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**Performance requirements and test
methods of medical face masks and
non-medical face masks**

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Foreword

This Japanese Industrial Standard has been established by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal for establishment of Japanese Industrial Standard submitted by Japan Hygiene Products Industry Association (JHPIA)/Japanese Standards Association (JSA) with a draft being attached, based on the provision of Article 12, paragraph (1) of the Industrial Standardization Act.

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Performance requirements and test methods of medical face masks and non-medical face masks

1 Scope

This Japanese Industrial Standard specifies the performance requirements and test methods of medical face masks and non-medical face masks.

2 Normative references

Part or all of the provisions of the following standards, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

- JIS K 0557 *Water used for industrial water and wastewater analysis*
- JIS K 0950 *Sterilized plastic petri dishes*
- JIS K 8123 *Calcium chloride (Reagent)*
- JIS K 8150 *Sodium chloride (Reagent)*
- JIS K 8263 *Agar (Reagent)*
- JIS K 9017 *Dipotassium hydrogenphosphate (Reagent)*
- JIS L 1041 *Test methods for resin finished textiles*
- JIS L 1091 *Testing methods for flammability of textiles*
- JIS L 1912 *Test methods for nonwoven fabrics of medical use*
- JIS L 1930 *Textiles — Domestic washing and drying procedures for textile testing*
- JIS L 1940-1 *Textiles — Methods for determination of certain aromatic amines derived from azo colorants — Part 1 : Detection of the use of certain azo colorants accessible with and without extracting the fibres*
- JIS L 1940-3 *Textiles — Methods for determination of certain aromatic amines derived from azo colorants — Part 3 : Detection of the use of certain azo colorants, which may release 4-aminoazobenzene*
- JIS T 8001 *Glossary of terms for respiratory protective devices*
- JIS T 8061 *Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X174 bacteriophage*
- JIS T 8062 *Clothing for protection against infectious agents — Face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)*

JIS Z 8122 *Contamination control — Terminology*

JIS Z 8401 *Rounding of numbers*

3 Terms and definitions

For the purpose of this Standard, the following terms and definitions, and those given in **JIS T 8001** and **JIS Z 8122** apply.

3.1

medical face mask

face mask mainly intended for use by medical workers, designed to prevent the entrance of fine particles, airborne droplets containing bacteria, airborne droplets containing viruses and body fluids into the wearer's body as well as to prevent the scattering of airborne droplets containing bacteria etc. into the air

Note 1 to entry It is also called a surgical mask.

3.2

non-medical face mask

face mask designed to prevent the entry of the intended target substance(s), including particulate matters (for example, PM 2.5), airborne droplets containing bacteria, airborne droplets containing viruses and pollen particles into the wearer's body as well as to prevent the scattering of airborne droplets containing bacteria etc. into the air

3.3

particle filtration efficiency (PFE)

ability to collect airborne fine particles

3.4

bacterial filtration efficiency (BFE)

ability to collect airborne droplets, specifically aerosols containing bacteria, released when coughing, sneezing, talking, etc.

3.5

viral filtration efficiency (VFE)

ability to collect airborne droplets, specifically aerosols containing viruses, released when coughing, sneezing, talking etc.

3.6

pollen particle filtration efficiency

ability to collect airborne pollen particles

3.7

differential pressure

index for breathability (air permeability), indicated by the difference in pressure between the front and rear of a face mask divided by the test area, when air suction through the mask is performed at a constant flow rate

3.8

synthetic blood penetration resistance

ability to prevent body fluid splashed from a patient during surgery or other medical practices from penetrating through to the rear of the mask

4 Classification and performance requirements

4.1 Medical face masks

Medical face masks are classified into Class I, Class II and Class III, and are required to meet the respective quality standards in Table 1 when tested by the methods specified in Clause 5.

Table 1 Quality standards of medical face masks

Item	Unit	Quality standard			Test method (relevant subclause)
		Class I	Class II	Class III	
Particle filtration efficiency (PFE)	%	≥95	≥98	≥98	5.1.1
Bacterial filtration efficiency (BFE)	%	≥95	≥98	≥98	5.1.2
Viral filtration efficiency (VFE)	%	≥95	≥98	≥98	5.1.3
Differential pressure	Pa/cm ²	<60	<60	<60	5.1.5
Synthetic blood penetration resistance	kPa	10.6	16.0	21.3	5.1.6
Flammability	—	Class 1	Class 1	Class 1	5.1.7
Free formaldehyde	µg/g	≤75			5.2.1
Certain azo colorants ^{a)}	µg/g	≤30 ^{b)}			5.2.2
Fluorescence ^{c)}	—	No significant fluorescence.			5.2.3
Note ^{a)} The test is applicable to coloured or dyed products.					
Note ^{b)} This limit shall be met for each of the 24 certain aromatic amines generated.					
Note ^{c)} It applies to the main body of a mask related to breathing, which does not include accessory parts such as ear straps.					

4.2 Non-medical face masks

Non-medical face masks are required to meet the quality standards in Table 2 when tested by the methods specified in Clause 5. For filtration efficiency, face masks shall satisfy at least one of the four indicated standards : particle (PFE), bacterial (BFE), viral (VFE) and pollen particle.

Table 2 Quality standards of non-medical face masks

Item	Unit	Quality standard		Test method (relevant subclause)
Particle filtration efficiency (PFE)	%	≥95	Efficiency(ies) to be marked on the product shall be tested.	5.1.1
Bacterial filtration efficiency (BFE)	%	≥95		5.1.2
Viral filtration efficiency (VFE)	%	≥95		5.1.3
Pollen particle filtration efficiency	%	≥95		5.1.4
Differential pressure	Pa/cm²	<60		5.1.5
Free formaldehyde	µg/g	≤75		5.2.1
Certain azo colorants ^{a)}	µg/g	≤30 ^{b)}		5.2.2
Fluorescence ^{c)}	—	No significant fluorescence.		5.2.3
Note ^{a)} The test is applicable to coloured or dyed products.				
Note ^{b)} This limit shall be met for each of the 24 certain aromatic amines generated.				
Note ^{c)} It applies to the main body of a mask related to breathing, which does not include accessory parts such as ear straps.				

Non-medical face masks conforming to Table 2 that assume reuse after washing and whose package etc. indicate the endurable number of washes shall be required to conform to the quality standard in Table 3 when washed for the indicated number of times by the indicated laundry method, or in the absence of an indicated laundry method, by the method specified in **JIS L 1930**.

Table 3 Quality standards of non-medical face masks after indicated number of washes

Item		Unit	Quality standard		Test method (relevant subclause)
After wash- ing	Particle filtration efficiency (PFE)	%	≥95	Efficiency(ies) to be marked on the product shall be tested.	5.1.1
	Bacterial filtration efficiency (BFE)	%	≥95		5.1.2
	Viral filtration efficiency (VFE)	%	≥95		5.1.3
	Pollen particle filtration efficiency	%	≥95		5.1.4
	Differential pressure	Pa/cm²	<60		5.1.5

5 Test methods

5.1 Functionality tests

5.1.1 Particle filtration efficiency (PFE) test

5.1.1.1 Principle

Filtered and dried air is passed through an atomizer to generate aerosol from a suspension containing latex particles. This generated aerosol, after being mixed and diluted with clean air and allowed to dry, is introduced into a chamber with a face velocity of 9.6 cm/s under a constant flow rate, and the aerosol particle count upstream and downstream of the test piece is measured to calculate the particle filtration efficiency

(PFE).

5.1.1.2 Reagents and other materials

- a) **Polystyrene latex particle reagents**, obtained by dispersing in pure water the spherical polystyrene-based standard particles of nominal particle size $0.1\ \mu\text{m}$, or if agreed between the interested parties, those of nominal particle size $0.3\ \mu\text{m}$.

The particle size of polystyrene latex particles used shall be indicated in the test report.

- b) **Ion exchange water**, of A1 specified in JIS K 0557.
c) **Ultra pure water**, of A4 specified in JIS K 0557.

5.1.1.3 Test apparatus and test instrument

The composition of the test apparatus is shown in Figure 1.

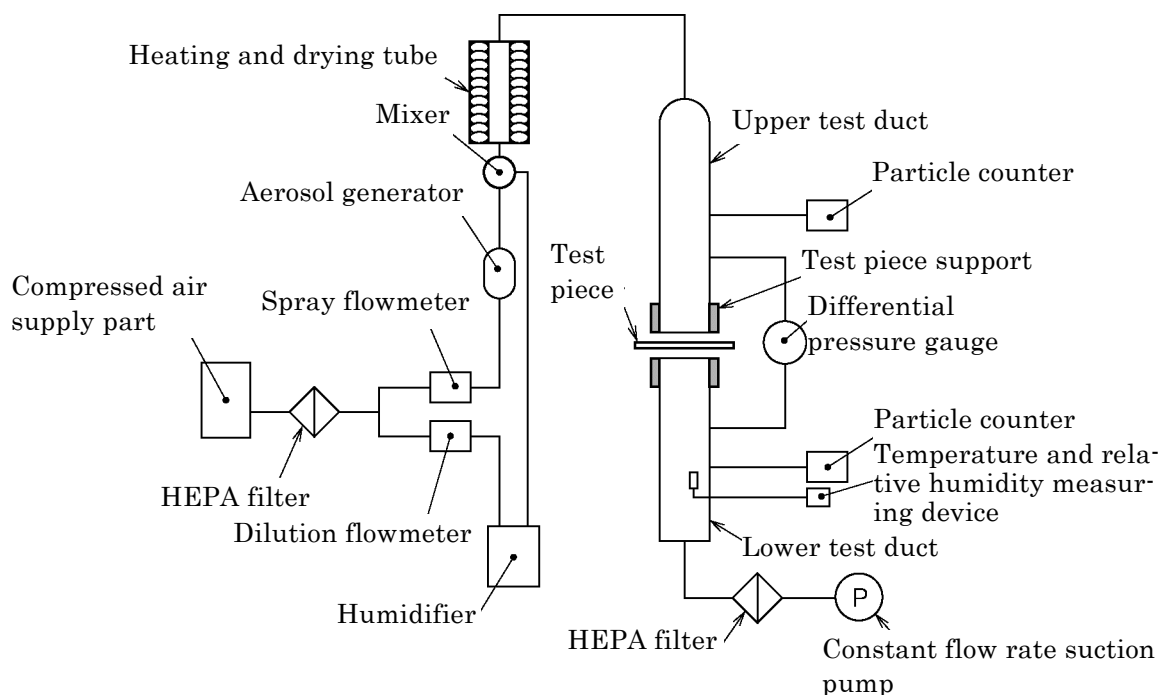


Figure 1 Example of composition of particle filtration efficiency (PFE) test apparatus

- a) **Compressed air supply part**, a compressor with a built-in oil-free air dryer capable of supplying compressed dry air not containing vaporized oil and having a discharge pressure of $0.2\ \text{MPa}$ or more and a discharge air volume of within $108\ \text{L/min}$.
b) **HEPA filter**, specified in JIS Z 8122, to be installed after the compressed air supply part to obtain clean air, and before discharge to the environment to filter the test particles from the air which has passed through the test pathway.