEVELOPMENT ZONE, Baoji, Shaanxi, 721305, P.R. China			
Prüfgegenstand: *Test item*:	Protective Face Mask For Medical use			
Bezeichnung / Typ-Nr.: *Identification / Type No.*:	15.5cm×10cm			
Auftrags-Inhalt: *Order content*:	Type test			
Prüfgrundlage: *Test specification*:	EN 14683:2019+AC:2019 except for clause 5.2.6			
Wareneingangsdatum: *Date of receipt*:	May 18, 2020	See Attachment: Photo documentation for details.		
Prüfmuster-Nr.: *Test sample No.*:	T20200513			
Prüfzeitraum: *Testing period*:	May 19, 2020 to Jun. 01, 2020			
Ort der Prüfung: *Place of testing*:	See page 3			
Prüflaboratorium: *Testing laboratory*:	TÜV Rheinland (Shenzhen) Co., Ltd.			
Prüfergebnis*: *Test result**:	Pass			

geprüft von / *tested by*:

Lucy Jiang

Jun. 03, 2020 Lucy Jiang / Assistant Project Engineer

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

kontrolliert von / *reviewed by*:

Angela Chen

Jun. 04, 2020 Angela Chen / Department Manager

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

Sonstiges / *Other*:

- The test report consists of EN 14683 test report including this cover page (12 pages) and attachment: Photo documentation (4 pages).
- The Biocompatibility (clause 5.2.6) is not evaluated in this test 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. ..... :	**60373866 001**
Date of issue..... :	**See cover page**
Total number of pages ..... :	**See cover page**
Testing Laboratory ..... :	**TÜV Rheinland (Shenzhen) Co., Ltd.**
Address..... :	1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Applicant's name ..... :	BAOJI TAIDAKANG MEDICAL TECHNOLOGY CO., LTD.
Address..... :	NO. 2 WORKSHOP, TANWANG TOWN, BAOJI HIGH-TECH DEVELOPMENT ZONE, Baoji, Shaanxi, 721305, P.R. 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..... :	Protective Face Mask For Medical use
Trade Mark..... :	泰达康 TAI DA KANG
Manufacturer ..... :	Same as the applicant
Model/Type reference ..... :	15.5cm×10cm
Classification..... :	Type IIR

List of Attachments (including a total number of pages in each attachment):	
Attachment – Photo Documentation (4 pages)	
Summary of testing:	
Tests performed (name of test and test clause): Construction check according to: Clause 5.1.1 Materials and construction Clause 5.1.2 Design	**Testing location:** **TÜV Rheinland (Shenzhen) Co., Ltd.** 1F East & 2-4F, Cybio Technology Building No.1, No.16 Kejibei 2nd Road, High-Tech Industrial Park North Nanshan District, 518057, Shenzhen, China
Clause 5.2.2 Bacterial filtration efficiency (BFE) Clause 5.2.3 Breathability Clause 5.2.4 Splash resistance Clause 5.2.5 Microbial cleanliness (Bioburden)	**Pony Testing Group Shanghai Co., Ltd.** 2/3/4/6/F., Building 35, No.680, Guiping Road, Xuhui District, Shanghai, China

Copy of marking plate
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks. **See attachment.**

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 the applicant

General product information:

1, The tested medical mask classified as type IIR.
2, The Biocompatibility (clause 5.2.6) is not evaluated in this test report.
3, 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 IIR	**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.	5 ply designed with two layers of polypropylene non-woven fabric, one layer of polypropylene hot air cotton and two layers of polypropylene melt spray cloth.	**P**
	The medical face mask shall not disintegrate, split or tear during intended use.		**P**
	In the selection of the filter and layer materials, attention shall be paid to cleanliness.		**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 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 nose clip	**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)**		**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 such 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.	Same characteristics and same layer-composition declared by manufacturer.	**N/A**
	The lowest performing panel or area shall determine the BFE value of the complete mask	See above	**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).		**N/A**
5.2.4	**Splash resistance**		**P**
	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.	See appended table 5.2.4	**P**
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.	The biocompatibility is not evaluated in this test report.	**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.	See attachment.	**P**
	The following information shall be supplied:		**P**
	a) number of this European Standard;		**P**

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	b) type of mask (as indicated in Table 1).		**P**
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be 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 Specimen 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**
T20200513	**1**	**125×120**	**95.0**	**28.3**	**1044**	**0**	**99.9%**	**--**
	2	**125×120**	**95.0**	**28.3**			**99.9%**	**--**
	3	**124×121**	**95.0**	**28.3**			**99.9%**	**--**
	4	**124×121**	**95.0**	**28.3**			**99.9%**	**--**
	5	**124×120**	**95.0**	**28.3**			**99.9%**	**--**

Supplementary information:
1, Each specimen was conditioned at 21 °C and 85 % 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: the inside of the test specimen.
3, The plate count collected by the cascade impactor.

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

5.2.3	TABLE: Breathability (Differential pressure)	P

Batch/ lot no.:	Test Specimen number- Test area number	Differential pressure for each test area (Pa/cm²)	The averaged differential pressure for each test specimen (Pa/cm²)	Flow rate (l/min)	Remarks
T2020 0513	1-1	25.0	25.2	8.0	--
	1-2	26.8		8.0	--
	1-3	24.6		8.0	--
	1-4	24.3		8.0	--
	1-5	25.2		8.0	--
	2-1	27.4	27.4	8.0	--
	2-2	26.3		8.0	--
	2-3	29.0		8.0	--
	2-4	28.3		8.0	--
	2-5	26.2		8.0	--
	3-1	31.1	31.9	8.0	--
	3-2	32.0		8.0	--
	3-3	32.9		8.0	--
	3-4	33.1		8.0	--
	3-5	30.3		8.0	--
	4-1	39.4	39.3	8.0	--
	4-2	40.7		8.0	--
	4-3	38.6		8.0	--
	4-4	39.4		8.0	--
	4-5	38.3		8.0	--
	5-1	39.4	38.8	8.0	--
	5-2	38.6		8.0	--
	5-3	37.5		8.0	--
	5-4	38.3		8.0	--
	5-5	40.0		8.0	--

Supplementary information:
Each specimen was conditioned at 21 °C and 85 % relative humidity for 4 h to bring them into equilibrium with

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

atmosphere prior to testing.

5.2.4	TABLE: Splash resistance			P
Batch/ lot no.:	**Test mask no.:**	**The material of tested mask**	**Test result (Pass/fail)**	**Remarks**
T20200513	**1**	**See clause 5.1.1**	**Pass**	**--**
	2		**Pass**	**--**
	3		**Pass**	**--**
	4		**Pass**	**--**
	5		**Pass**	**--**
	6		**Pass**	**--**
	7		**Pass**	**--**
	8		**Pass**	**--**
	9		**Pass**	**--**
	10		**Pass**	**--**
	11		**Pass**	**--**
	12		**Pass**	**--**
	13		**Pass**	**--**
	14		**Pass**	**--**
	15		**Pass**	**--**
	16		**Pass**	**--**
	17		**Pass**	**--**
	18		**Pass**	**--**
	19		**Pass**	**--**
	20		**Pass**	**--**
	21		**Pass**	**--**
	22		**Pass**	**--**
	23		**Pass**	**--**
	24		**Pass**	**--**
	25		**Pass**	**--**
	26		**Pass**	**--**
	27		**Pass**	**--**
	28		**Pass**	**--**

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Clause	Requirement + Test	Result - Remark	Verdict

	29		**Pass**	**--**
	30		**Pass**	**--**
	31		**Pass**	**--**
	32		**Pass**	**--**

Supplementary information:

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

2, The description of target area tested: the centre of the specimen.

3, Any technique used to enhance visual detection of synthetic blood: cotton absorbent swab.

4, The temperature and relative humidity for testing: 21 °C and 85 %.

5, Description of any pre-treatment techniques used: N/A.

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**
T20200513	**1**	**3.68**	**4**	**--**
	2	**3.66**	**<1**	**--**
	3	**3.65**	**2**	**--**
	4	**3.67**	**1**	**--**
	5	**3.65**	**2**	**--**

Supplementary information:

End of EN 14683 test report

Product: Protective Face Mask For Medical use

Type Designation: 15.5cm×10cm

Figure 1 Front view of packaging bag
(The marking shown above will be replaced by the marking in Figure 3 in final packaging bag)

Figure 2 Back view of packaging bag

Product: Protective Face Mask For Medical use

Type Designation: 15.5cm×10cm

Figure 3 Front view of packaging bag
(The LOT number and manufacturing date are used in the back of packaging bag)

Product: Protective Face Mask For Medical use

Type Designation: 15.5cm×10cm

Figure 4 View of face mask

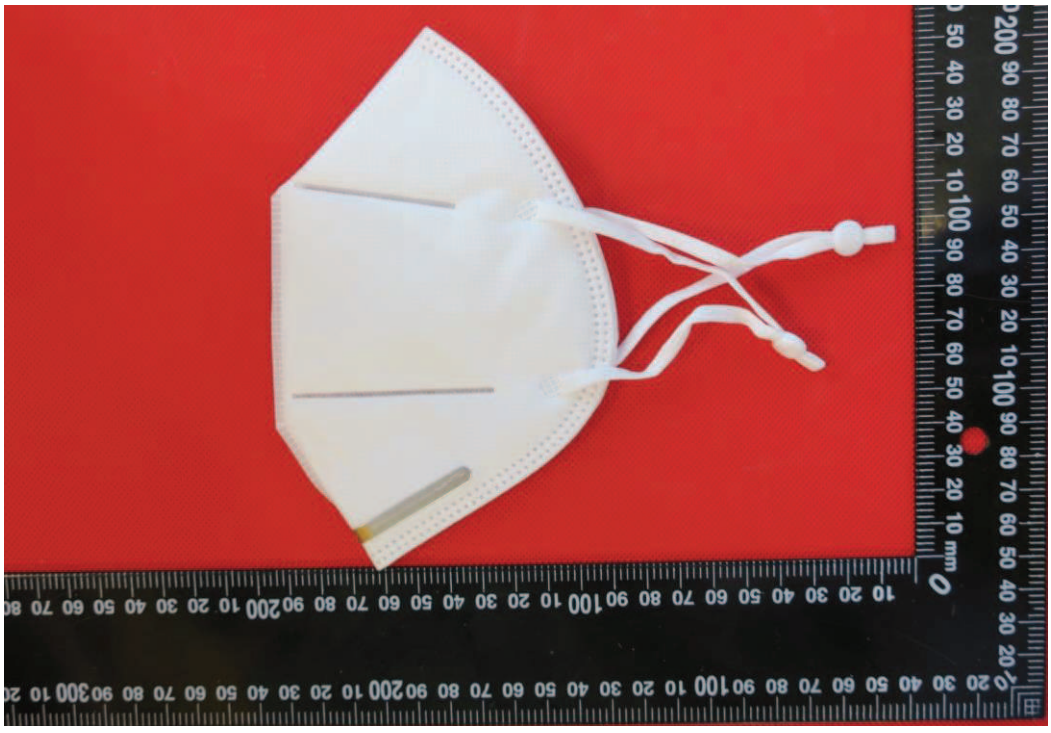

Figure 5 View of face mask

Product: Protective Face Mask For Medical use

Type Designation: 15.5cm×10cm

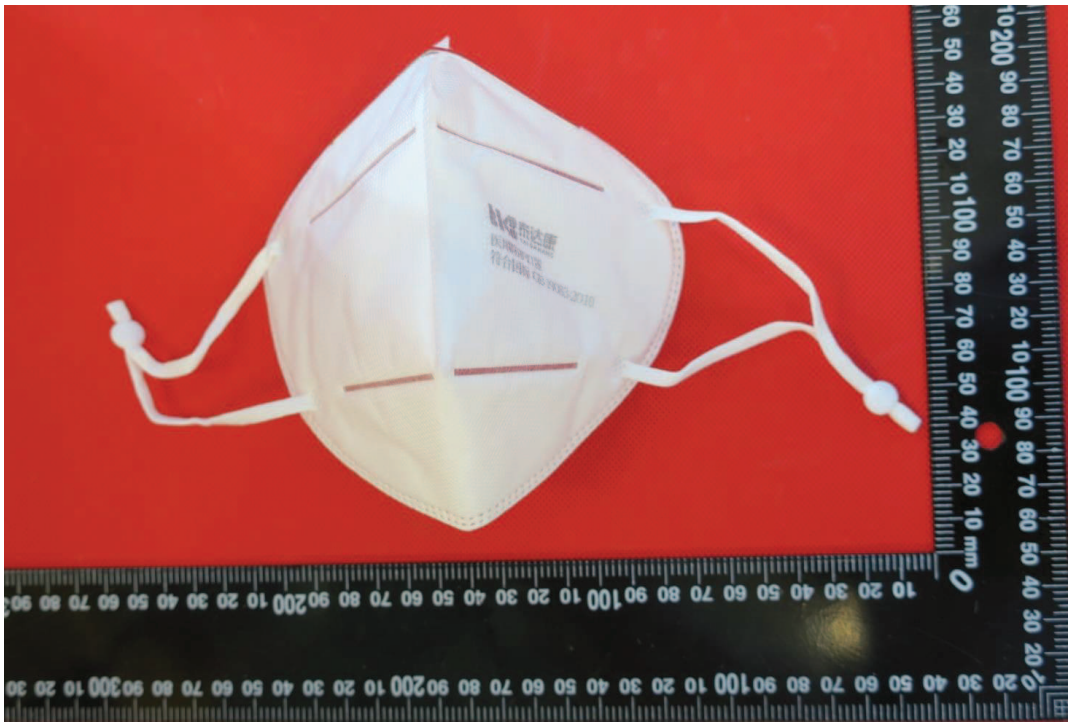

Figure 6 View of face mask

Figure 7 View of face mask (5-ply)

END OF THE PHOTO DOCUMENTATION