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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 0341-2009
Replace YY 0341-2002

General technological requirements for non-active metallic surgical implants for osteosynthesis

骨接合用无源外壳金属植入物通用技术条件

Issued on December 30, 2009 Implemented on June 01, 2011

Issued by China Food and Drug Administration

Contents

Foreword

Definitions in this Standard are quoted from YY/T 0340-2009 *Surgical Implant – Basic Principles* (ISO/TR 14283: 2004, IDT), YY/T 0640 – 2008 *Non-active Surgical Implant – General Requirements* (ISO 14630: 2005, IDT), GB/T 12417.1 – 2008 *Non-active Surgical Implant – Osteosynthesis and Joint Replacement Implant, Part I: Special Requirements for Implants for Osteosynthesis* (ISO 14602: 1998, IDT).

This Standard replaces YY 0341 – 2002 *General technological requirements for non-active metallic surgical implants for osteosynthesis*.

Main differences between this Standard and YY 0341 – 2002 Standard are as follows:

-- Chapter 3, 6, 7, 8 and 9 are revised according to corresponding international standards;

-- Static and/or dynamic load evaluation tests are added in accordance with GB/T 12417.1 – 2008;

-- Informative annex D is added as a reference, introducing some American standards for testing and evaluation.

Annex A, Annex B, Annex C and Annex D is this Standard are all informative annex.

This Standard is proposed by State Food and Drug Administration.

This Standard is under the jurisdiction of national standardization technical committee of surgical implants and orthopedic devices (SAC/TC 110).

This Standard is drafted by Tianjin medical device quality supervision and inspection center of State Food and Drug Administration.

Major drafters of this Standard: Fan Bo, Yang Jiangang, Song Duo, Qi Baofen and Jiang Hua.

General technological requirements for non-active metallic surgical implants for osteosynthesis

1 Scope

This Standard determines the definitions, requirements, testing methods, inspection rules, use instructions, marks, packaging, transport, storage, usage requirements, etc. of the non-active surgical implants for osteosynthesis.

This Standard is applicable to non-active surgical implants for osteosynthesis (referred to as “implants for osteosynthesis”) which are made of metallic materials.

This Standard is not applicable to implants for osteosynthesis which are with coating on the surface.

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 191 Packaging - Pictorial marking for handling of goods (GB/T 191-2008, ISO 780: 1997, MOD)

GB/T 228 Metallic materials--Tensile testing at ambient temperature (GB/T 228-2002, eqv ISO 6892: 1998)

GB/T 2829 Sampling procedures and tables for periodic inspection by attributes (Apply to inspection of process stability)

GB/T 4340.1 Metallic materials—Vickers hardness test—Part 1: Test method (GB/T 4340.1-1999, eqv ISO 6507-1: 1997)

GB/T 14233.2 Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods

GB/T 15239 Sampling procedures and tables for isolated lot inspection by attributes

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

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