

Prüfbericht-Nr.: Test report no.:	CN20H15I 001	Auftrags-Nr.: Order no.:	168288557	Seite 1 von 10 Page 1 of 10
Kunden-Referenz-Nr.: Client reference no.:	N/A	Auftragsdatum: Order date:	2020-11-01	
Auftraggeber: Client:	GUANGDONG KINGFA SCI.&TECH.CO.,LTD. No.28 Delong Avenue, Shijiao Town, Qingcheng District, 511545, Qingyuan City, Guangdong Province, China			
Prüfgegenstand: Test item:	Medical surgical mask			
Bezeichnung / Typ-Nr.: Identification / Type no.:	KF-B P01(R)			
Auftrags-Inhalt: Order content:	Type test			
Prüfgrundlage: Test specification:	Clause 4, clause 5.1, clause 5.2.1, clause 5.2.2, clause 5.2.3, clause 5.2.4 & clause 5.2.5 of EN 14683:2019+AC:2019			
Wareneingangsdatum: Date of sample receipt:	2020-11-02	See Attachment: Photo documentation for details.		
Prüfmuster-Nr.: Test sample no.:	25003320 (Batch code)			
Prüfzeitraum: Testing period:	2020-11-02 – 2020-11-11			
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:	Larry Yuan	genehmigt von: authorized by:	Angela Chen	
Datum: Date:	2020-11-11	Ausstellungsdatum: Issue date:	2020-11-11	
Stellung / Position:	Assistant Project Engineer	Stellung / Position:	Department Manager	
Sonstiges / Other: - The test report consists of EN 14683 test report including this cover page (10 pages) and attachment: Photo documentation (2 pages).				
Zustand des Prüfgegenstandes bei Anlieferung: Condition of the test item at delivery:		Prüfmuster vollständig und unbeschädigt 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				
Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens. This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.				

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EN 14683:2019+AC: 2019 Medical face masks — Requirements and test methods	
Report Reference No. :	CN20H15I 001
Date of issue :	See cover page
Total number of pages :	See cover page
Testing Laboratory :	TÜV Rheinland (Shenzhen) Co., Ltd.
Address :	1601 R&D Room, 1602-1604, 17-18F, Building 7 Site C, Vanke Cloud City Phase I, Xingke First Street, Xili Street, Xili Community, Nanshan District, Shenzhen 518052, P.R. China
Applicant's name	GUANGDONG KINGFA SCI.&TECH.CO.,LTD.
Address :	No.28 Delong Avenue, Shijiao Town, Qingcheng District, 511545, Qingyuan City, Guangdong Province, China
Test specification:	
Standard :	Clause 4, clause 5.1, clause 5.2.1, clause 5.2.2, clause 5.2.3, clause 5.2.4 & clause 5.2.5 of EN 14683:2019+AC:2019
Test procedure :	Type test
Non-standard test method :	N/A
Test Report Form No. :	EN 14683:2019+AC:2019_B
Test Report Form Originator :	TÜV Rh (SZ)
Master TRF :	2020-09
Test item description :	Medical surgical mask
Trade Mark :	KINGFA
Manufacturer	Same as the applicant
Model/Type reference :	KF-B P01(R)
Classification :	Type IIR

List of Attachments (including a total number of pages in each attachment):	
Attachment – Photo Documentation (2 pages)	
Summary of testing:	
Tests performed (name of test and test clause):	Testing location:
Construction check according to: Clause 5.1.1 Materials and construction Clause 5.1.2 Design	TÜV Rheinland (Shenzhen) Co., Ltd. 1601 R&D Room, 1602-1604, 17-18F, Building 7 Site C, Vanke Cloud City Phase I, Xingke First Street, Xili Street, Xili Community, Nanshan District, Shenzhen 518052, P.R. 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)	TÜV Rheinland (Shanghai) Co., Ltd. Shanghai TÜV Rheinland Building, No.177, Lane 777, West Guangzhong Road, Jing'an District, Shanghai, 200072, P.R. China

Copy of marking plate
<p>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.</p> <p>Not evaluated in this test report</p>

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 <input type="checkbox"/> comma / <input checked="" type="checkbox"/> 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 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.	It is made up of two layers non-woven, one layer filtration material (melt-blown fabric), mask belt and nose clip.	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 ≤ 30 CFU/g tested (see Table 1).	See appended table 5.2.5	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
2500332 0	1	100 x100	50	28.3	2174	<1	99.9	--
	2	100 x100	50	28.3			99.9	--
	3	100 x100	50	28.3			99.7	--
	4	100 x100	50	28.3			99.9	--
	5	100 x100	50	28.3			99.9	--
Supplementary information:								
1, Each specimen was conditioned at <u> 21 </u> °C and <u> 85 </u> % relative humidity for <u> 4 </u> h to bring them into equilibrium with atmosphere prior to testing.								
2, The side of the test specimen was facing towards the challenge aerosol: <u> Face side of mask </u>								

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/cm ²)	The averaged differential pressure for each test specimen (Pa/cm ²)	Flow rate (l/min)	Remarks
250033 20	1-1	36.1	36.7	8.0	--
	1-2	35.5		8.0	--
	1-3	37.2		8.0	--
	1-4	38.7		8.0	--
	1-5	36.2		8.0	--
	2-1	36.9	35.8	8.0	--
	2-2	33.8		8.0	--
	2-3	37.0		8.0	--
	2-4	38.9		8.0	--
	2-5	32.6		8.0	--
	3-1	36.2	36.7	8.0	--
	3-2	35.6		8.0	--
	3-3	38.5		8.0	--
	3-4	38.6		8.0	--
	3-5	34.5		8.0	--
	4-1	39.0	38.6	8.0	--
	4-2	38.6		8.0	--
	4-3	39.1		8.0	--
	4-4	40.9		8.0	--
	4-5	35.6		8.0	--
5-1	38.4	37.5	8.0	--	
5-2	38.3		8.0	--	
5-3	36.5		8.0	--	
5-4	39.7		8.0	--	
5-5	34.4		8.0	--	
Supplementary information:					
Each specimen was conditioned at <u>21</u> °C and <u>85</u> % relative humidity for <u>4</u> h to bring them into equilibrium with atmosphere prior to testing.					

EN 14683:2019+AC:2019				
Clause	Requirement + Test		Result - Remark	Verdict
5.2.4	TABLE: Splash resistance			P
Batch/ lot no.:	Test mask no.:	The material of tested mask	Test result (Pass/fail)	Remarks
25003320	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	--
	29		Pass	--

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	30	Pass	--
	31	Pass	--
	32	Pass	--
Supplementary information: 1, Splash resistance pressure ≥ 16.0 kPa. 2, Each specimen was conditioned at <u>21</u> °C and <u>85</u> % relative humidity for <u>4</u> h to bring them into equilibrium with atmosphere prior to testing. 3, The description of target area tested: <u>The center of outside</u> 4, Any technique used to enhance visual detection of synthetic blood: <u>none</u> 5, The temperature and relative humidity for testing: <u>21</u> °C and <u>85</u> % 6, Description of any pre-treatment techniques used: <u>constant temperature and humidity machine was used</u>			

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)	Total bioburden per gram (CFU/g)	Remarks
25003320	1	3.48	27	7.75	--
	2	3.49	30	8.60	--
	3	3.49	27	7.74	--
	4	3.50	24	6.85	--
	5	3.49	33	9.46	--
Supplementary information:					

End of test report

Product: Medical surgical mask

Type Designation: KF-B P01(R)



Figure 1 General view of packaging bag

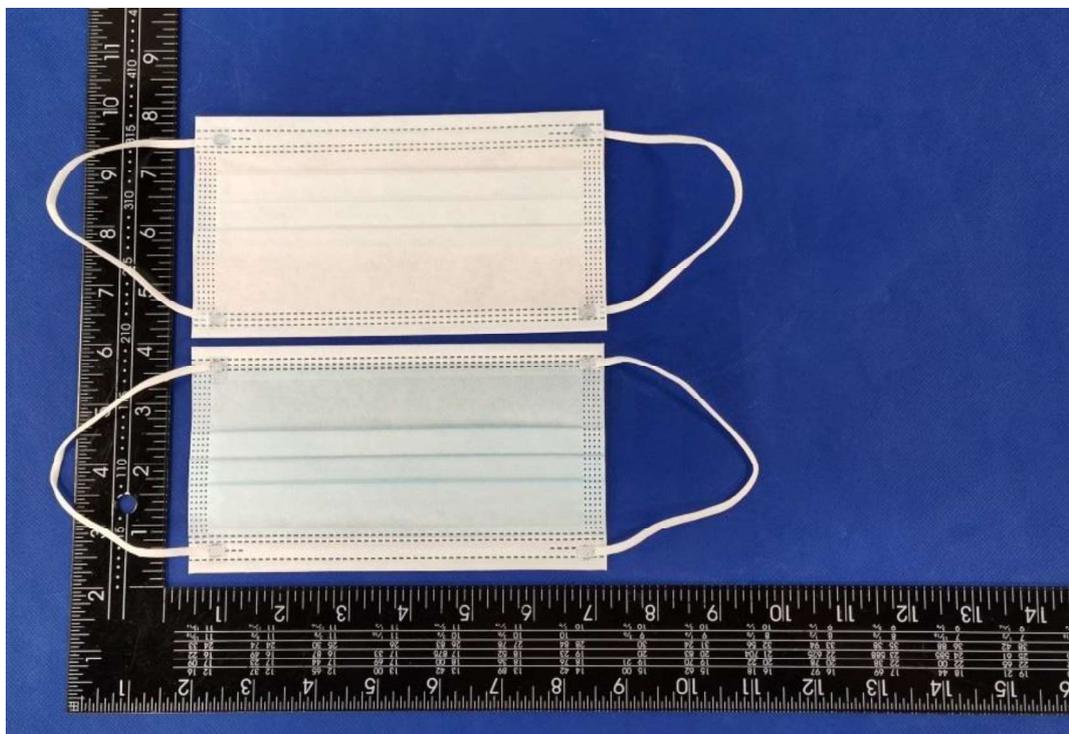


Figure 2 View of medical mask

Product: Medical surgical mask

Type Designation: KF-B P01(R)

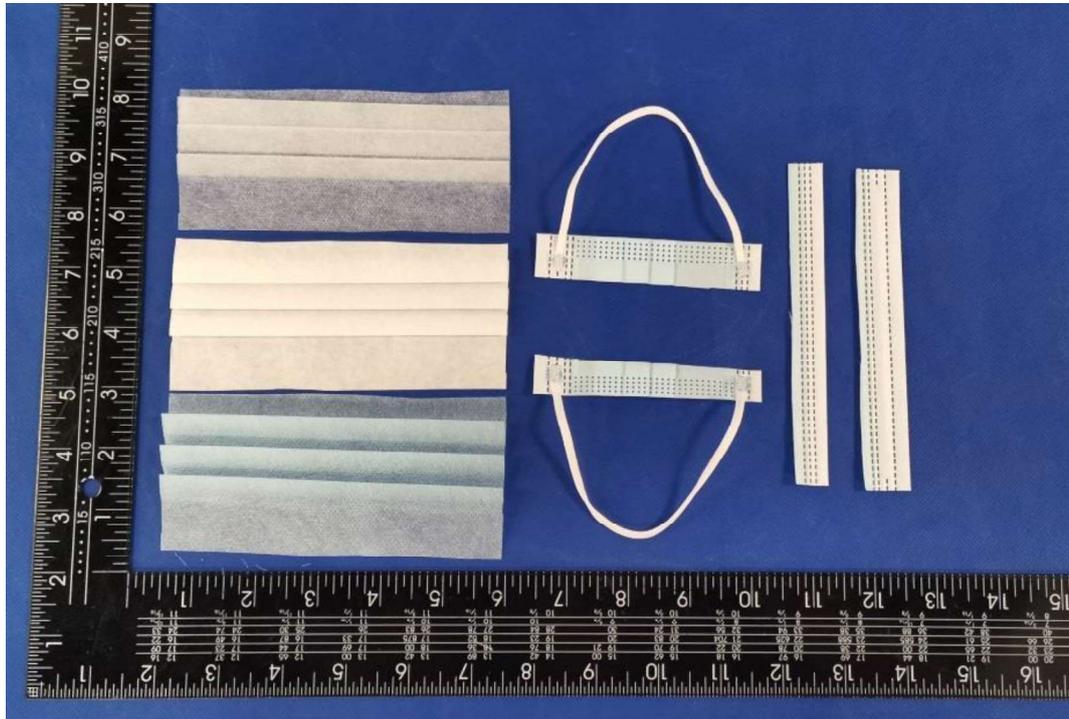


Figure 3 View of mask (3-ply)

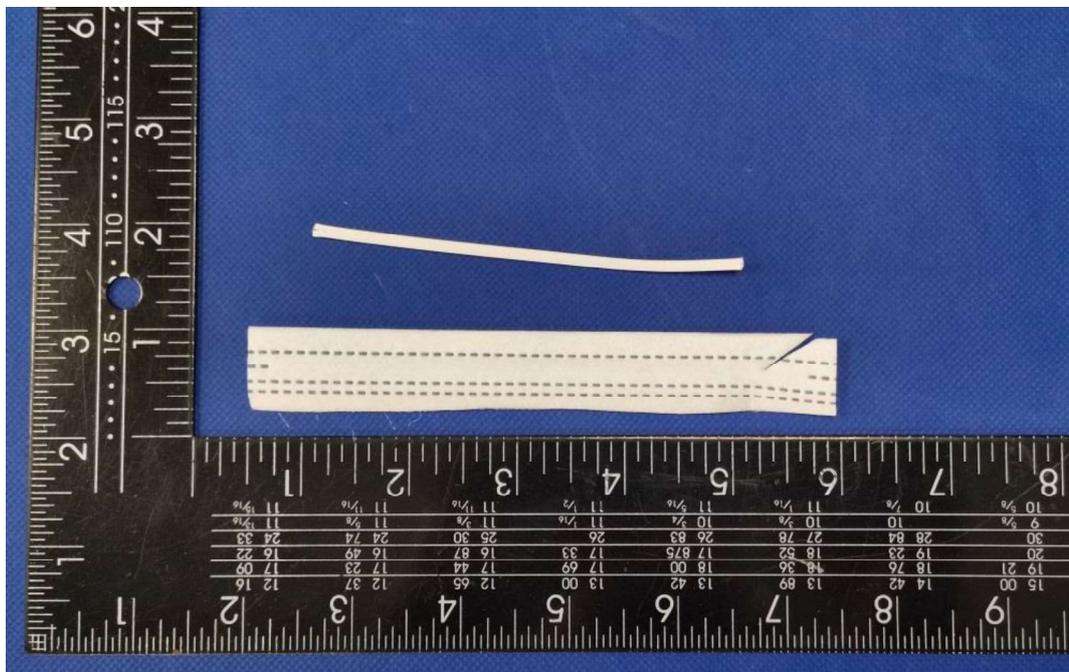


Figure 4 View of nose clip

END OF THE PHOTO DOCUMENTATION