

Corporate Standard of TESTEX

TS M004-2020

Quality Control Standard of Nose Wire for Face Mask

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Foreword

This standard is the recommended standard, it serves as the supply, purchasing and production standard of nose wires for the production of medical masks, and is only used for the production of masks.

1 Scope of application

This standard is used to regulate the nose wire used in the production of masks, to guide the production process of masks, mainly to solve the problems that the texture of the nose wire is too soft to fit the face, and the nose wire is not harmful to the human body.

2 Reference

GB19083-2010 Medical protective mask technical requirements

3 Terms and definitions

The galvanized iron wire, polyethylene resin and polypropylene resin used to produce the nose wire should be non-toxic, harmless, pollution-free and non-irritating to human skin.

The single-stranded nose wire is extruded and wrapped with single-strand galvanized iron wire with polyethylene resin or polypropylene resin:

The double-stranded nose wire is extruded with double-stranded galvanized iron wire wrapped with polyethylene resin or polypropylene resin.

4 Technology requirement

4.1 Specification size

Item	Requirement
For flat mask (single wire)	Width: 3.2mm±0.2mm Thickness: 1.0mm±0.2mm
N95 (Double wire)	Width: 4.8mm±0.2mm Thickness: 1.0mm±0.2mm
Wire diameter	0.45mm ± 0.05mm

4.2 Exterior requirements

The exterior of the nose wire should be smooth and tidy, no burrs, no stains, no damage, and the iron core type should have no leakage except for the ends.

4.3 Plasticity

The shape of the bridge of the nose should not rebound after the 5.2 test.

4.4 Folding endurance

The nose wire should not break after the 5.3 test.

4.5 Hygiene standard

The hygienic index of the nose bridge should meet the requirements of the following table.

Item	Requirement
Coliform	Not detectable
Pseudomonas aeruginosa	Not detectable
Staphylococcus aureus	Not detectable
Hemolytic Streptococcus	Not detectable
Total number of fungal colonies/(cro/g) w	100
Total bacterial colonies/ (CFU/g) W	200

5 Experiment method

5.1 External assessment

The bright place is visually inspected by the inspector

5.2 Plasticity test

Take the nose wire with a length of 10 cm, and the initial flattening is "in-line". The tester will fold the wide side of the nose wire into 30° from the midpoint, and observe the state of the sample after unloading.

5.3 Folding resistance test

Take the nose wire with a length of 10cm, and the initial flattening is "in-line". The tester folds the wide side of the nose wire from the midpoint, and then restores it to "in-line". Repeat the operation once to observe the state of the sample.

5.4 Hygiene standard

According to the provisions of GB 15979.

6 Testing regulations

6.1 Raw materials storage inspection

The raw materials and auxiliary materials should be inspected by the company's technical inspection department according to the requirements of the raw materials and auxiliary materials before entering the warehouse.

6.2 Batch

Products with the same batch of raw materials, the same production line and the same shift production date and the same specifications are "batch"

6.3 Sampling

The factory inspection takes one delivery as a batch, adopts random sampling, and the sampling plan is carried out according to the following table.

Quantity (Roll)	Sampling ratio	Remarks
W500	>10%	No less than 3 rolls
500~1000	>5%	—
M1000	>3%	—

6.4 Factory inspection

6.4.1 Each batch of products should be inspected before leaving the factory.

6.4.2 The factory inspection items of the nose wire include size, appearance, plasticity and folding resistance.

6.5 Quality judgment

If the health index fails, the batch is judged as unqualified. If only other items are unqualified, it is allowed to double the number of samples in the same batch of products, re-examine the unqualified items, and the negative test results shall prevail.

7 Marks, packaging, transportation and storage

7.1 Marks

7.1.1 The product shall be affixed with a qualified label. The content of the label shall include the production batch number, production date, inspection personnel, and qualified seal.

7.1.2 There should be obvious words and signs such as "upward" and "No rain" on the packaging.

7.2 Packaging

7.2.1 The sealing of the bottom and lid of the outer packaging box should be tight and firm; the inner packaging should be sealed with plastic bags according to different specifications.

7.2.2 The inner and outer packaging should be marked with product name, specifications, number of stars, manufacturer name, production date, product implementation standard number, etc.

7.2.3 Other special requirements for packaging can be agreed by both parties.

7.3 Transportation and storage

7.3.1 The product should be transported by means of transportation without corrosive and non-polluting substances to prevent rain and impurities.

7.3.2 The product should be stored in a ventilated, dry, non-corrosive warehouse.