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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0174-2019

**Scalpel blade
(English Translation)**

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Foreword

This Standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This Standard replaces YY 0174-2005 "Scalpel blade".

Compared with YY 0174-2005, the main changes in this Standard are as follows.

- modified the scope of application (see Clause 1 of this Edition, Clause 1 of Edition 2005);
- modified the manufacturing materials (see 3.3 of this Edition, 3.2 of Edition 2005);
- added the marking requirements for the blade (see 3.4 of this Edition);
- modified the hardness requirements (see 4.4 of this Edition, 4.4.1 of Edition 2005);
- added the anti-rust performance requirements (see 4.6 of this Edition);
- added the ethylene oxide residue requirements (see 4.8 of this Edition);
- added the packaging label and instructions requirements (see 4.9 of this Edition);
- modified the test method for surface roughness (see 5.2.1 of this Edition, 5.2.1 of Edition 2005);

- modified the test method for edge sharpness (see 5.3 of this Edition, 5.3 of Edition 2005);
- modified the type inspection (see Clause 6 of this Edition, Clause 6 of Edition 2005);
- modified the labeling and instructions requirements (see Clause 7 of this Edition, Clause 7 of Edition 2005);
- modified the packaging, transportation and storage requirements (see Clause 8 of this Edition, Clause 8 of Edition 2005).

Attention is drawn to the possibility that some of the elements of this Standard may be the subject of patent rights. The issuing authority shall not be held responsible for identifying any or all such patent rights.

This Standard was proposed by National Medical Products Administration.

This Standard shall be under the jurisdiction of National Technical Committee on Surgical Instruments of Standardization Administration of China (SAC/TC

1 Scope

This Standard specifies the classification and marks, requirements, test methods, type inspection, labels and instructions on use, packaging, transportation, storage and valid period of scalpel blade.

This Standard is applicable to the scalpel blade that is installed on the scalpel handle for cutting soft tissue (hereinafter referred to as the blade).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 191, Packaging and storage marks GB/T 1299, Alloy tool steels GB/T 4340.1, Metallic materials - Vickers hardness test - Part 1: Test method GB 8662, Fitting dimension between scalpel blades and handles GB/T 9969, General Principles for Preparation of Instructions for Use of Industrial Products GB/T 14233.1, Test methods for infusion transfusion injection equipment for medical use - Part 1: Chemical analysis methods YY 0167-2005, Non-absorbable surgical suture

3.1 Delivery state

The blade has two delivery states. aseptic and non-sterile (hereinafter referred to as sterile blade and non-sterile blade).

3.2 Specification type

Refer to Annex A for the specifications and dimensions of the blade, as well as the assembly specifications of the handle.

3.4 Marking requirements

According to YY/T 1052, the surface of the blade shall at least be marked with the manufacturer code, material code (non-alloy tool steel, marking default) and specifications. See Figure 1 for marking positions.

4.1 Dimensions

The blade assembly dimensions α , δ , b , b_1 , L_1 and L_2 , see Figure 1, shall comply with the provisions of GB 8662.

4.3 Edge sharpness

The blade edge shall be sharp. The cutting force shall not be greater than 0.80N.

4.4 Hardness

The blade shall be heat treated. Its hardness is not less than 650HV10.

4.5 Elasticity

The blade shall have good elasticity. After the test, there is no fracture and no obvious deformation.

4.6 Anti-rust performance

The blade shall have good rust resistance. There shall be no rust spots on the surface.

4.9 Packaging labels and instructions on use

The packaging labels shall be clear and meet the requirements of Clause 7.

The instructions on use shall specify detailed sterilization or disinfection methods.

5.1 Dimensions

Use universal measuring tools to measure, in accordance with the provisions of 4.1.

5.3 Edge sharpness

See Annex B for test methods, in accordance with the provisions of 4.3.

5.4 Hardness

Conduct the test according to the method specified in GB/T 4340.1. Test three points on the blade. Take its arithmetic mean, in accordance with the provisions of 4.4.

5.5 Elasticity

See Annex C for the test method, in accordance with the provisions of 4.5.

5.7 Sterility

Conduct it according to the General Principle 1101 "Test of Sterility" of Pharmacopoeia of the People's Republic of China (Edition 2015· Fourth Edition), in accordance with the provisions of 4.7.

5.8 Residual ethylene oxide

Conduct according to the method specified in GB/T 14233.1, in accordance with the provisions of 4.8.

6 Type inspection

The inspection items, inspection quantity and determination rules of the blade are shown in Table 1.

7.1 Labels

7.1.1

The minimum package of non-sterile blades shall have at least the following contents or symbols.

7.1.2

The minimum package of sterile blades shall have at least the following contents or symbols.

7.1.3

The minimum sales unit packaging shall have at least the following contents or symbols.

7.1.4

There shall be an inspection certificate in each minimum sales unit. At least the following content shall be included on the certificate.

7.1.5

The packaging, storage and transportation marks on the package shall comply with the relevant regulations of GB/T 191 and YY/T 0466.1.