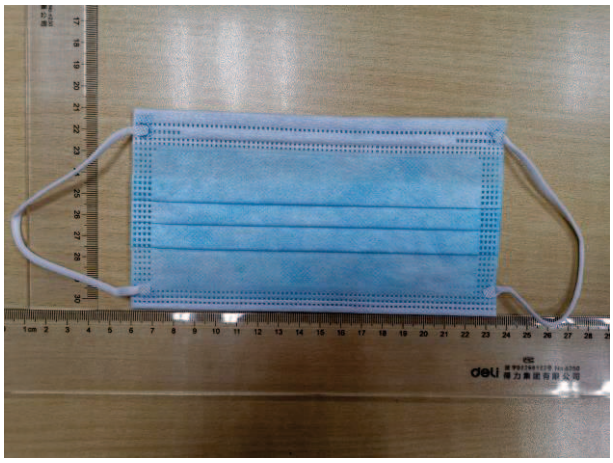
Prüfbericht-Nr.: *Test Report No.:*	**50370080 001**	**Auftrags-Nr.:** *Order No.:*	**244235194**	Seite 1 von 13 *Page 1 of 13*
Kunden-Referenz-Nr.: *Client Reference No.:*	**2159138**	**Auftragsdatum:** *Order date:*	**07.05.2020**	
Auftraggeber: *Client:*	**Changzhou Huankang Medical Device Co., Ltd.** 22 Changhe Road, Changzhou, Jiangsu, China			
Prüfgegenstand: *Test item:*	**Disposable Medical Face Masks**			
Bezeichnung / Typ-Nr.: *Identification / Type No.:*	**HK-Z01**			
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:*	07.05.2020
Prüfmuster-Nr.: *Test sample No.:*	A002822075-001
Prüfzeitraum: *Testing period:*	08.05.2020 to 21.05.2020
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*:

22.05.2020 Rainbow Pan/PE

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

kontrolliert von / *reviewed by*:

22.05.2020 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 (13 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*

TUV Rheinland (Shanghai) Co., Ltd. TÜV Rheinland Building, No. 177, Lane 777, West Guangzhong Road, Jing'an District, Shanghai 200072, P.R. China

Digitally signed by Guțan Ghenadie
Date: 2021.04.22 12:03:22 EEST
Reason: MoldSign Signature
Location: Moldova

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 ..... :	**Changzhou Huankang Medical Device Co., Ltd.**
Address ..... :	22 Changhe Road, Changzhou, Jiangsu, 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 Masks
Trade Mark ..... :	N/A
Manufacturer ..... :	Same as applicant
Model/Type reference ..... :	HK-Z01
Classification ..... :	Type II

List of Attachments (including a total number of pages in each attachment):	
N/A	
Summary of testing:	
Tests performed (name of test and test clause): **Construction check was performed according to:** Clause 5.1.1 Materials and construction; Clause 5.1.2 Design	**Testing location:** **TÜV Rheinland (Shanghai) Co., Ltd.** No.177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China
Other tests were performed: Clause 5.2.2 Bacterial filtration efficiency; Clause 5.2.3 Breathability; Clause 5.2.5 Microbial cleanliness Note: All tests listed as above have been conducted in the competent external lab under the supervision of a TUV engineer.	**Pony Testing Group Shanghai Co.,Ltd.** 2/3/4/6/F., Building 35, No.680, Guiping Road, Xuhui District, Shanghai, China

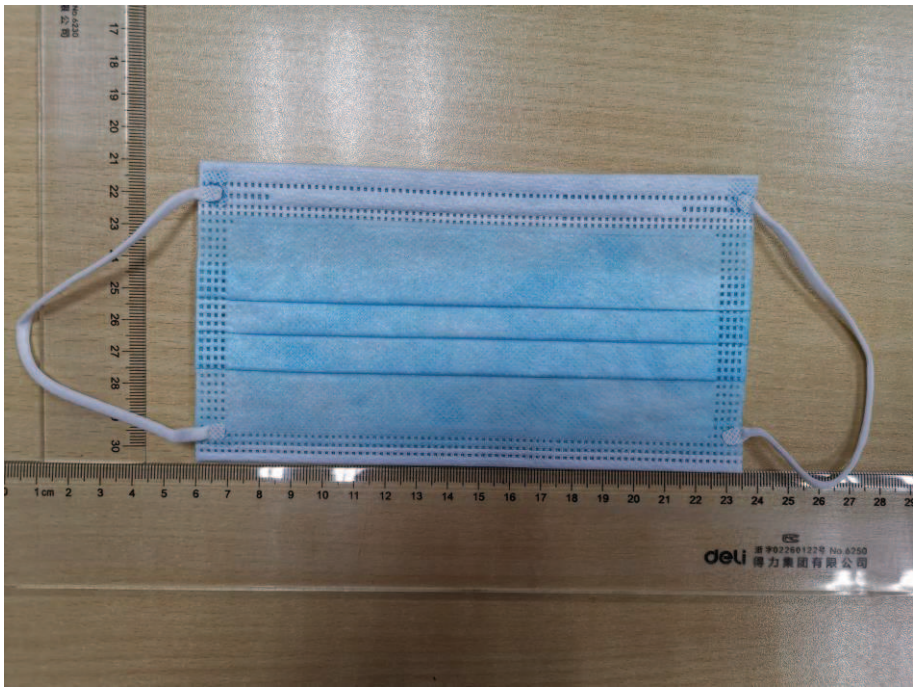
Copy of marking plate

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.

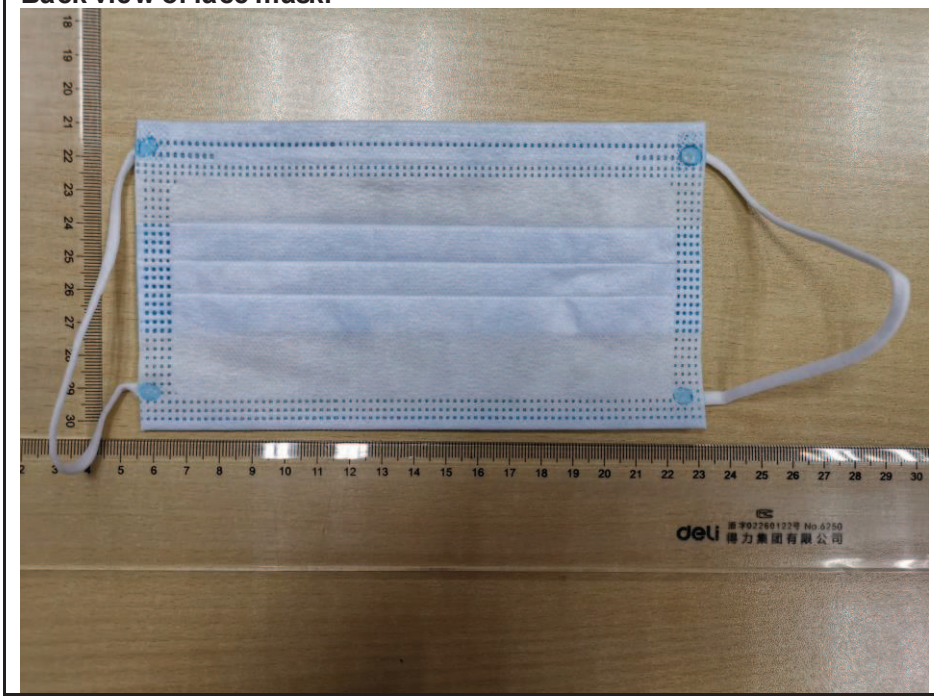
Box:

Remark: According to information from applicant, there are 50pcs medical face masks including in final small package during mass production.

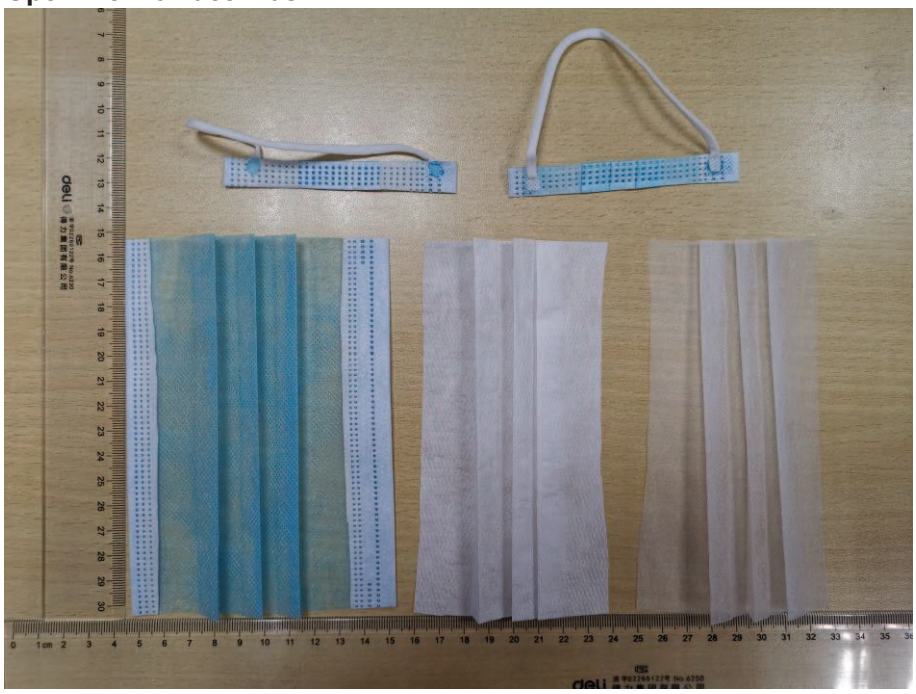
Front view of face mask:



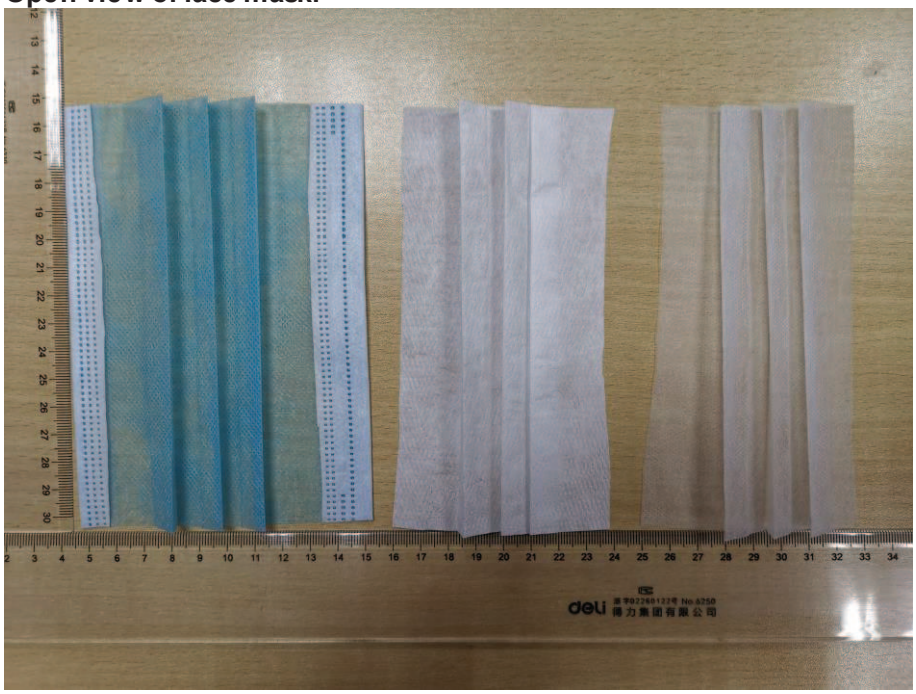
Back view of face mask:



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 face 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
A00282 2075-001	1	175×95	Φ11cm	28.3	1082	0	99.3	P
	2	175×95	Φ11cm	28.3	1082	0	99.0	P
	3	175×95	Φ11cm	28.3	1082	0	99.2	P
	4	175×95	Φ11cm	28.3	1082	0	99.0	P
	5	175×95	Φ11cm	28.3	1082	0	99.1	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_

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 22075-001	1-1	28.8	28.5	8.0	P	
	1-2	27.3		8.0	P	
	1-3	27.9		8.0	P	
	1-4	29.8		8.0	P	
	1-5	28.9		8.0	P	
	2-1	29.7	29.3	8.0	P	
	2-2	29.2		8.0	P	
	2-3	28.3		8.0	P	
	2-4	30.1		8.0	P	

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

	2-5	29.4		8.0	P
	3-1	27.0	27.6	8.0	P
	3-2	27.0		8.0	P
	3-3	28.2		8.0	P
	3-4	28.7		8.0	P
	3-5	27.3		8.0	P
	4-1	25.6	25.9	8.0	P
	4-2	26.3		8.0	P
	4-3	27.6		8.0	P
	4-4	25.0		8.0	P
	4-5	24.9		8.0	P
	5-1	30.4	30.1	8.0	P
	5-2	30.5		8.0	P
	5-3	30.4		8.0	P
	5-4	30.7		8.0	P
	5-5	28.5		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	--	--	--
	16	--	--	--
	17	--	--	--
	18	--	--	--
	19	--	--	--
	20	--	--	--
	21	--	--	--
	22	--	--	--
	23	--	--	--
	24	--	--	--
	25	--	--	--
	26	--	--	--
	27	--	--	--
	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**
A002822075-001	**1**	**3.38**	**＜1**	**P**
	2	**3.39**	**＜1**	**P**
	3	**3.41**	**＜1**	**P**
	4	**3.44**	**＜1**	**P**
	5	**3.36**	**＜1**	**P**
Supplementary information: **Remark:** Limit value: Type I ≤30; Type II ≤30; Type IIR ≤30.				

End of test report