[redacted]

TEST REPORT

Report No.: [redacted]

EN 14683:2019

Medical Surgical Mask – Requirements and test methods

Applicant : [redacted]

Address : [redacted]

Product(s)	:	Medical Surgical Mask
Brand name	:	Non-Sterile Flat Earhook
Model(s)	:	[redacted]
Standard(s)	:	EN 14683:2019

[redacted] Testing Center

Test Report No.: [redacted] Date: March 07. 2020 1 / 5

TEST REPORT FOR COMPLIANCE WITH

EN 14683:2019

Medical surgical masks – Requirements and test methods

Applicant	[redacted]	
Applicant Address	[redacted] CHINA	
Trade mark	Non-Sterile Flat Earhook	
Product Name	Medical surgical mask	
Model / Specification	[redacted]	
Series Model(s) / Specifications	[redacted]	
Test Report No.	[redacted]	
Standards	EN 14683:2019	
ComplianceDate of Testing	2020.2.12-2020.3.07	
Testing Laboratory	[redacted]	
Tested by	**Wang Gang**	2020.3.7
Approved by	**Qi Weiyan**	2020.3.7

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Clause	Requirement-Test	Result-Remark	Verdict
4	Classification		
	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 I	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(Absence of particle matter)		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).		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.		P
5.2.2	Bacterial filtration efficiency (BFE)		P

Clause	Requirement-Test	Result-Remark	Verdict
	When tested in accordance with Annex B of EN 14683:2019, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	⩾95	P
5.2.3	Breathability		P
	When tested in accordance with Annex C of EN 14683:2019, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.		P
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).	<30	P
	To determine the mask's bioburden according to EN ISO 11737-1:2018, follow to the procedure.		P
	The number of masks that shall be tested is minimum 5 of the same batch/lot.		P
	Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l polysorbate surfactant 20 [e.g. Tween 20, Alkest TW 20]).		P
	100 ml of the extraction liquid is filtered through a 0,45 µm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30 °C and 7 days at (20 to 25) °C for TSA and SDA plates respectively. The total bioburden is expressed		P

Clause	Requirement-Test	Result-Remark	Verdict
	by addition of the TSA and SDA counts.		
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 documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request.		P
	As a minimum, EN ISO 10993-5 and EN ISO 10993-10 shall be considered.		P
5.2.7	Summary of performance requirements		P
6	Labelling and information to be supplied		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 in addition.		---
	a) number of this European Standard	EN 14683	P
	b) type of mask	Type I	P
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.		P

Remark:

--N (Not Applicable)

--P (Pass)

--F (Fail)

Table 1

Test	Type I a	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm²)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30
a 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.			

Table 2 Test Results

Test Article Number	Percent BFE(%)	Delta P(mm $H_2O/cm^{2)}$	Delta P(Pa/cm²)
1	98.9	2.6	25.7
2	96.8	2.7	26.3
3	98.5	2.6	25.6
4	97.6	2.5	24.5
5	98.7	2.6	25.3

The filtration efficiency percentages were calculated using the following equation:

%BFE={(C-T) /C}x100

C=Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon reques