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YY/T 0681.11-2014

Test Methods for Sterile Medical Device Package - Part 11: Determining Integrity of Seals for Medical Packaging by Visual Inspection

无菌医疗器械包装试验方法

第 11 部分：目力检测医用包装密封完整性

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Foreword

YY/T 0681 is “Test methods for sterile medical device package” consists of the following parts:

- Part 1: Test guide for accelerated aging;
- Part 2: Seal strength of flexible battier materials;
- Part 3: Internal pressurization failure resistance of unrestrained packages;
- Part 4: Detecting seal leaks in porous packages by dye penetration;
- Part 5: Detecting gross leaks in medical packaging by internal pressurization (bubble test);
- Part 6: Evaluation of chemical resistance of printed inks and coatings on flexible packaging materials;
- Part 7: Evaluating inks or coating adhesion to flexible packaging materials using tape;
- Part 8: Coating/adhesive weight determination;
- Part 9: Burst testing of flexible package seals using internal air pressurization weight restraining plates;
- Part 10: Test for microbial barrier ranking of porous package material;
- Part 11: Determining integrity of seals for medical packaging by visual inspection;
- Part 12: Flex durability of flexible barrier films;
- Part 13: Slow rate penetration resistance of flexible barrier films and laminates.

This Part is Part 11 of YY/T 0681.

This Part was drafted according to the rules given in GB/T 1.1-2009.

This Part was formulated by referencing ASTM F 1886-1998 “Determining Integrity of Seals for Medical Packaging by Visual Inspection”.

Please note that some of the content of this document may involve patents. The issuing agency of this document does not undertake the responsibility of identifying these patents.

This Part shall be under the jurisdiction of the National Standardization Technical

Test Methods for Sterile Medical Device Package - Part 11: Determining Integrity of Seals for Medical Packaging by Visual Inspection

1 Scope

The test method specified in this Part of YY/T 0681 covers the determination of channels in the package seal down to a width of 75 μm with a 60 % ~ 100 % probability (see Appendix B).

This test method is applicable to flexible and rigid packages with at least one transparent side, so that the seal area may be clearly viewed.

2 Normative references

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this document.

ASTM F 17 Standard terminology relating to flexible barrier packaging

3 Terms and definitions

The following terms and definitions apply to this document.

3.1

Channel

Any unimpaired pathway across the entire width of the intended seal.

3.2

Sterile package integrity

Property of the package seal and material, which ensures that it presents a microbial

Bibliography

[1] ASTM E 691 Practical for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

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