

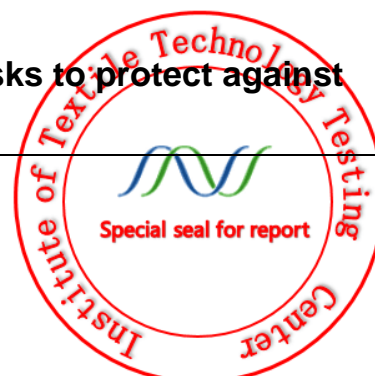




TEST REPORT

Manufacturer: NINGBO DOKEE MEDICAL TECHNOLOGY CO.,LTD.

TEST REPORT EN 149 : 2001 + A1 : 2009 Respiratory protective devices. Filtering half masks to protect against particles.	
Report Number	QA2020031129
Tested by (name + signature) ..	Qinggang 
Approved by (+ signature)	Zengtao 
Date of issue	2020-03-18
Total number of pages	14
Name of Testing Laboratory preparing the Report	
Institute of Textile Technology Testing Center	
Address	
No.496 Fenghua Road, Jiangbei District, Ningbo, China	
Applicant's name	
NINGBO DOKEE MEDICAL TECHNOLOGY CO.,LTD.	
Address	
28#ChuangyeRD,Nanbubinhaixinqu, Ningbo, Zhejiang, China	
Manufacturer's name	
NINGBO DOKEE MEDICAL TECHNOLOGY CO.,LTD.	
Address	
28#ChuangyeRD,Nanbubinhaixinqu, Ningbo, Zhejiang, China	
Test specification:	
Standard	EN 149:2001+A1:2009
Test procedure	CE
Non-standard test method	N/A
Test item description	
Disposable Protective Mask	
Trade Mark	
N/A	
Model/Type reference	
KN95	
The test 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 Laboratory. The authenticity of this Test Report and its contents can be verified by contacting the Laboratory, responsible for this Test Report.	



Summary of testing:	
<p>Tests performed (name of test and test clause):</p> <p>Full tests of the following standard: EN 149:2001+A1:2009</p> <p>The submitted samples were found to comply with the requirements of above standards.</p>	<p>Testing location:</p> <p>Institute of Textile Technology Testing Center No.496 Fenghua Road, Jiangbei District, Ningbo, China, 315000</p>
<p>Possible test case verdicts:</p> <ul style="list-style-type: none"> - test case does not apply to the test object .. : N/A - test object does meet the requirement..... : P (Pass) - test object does not meet the requirement .. : F (Fail) 	
<p>Testing :</p> <p>Date of receipt of test item..... : 2020-03-13</p> <p>Date (s) of performance of tests..... : 2020-03-13 to 2020-03-18</p>	
<p>General remarks:</p> <p>Throughout this report a <input checked="" type="checkbox"/> comma / <input type="checkbox"/> point is used as the decimal separator.</p>	
<p>General product information:</p> <p>Protective mask is a kind of respiratory protective equipment for the purpose of preventing the spread of certain respiratory infectious microorganisms and protecting the health of the body.</p>	

Summary of assessment*

Clause		Assessment (see Key)	
	Model:	KN95	
7.4	Packaging	P	
7.5	Material	P	
7.6	Cleaning and disinfecting		
7.7	Practical performance	P	
7.8	Finish of parts	P	
7.9.1	Total inward leakage	P	
7.9.2	Penetration of filter material: Sodium chloride	P	
7.9.2	Penetration of filter material: Paraffin oil	P	
7.10	Compatibility with skin		
7.11	Flammability	P	
7.12	Carbon dioxide content of the inhalation air	P	
7.13	Head harness	P	
7.14	Field of vision	P	
7.15	Exhalation valve(s)	P	
7.16	Breathing resistance	P	
7.17	Clogging		
7.18	Demountable parts	P	
9	Marking		
10	Information to be supplied by the manufacturer		

	Shading shows the clauses requested. Any other 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
NAs	Assessment not carried out.
NAp	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

* Assessment relates only to those specimens which were tested and are the subject of this report.

Product characteristics

Property	Characteristic
Model	KN95
Classification claimed	FFP2 NR
Exhalation valve(s)	N

Submission details

Product	Quantity	Date received	QA specimen no. (1F0171 +)
KN95	123	13 March 2020	101 to 163 and 201 to 263

Procedures

The specimens detailed within the submissions above were used for the tests covered by this report.

Testing was performed in accordance with BS EN 149 : 2001 incorporating corrigendum No. 1 (July 2002) and amendment A1 (March 2009), unless otherwise specified below. Reference should be made to the standard when reading this report.

Unless stated otherwise, specimens were tested in the condition as received by QA

Result details

7.4	Packaging Model: KN95	
	The masks were not packaged as offered for sale. Manufacturer to certify regarding the final packaging to be used.	NAs
	The masks were packaged in sealed plastic bags which gave some protection against mechanical damage or contamination before use.	Pass

7.5	Material Model: KN95	
	The masks were not packaged as offered for sale. Manufacturer to certify regarding the final packaging to be used.	<u>Pass</u>
	The masks were packaged in sealed plastic bags which gave some protection against mechanical damage or contamination before use.	<u>NAs</u>
	Specimens 120 to 125 were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse.	<u>Pass</u>
	Specimens 106 to 110, 117 to 119, 126 to 131, 133, 139, 140, 146, 147, 156 to 158 and 161 to 163 were conditioned in accordance with 8.3.2. None of the specimens conditioned suffered collapse.	<u>Pass</u>
	The effects of filter media release were not assessed. Manufacturer to certify.	<u>NAs</u>

7.7 Practical performance

Specimen and subject details

Specime	Subject
1	VE
1	KDS

No adverse comments were made following testing.

Specimen and subject details

Specimen	Subject
248 + 348	EM
249 + 349	AGI

Specimen	Subject
250 + 350	PU
251 + 351	CKN

No adverse comments were made following testing.

7.8	Finish of parts	
	None of the specimens used in laboratory testing showed evidence of sharp edges or burrs	<u>Pass</u>

7.9.1 Total inward leakage (%)

Subject	Specimen	Cond.	Walk	Head side/ side	Head up/down	Talk	Walk	Mean
RW	101	A.R.	1.98	2.95	2.33	1.60	1.09	1.99
ED	102	A.R.	0.15	0.16	0.20	0.28	0.11	0.18
AH	103	A.R.	0.40	0.65	2.06	1.48	0.40	1.00
PBU	104	A.R.	4.76	2.69	2.90	2.42	2.82	3.12
CKN	105	A.R.	1.00	1.28	1.34	1.06	1.11	1.16
VE	106	T.C.	0.80	1.00	0.52	0.42	0.38	0.63
KDS	107	T.C.	0.90	1.42	0.34	0.93	1.74	1.06
INH	108	T.C.	0.80	0.73	0.73	0.70	0.74	0.74
SAH	109	T.C.	0.60	0.89	1.44	0.54	0.30	0.75
GW	110	T.C.	0.62	0.52	0.30	1.48	0.53	0.69
Maximum permitted			11					8

All 50 individual exercise results were not greater than 11% Pass

All 10 individual wearer arithmetic means were not greater than 8% Pass

Subject facial dimensions:

Subject	Face Length (mm)	Face Width (mm)	Face Depth	Mouth Width (mm)
KN95	/	/	/	/

7.9.2 Penetration of filter material

Sodium chloride: Pass

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max.during exposure
111	A.R.	0.08	
112		0.12	
113		0.17	
120	S.W.	0.16	
121		0.25	
122		0.21	
126	M.S. + T.C.	0.36	0.35
127		0.28	0.27
128		0.26	0.26
Maximum permitted		6.0	

Paraffin oil:

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max. during exposure
114	A.R.	0.70	
115		0.76	
116		0.77	
123	S.W.	2.36	
124		1.02	
125		1.56	
129	M.S. + T.C.	0.78	1.47
130		1.67	3.16
131		2.35	4.60
Maximum permitted		6.0	

7.10	Compatibility with skin	
	No problems were encountered during practical performance testing.	Pass
	No problems were encountered during total inward leakage testing.	Pass

7.11	Flammability	
	Specimens 144 and 145 (A.R.) and 146 and 147 (T.C.) were tested. specimens ignited.	Pass

7.12 Carbon dioxide content of the inhalation air

Specimen	CO2 (%)
135	0.66
136	0.72
137	0.60
Maximum permitted	1.0

7.13	Flammability	
	The head harness was designed to allow the particle filtering half-mask to be donned and removed easily during practical performance and total inward leakage testing	Pass
	The product satisfied the total inward leakage requirements. See 7.9.1 for results.	Pass

7.14	Field of vision	
	There were no adverse comments following practical performance tests.	Pass

7.15 Exhalation valve **N/A**

7.16 Breathing resistance

Specimen	Condition	Inhalation resistance (mbar)		Exhalation resistance (mbar)
		At 30 l/min	At 95 l/min	At 160 l/min
111	A.R.	0.51	1.67	2
112		0.31	1.45	2
113		0.38	1.38	2
117	T.C.	0.54	1.71	2
118		0.47	1.64	2
119		0.36	1.48	2
120	S.W.	0.46	1.64	1
121		0.45	1.58	2
122		0.42	1.62	2
138	A.R. + F.C.	0.47	1.62	2
139	T.C. + F.C.	0.45	1.67	2
140		0.45	1.58	1
Maximum permitted		0.7	2.4	3

7.18	Demountable parts	
	The following parts were demountable: the exhalation valve cover was readily connected by hand.	<u>Pass</u>

Estimates of the uncertainty of measurement

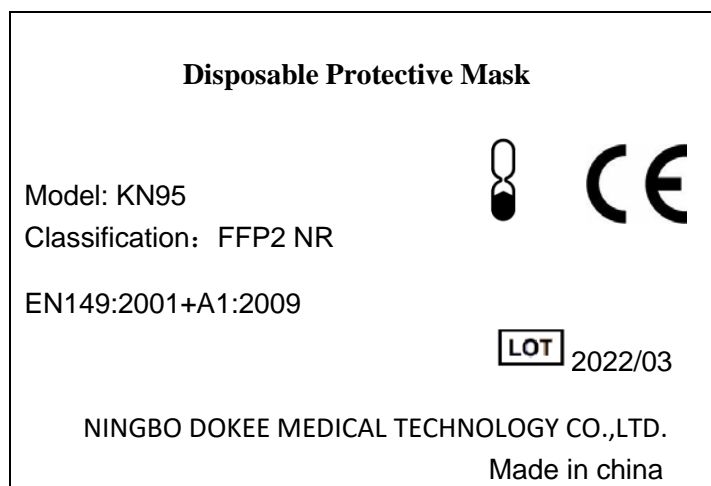
Clause	Test	Uncertainty
7.4	Packaging	Not applicable
7.5	Material	See Note 1
7.6	Cleaning and disinfecting	Not applicable
7.7	Practical performance	See Note 1
7.8	Finish of parts	Not applicable
7.9.1	Total inward leakage	± 4.8%
7.9.2	Penetration of filter material - Sodium chloride	± 4.8%
7.9.2	Penetration of filter material - Paraffin oil	± 4.3%
7.10	Compatibility with skin	Not applicable
7.11	Flammability	See Note 1
7.12	CO ₂ content of the inhalation air	± 8.0%
7.13	Head harness	Not applicable
7.14	Field of vision	See Note 1
7.16	Breathing resistance	± 4.9%
7.17.2	Breathing resistance after clogging	± 7.7%
7.17.3	Filter penetration after clogging - Sodium chloride	± 4.8%
7.17.3	Filter penetration after clogging - Paraffin oil	± 4.3%
7.18	Demountable parts	Not applicable

Note 1 The acceptance criterion for this test is a straightforward “Pass/Fail”, rather than a numerical value. Consequently, as there is no value to be reported, uncertainty has not been reported either.

Note 2 The uncertainty value is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which provides for a confidence level of approximately 95%. Values expressed as a percentage (%) are relative.

Note 3 It should be noted that the above values have not been taken into account when making assessment to the pass/fail criteria.

Nameplate



ANNEX

This Annex comprises one section.

1. Photographs of the products tested.

END OF REPORT

Disposable Protective Mask



KN95