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**PROFESSIONAL STANDARD OF THE PEOPLE'S
REPUBLIC OF CHINA**

中华人民共和国医药行业标准

YY/T 0148-2006

Replace YY 0148-1993

Medical adhesive bandages—General requirements

医用胶带 通用要求

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Foreword

This standard will replace YY 0148-1993 *Adhesive plaster*. Comparison with YY 0148-1993, main changes of this standard are extended the scope of application. The technical contents use relevant requirements for *British Pharmacopoeia* 1993.

Annex A, B C and F of this standard are normative annex. Annex D and E of this standard are informative annex.

This standard is under the jurisdiction of Jinan MDSIN Quality Inspection Center of NADFC.

The responsible drafting organization is Shandong MDSIN Quality Inspection Center.

The participation drafting organization is Henan Piaoan Co., Ltd.

The chief drafting staff of this standard includes Luo Hongyu, Liu Bin, Sun Guangyu, Fan Xiangyang and Wan Min.

Introduction

General requirements stipulated in Chapter 5 of this standard apply to all kinds of adhesive bandages; special requirements stipulated in Chapter 6 are only suitable for products with related instruction. As for certain special adhesive bandages, meeting this standard doesn't mean it will meet clinical requirements. For these products, requirements not listed in this standard may also be necessary.

The quality of adhesive materials on medical adhesive bandages, organizational structure of the fabric and thread count is important parameters of product quality control. As there are so many kinds of adhesive bandages, this standard can not give unified stipulations to these characters. Furthermore, this standard is not involved in the requirements about the supply form and package.

Most medical adhesive bandages don't contact directly with the wound surface, but some are expected to contact directly with the wound surface so they are also called adhesive dressing, which are required sterile supply clinically.

Medical adhesive bandages—General requirements

1 Scope

This standard specifies general requirements of all kinds of medical adhesive bandages (also known as adhesive bandages) which contact with body surface or wound surface and adhesive dressing. This standard doesn't include:

- a) Requirements of adhesive face protective covering of medical adhesive bandages (including adhesive dressing);
- b) Requirements of dressing pad of adhesive dressing;
- c) Package requirements of medical adhesive bandages.

2 Normative References

The articles contained in the following documents have become this standard when they are quoted herein. For the dated documents so quoted, all the modifications (excluding corrections) or revisions made thereafter shall not be applicable to this Standard. For the undated documents so quoted, the latest editions shall be applicable to this Standard.

GB/T 16886.1 Biological evaluation of medical devices--Part 1: Evaluation and testing (GB/T 16886.1-2001, idt ISO 10993-1: 1997)

YY 0466 Medical devices -- Symbols to be used with medical device labels labelling and information to be supplied (YY 0466-2003, ISO 15233: 2000, IDT)

YY/T 0471.3-2004 Test methods for primary wound dressings — Part 3: Waterproofness

YY/T 0471.4-2004 Test methods for primary wound dressing—Part 4: Conformability

3 Terms and definitions

For the purpose of this standard, the following terms and definitions given in YY/T 0471 apply.

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