

TEST REPORT EN 14683 Medical face masks - Requirements and test methods	
Report reference No.....	: A20032817SR-01
Tested by (+signature).....	: Steven  see cover page.....
Approved by (+ signature)...	: Liuze  see cover page.....
Date of issue.....	: Mar.,25, 2020
	
Testing laboratory	
Name.....	: United Testing Technology (Hong Kong) Limited
Address.....	: Unit 04,7/F,Bright Way Tower,No.33 Mong Kok Road, Kowloon, HK.
Test location.....	: (Same as above)
Client	
Name.....	: Gansu Newshanyou Medical Instruments Co., Ltd.
Address.....	: No. 1, Floor 4, Building 2, Qijuzhongchuang Incubation Park Linxia gansu
Test specification	
Standard.....	: EN 14683:2005
Test procedure.....	: CE- MDD
Procedure deviation.....	: N.A.
Non-standard test method..	: N.A.
Test Report Form No.....	: EN_14683
Test item	
Description.....	: Disposable MEDICAL mask KN95
Model No.	: KN95, N95, FFP2, DISPOSABLE MEDICAL MASK
Trade Mark.....	: Newshanyou
Manufacturer.....	: Gansu Newshanyou Medical Instruments Co., Ltd.
Address.....	: No. 1, Floor 4, Building 2, Qijuzhongchuang Incubation Park Linxia gansu
Classification.....	: Type II

Test case verdicts

Test case does not apply to the test object..... : N(.A.)

Test item does meet the requirement..... : P(ass)

Test item does not meet the requirement..... : F(ail)

Testing

Date of receipt of test item: Feb., 25, 2020

Date(s) of performance of test: Feb., 25, 2020 - Mar., 24, 2020

General remarks

This test report shall not be reproduced except in full without the written approval of the testing laboratory.

The test results presented in this report relate only to the item tested.

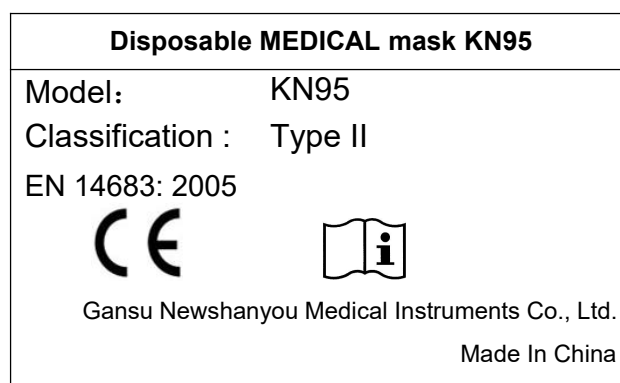
"(see remark #)" refers to a remark appended to the report.

"(see appended table)" refers to a table appended to the report.

Throughout this report a comma is used as the decimal separator.

Remark:

The EUT complies with the standard EN 14683 requirement.

Copy of marking plate:

EN 14683			
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. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness.	Meet the requirements	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.	The wire holds the shape and makes the mask fit tightly to the 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)		N
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	All tests shall be carried out on finished products or samples cut from finished products.		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 table 1.	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		P
	When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. The lowest performing panel or area		P

EN 14683			
Clause	Requirement + Test	Result - Remark	Verdict
	shall determine the BFE value of the complete mask.		
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		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
5.2.4	Splash resistance		N
	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.		N
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).	1# : 27.2 CFU/g; 2# : 26.6 CFU/g; 3# : 24.0 CFU/g; 4# : 25.5 CFU/g 5# : 26.2 CFU/g	P
	NOTE EN ISO 11737-1:2018 specifies requirements and provides guidance for the enumeration and microbial characterization of the population of viable microorganisms on or in a medical device, component, raw material or package.		P
	To determine the mask' s bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D.		P
	The number of masks that shall be tested is minimum 5 of the same batch/lot.		P
	Other test conditions as described in EN ISO 11737-1:2018 may be applied.		P
	In the test report, indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram.	27.00	P
5.2.6	Biocompatibility		P
	According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact. 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. The results of testing should be		P

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	documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request.		
5.2.7	Summary of performance requirements		P
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.		P
	The following information shall be supplied:		P
	a) number of this European Standard;	EN 14683:2005	P
	b) type of mask (as indicated in Table 1).	Type II	P
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.		P

Table 1 — Performance requirements for medical face masks

Table 1	The performance test			Result
Test	Type I a	Type II	Type IIR	Type II
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98	98.2
Differential pressure (Pa/cm ²)	< 40	< 40	< 60	36.9
Splash resistance pressure (kPa)	Not required	Not required	$\geq 16,0$	--
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30	27.55
Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.				

Appendix
Photo documentation

Photo 1

View:

- ☒ front
☐ rear
☐ right side
☐ left side
☐ top
☐ bottom
☐ internal

**Photo 2**

View:

- ☐ front
☒ rear
☐ right side
☐ left side
☐ top
☐ bottom
☐ internal



***** End of this report *****