

**Test Report No.:** 178140670a 001

Page 1 of 11

**Client:** **Yancheng Xiangbang Medical Equipment Co., Ltd**  
No 5, Minjiang Rd, Yancheng City, Jiangsu, China

Contact Person: Gardon Guo

**Sample Description As Declared :**

No. Of Sample : 90 Pcs  
Product Description : KN95 Face Mask  
Model No. : XB0116  
Sales Destination(country) : Europe(country name not provided)  
Test type : Partial test  
Product type : Single shift use only  
Claimed Classification : FFP2 NR

**Sample obtaining method:** Sending by customer

**Sample Receiving date:** 2020-05-26

**Delivery condition:** Apparent good, Samples tested as received

**Test Period:** 2020-05-28 to 2020-07-13

**Test specification:**

**Test result:**

Particulate respirator-half facepiece  
EN 149:2001 + A1:2009 Respiratory protective devices - Filtering half masks  
to protect against particles - Requirements, testing, marking^

Please refer to result page

**For and on behalf of**

**TÜV Rheinland / CCIC (Qingdao) Co., Ltd.**



2020-07-14

Alex Zhou / General Manager

Date

Name/Position

*Sample information is provided by customer. Test result is drawn according to the kind and extent of tests performed. This test report relates to the above mentioned 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 safety mark on this or similar products.*

**Material list**

Material	Color	Location
Textile	White	White folding mask

**Note:**

	Shading shows the clauses requested
NRq	The clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing requested was insufficient completely to verify compliance with the clause. Refer to the "result details section for more information.
Fail	Requirement not satisfied. Refer to the "result details section for more information.
NAs	Assessment not carried out.
NAP	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

**Result:**

EN 149:2001+A1:2009 Respiratory protective devices—Filtering half masks to protect against particles—Requirement, testing, marking.

**7.4 Package<sup>^</sup>** **PASS<sup>1</sup>**  
 Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.  
 Note 1: In accordance with the requirement.

**7.5 Material<sup>^</sup>** **PASS<sup>2</sup>**  
 Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.

After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

Note 2: In accordance with the requirement.

Specimens -14, -15, -16 were conditioned in accordance with 8.3.1, None of the specimens conditioned suffered mechanical failure or collapse.

Specimens -01, -02, -03 were conditioned in accordance with 8.3.2, None of the specimens conditioned suffered collapse.

**7.6 Cleaning and disinfecting<sup>^</sup>** **NAP<sup>3</sup>**  
 If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.

With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.

Note 3: Single shift use only.

**7.7 Practical performance^**
**PASS<sup>4</sup>**

The particle filtering half mask shall undergo practical performance tests under realistic conditions

Note 4: No imperfections.

Specimen and subject details:

Specimen	Subject
-41	LCF
-42	YZF

**7.8 Finish of parts^**
**PASS<sup>5</sup>**

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

Note 5: None of the specimens used in limited laboratory testing undertaken showed the evidence of sharp edges or burrs.

**7.9.1 Total inward leakage^**
**PASS<sup>6</sup>**

For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3;

And, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22% for FFP1, 8% for FFP2, 2% for FFP3.

Note 6: 48 out of the 50 individual exercise results were not greater than 11%; 10 of the 10 individual wearer arithmetic means were not greater than 8%. Detailed data are showed below.

Table 7.9.1-A Inward leakage test data

Test specification: EN149-2001 Clause 8.5

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head Up/down(%)	Talk(%)	Walk(%)	Mean(%)
LCF	-41	A.R.	0.8	0.2	0.3	0.3	0.3	0.4
YZF	-42	A.R.	5.9	8.8	11.5	7.5	5.6	7.9
GJB	-43	A.R.	2.5	3.9	5.2	3.3	2.4	3.5
ZH	-44	A.R.	4.8	5.0	6.8	5.8	5.9	5.7
TLX	-45	A.R.	1.8	1.5	2.1	1.2	1.7	1.7
NXL	-04	T.C.	3.0	6.2	3.5	5.0	2.9	4.1
TJ	-05	T.C.	3.4	2.7	3.2	2.5	2.6	2.9
CJW	-06	T.C.	2.0	3.5	4.2	12.3	3.3	5.1
YB	-07	T.C.	7.2	5.7	7.8	6.7	6.7	6.8
TS	-08	T.C.	1.3	2.2	3.1	1.8	1.3	1.9
Maximum permitted			<b>11</b>					<b>8</b>

Table 7.9.1-B Facial dimension

Subject	Face length(mm)	Face width(mm)	Face Depth(mm)	Mouth Width(mm)
LCF	119	165	121	56
YZF	113	151	106	48
GJB	109	154	109	57
ZH	102	152	113	55
TLX	104	153	112	40
NXL	113	147	108	53
TJ	105	151	110	52
CJW	114	147	101	65
YB	112	150	119	66
TS	97	146	102	51

**7.9.2 Penetration of filter material<sup>^</sup>**
**PASS**

The penetration of the filter of the particle filtering half mask shall meet the requirements of below:

Classification	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP 1	≤ 20%	≤ 20%
FFP 2	≤ 6%	≤ 6%
FFP 3	≤ 1%	≤ 1%

Table 7.9.2- Penetration of filter material

Test specification: EN149-2001 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)		Assessment
			After 3 minutes	Max. during exposure	
Sodium chloride test	A.R.	-26	0.87		<b>PASS</b>
		-27	1.02		
		-28	0.95		
	S.W.	-14	0.51		
		-15	0.60		
		-16	0.57		
	M.S. + T.C.	-20	0.91	0.99	
		-21	0.45	0.55	
		-22	0.87	0.94	
Paraffin oil test	A.R.	-29	2.84		
		-30	1.94		
		-31	2.32		
	S.W.	-17	1.19		
		-18	1.95		
		-19	1.87		
	M.S. + T.C.	-23	1.69	4.28	
		-24	1.88	4.49	
		-25	1.74	2.31	
<b>Maximum permitted</b>		<b>6</b>			
Flow conditioning:		Single filter: 95.0 L/min			

**7.10 Compatibility with skin<sup>^</sup> PASS<sup>7</sup>**

Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

Note 7: Specimens -41, -42, -43, -44, -45 (A.R.) and specimens -04, -05, -06, -07, -08 (T.C.) were tested. No irritation or any other adverse effect to health.

**7.11 Flammability<sup>^</sup> PASS**

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

Table 7.11- Flammability

Test specification: EN149-2001 Clause 8.6

Condition	Sample No.	Result	Assessment
A.R.	-32	Burn for 0.3 s	PASS
	-33	Burn for 0.4 s	
T.C.	-09	Burn for 0.5 s	
	-10	Burn for 0.6 s	

**7.12 Carbon dioxide content of the inhalation air<sup>^</sup> PASS**

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).

Table 7.12- Carbon dioxide content of the inhalation air

Test specification: EN149-2001 Clause 8.7

Condition	Sample No.	Result	Assessment
A.R.	-32	0.28%	PASS
	-33	0.29%	
	-34	0.28%	
<b>Maximum permitted</b>		1.0%	

**7.13 Head harness<sup>^</sup> PASS<sup>8</sup>**

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

Note 8: Specimens -41, -42, -43, -44, -45 (A.R.) and specimens -04, -05, -06, -07, -08 (T.C.) were tested. Head harness (ear straps) can be donned and removed easily, adjustable or self-adjusting, and have sufficiently robust to hold the face mask firmly. The product satisfied the total inward leakage requirements. See 7.9.1 for results.

**7.14 Field of vision<sup>^</sup> PASS<sup>9</sup>**

The field of vision is acceptable if determined so in practical performance tests.

Note 9: Specimens -41 and -42 (A.R.) were tested. Pass the practical performance tests and no adverse comments.

**7.15 Exhalation valve<sup>^</sup>**
**NAP**

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.

Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

**7.16 Breathing resistance<sup>^</sup>**
**PASS<sup>10</sup>**

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min or (25 cycles/min x 2.0 l/stroke)
FFP1	0,6	2,1	3,0
FFP2	0,7	2,4	3,0
FFP3	1,0	3,0	3,0

Note 10: FFP2 Filtering face mask. Test result are shown in below Table.

Table 7.16 Breathing resistance (mbar)

Test specification: EN149-2001 Clause 8.9

Specimen	Condition	Inhalation resistance(mbar)		Exhalation resistance(mbar)				
		At 30 l/min	At 95 l/min	Breathing machine(25 cycles/min x 2.0 l/stroke )				
				A	B	C	D	E
-35	A.R.	0.26	0.81	1.66	1.64	1.65	1.67	1.68
-36		0.27	0.89	1.77	1.73	1.71	1.74	1.76
-37		0.25	0.80	1.61	1.62	1.63	1.59	1.58
-11	T.C.	0.28	0.91	1.78	1.74	1.79	1.71	1.80
-12		0.27	0.87	1.71	1.73	1.72	1.71	1.70
-13		0.26	0.81	1.69	1.67	1.68	1.67	1.65
-17	S.W.	0.25	0.80	1.57	1.58	1.54	1.60	1.62
-18		0.28	0.91	1.79	1.74	1.76	1.81	1.78
-19		0.27	0.89	1.76	1.74	1.75	1.71	1.77
	A.R. + F.C.							
	T.C. + F.C.							
<b>Maximum permitted</b>		0.7	2.4	3.0				

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side.

### 7.17 Clogging<sup>^</sup>

 NRq<sup>11</sup>

#### 7.17.2 Breathing resistance

Valved particle filtering half masks:

After clogging, the inhalation resistances shall not exceed,

FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95 l/min continuous flow;

The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.

Valveless particle filtering half masks:

After clogging the inhalation and exhalation resistances shall not exceed:

FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95 l/min continuous flow.

#### 7.17.3 Penetration of filter material

Classification	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP 1	≤ 20%	≤ 20%
FFP 2	≤ 6%	≤ 6%
FFP 3	≤ 1%	≤ 1%

Note 11: Single shift use only.

### 7.18 Demountable parts<sup>^</sup>

 NAp<sup>12</sup>

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.

Note 12: No demountable parts were used.

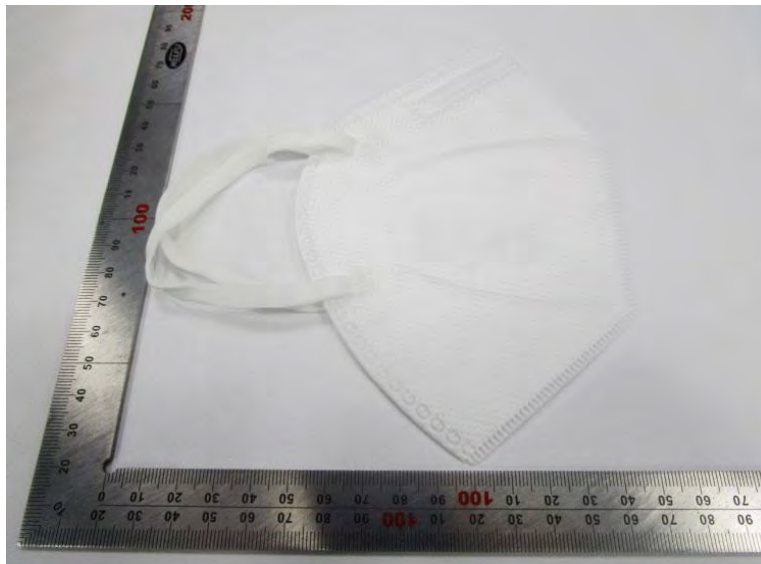


- 9 **Marking<sup>^</sup>** NRq
- 9.1 **Packaging**
- The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.
- 9.1.1** The name, trademark or other means of identification of the manufacturer or supplier.
- 9.1.2** Type-identifying marking.
- 9.1.3** Classification
- The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.
- 9.1.4** The number and year of publication of this European Standard.
- 9.1.5** At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.
- 9.1.6** The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.
- 9.1.7** The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.
- 9.1.8** The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". ID This letter shall follow the classification marking preceded by a single space.
- 9.2 **Particle filtering half mask<sup>^</sup>**
- Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:
- 9.2.1** The name, trademark or other means of identification of the manufacturer or supplier.
- 9.2.2** Type-identifying marking.
- 9.2.3** The number and year of publication of this European Standard.
- 9.2.4** Classification
- The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.
- 9.2.5** If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space (see 9.2.4).  
Example FFP3 NR D, FFP2 R D.
- 9.2.6** Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

- 10 Information to be supplied by the manufacturer<sup>^</sup>** **NRq**
- 10.1 Information supplied by the manufacturer shall accompany every smallest commercial available package.
- 10.2 Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.
- 10.3 The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on  
  
application/limitations; the meaning of any colour coding; checks prior to use; donning fitting; use; maintenance(e.g. cleaning, disinfecting), if applicable; storage; the meaning of any symbols/pictograms used of the equipment.
- 10.4 The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.
- 10.5 Warning shall be given against problems likely to be encountered, for example:
- fit of particle filtering half mask (check prior to use);
  - it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;
  - air quality (contaminants, oxygen deficiency);
  - use of equipment in explosive atmosphere.
- 10.6 The information shall provide recommendations as to when the particle filtering half mask shall be discarded.
- 10.7 For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift.

**Remark:** "<sup>^</sup>" indicates that the test is sub-contracted to the lab China Academy of Safety Science and Technology which complies with the requirement of ISO/IEC 17025:2017, the registration No. CNAS L0118.

**Photo:**



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