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

YY 0875-2023

Replacing YY 0875-2013; YY 0876-2013

Surgical instruments - Linear staplers and cartridges

外科器械 直线型吻合器及组件

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1. Structure and Drafting Rules of Standardization Documents" Drafting. This document replaces YY 0875-2013 "Linear Staplers and Components" and YY 0876-2013 "Linear Cutting Staplers and Components". Compared with YY 0875-2013 and YY 0876-2013, the main technical differences are as follows:

---Changed the scope and added "This document does not apply to special vascular staplers and curved staplers" (see Chapter 1, YY 0875- 2013, Chapter 1 of YY 0876-2013);

---Added product types (see 4.1);

---Deleted the requirements for main parts and materials of staplers and components (see 4.5 of YY 0875-2013,

3.4 of YY 0876-2013);

---Changed the requirements for specification marking and added marking examples of unequal height staples (see 4.3,

4.6 of YY 0875-2013,

3.5 of YY 0876-2013);

---Added a note on staple materials, clarifying that staples can also use materials that have been verified and evaluated as safe (see 5.1);

---Changed the requirements for surface roughness (see 5.4,

5.7 of YY 0875-2013,

4.8 of YY 0876-2013);

1 Scope

YY 0875 is the mandatory Chinese standard for linear surgical staplers and their cartridges,

the instruments that close and divide bowel, lung and stomach in a single action. It sets the requirements such instruments have to meet and the test methods that verify them, covering the formation of the staple line and its consistency, the leak resistance of the closure, the cutting, the firing force, the compatibility between instrument and cartridge and the sterility of the disposable parts. A staple line that fails becomes an anastomotic leak, one of the most lethal complications in gastrointestinal surgery. Being a YY standard without the /T suffix, compliance is compulsory in China. The 2023 edition consolidates and replaces YY 0875-2013 and YY 0876-2013 and takes effect in September 2026.

YY/T 0149-2006 Test method for corrosion resistance of stainless steel medical instruments

YY 0167 non-absorbable surgical suture

YY/T 0966 Surgical implant metal material pure tantalum

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB/T 228.1 Tensile testing of metallic materials Part

GB/T 16886 (all parts) Biological evaluation of medical devices

ISO 13782 Metallic materials for surgical implants Pure tantalum materials for surgical implants (Implants for surgery-Metallic Pharmacopoeia of the People's Republic of China (2020 Edition) Part Four

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 component cartridge Built-in staples are only used once.

3.2 reusable stapler reusable stapler The device has been repeatedly sterilized and used in multiple surgeries and is used with sterile packaged components.