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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

# YY/T 0640-2016 / ISO 14630:3012

Replacing YY/T 0640-2008

# Non-active surgical implants - General requirements

无源外科植入物 通用要求

(ISO 14630:2012, IDT)

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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/T 0640-2008 *Non-active surgical implants - General requirements*. Compared with YY/T 0640-2008, the main differences in this Standard are as follows:

- modified the scope of the standard because this Standard does not apply to the implants from active animal tissues;
- added the terms and definitions for “magnetic resonance environment” (see 3.4) and “magnetic resonance imaging” (see 3.5);
- added some requirements for design attributes [see Clause 5 f], s), t), u), v)];
- made more detailed provisions on “pre-clinical evaluation” (see 7.2) and “post-market surveillance” (see 7.4);
- made more detailed provisions on “instructions for use” [see 11.3 a], t), u)];
- deleted “Annex A” of Edition 2008 and the content of “correspondence of basic principles outlined in ISO/TR 14283”.

This Standard uses translation method to identically adopt ISO 14630:2012 Non-active surgical implants -- General requirements.

The Chinese documents which have consistency with the international normative reference in this Standard are as follows:

- GB/T 7408-2005, *Data elements and interchange formats - Information interchange - Representation of dates and times* (ISO 8601:2000, IDT)
- GB/T 16886.1-2011, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* (ISO 10993-1:2009, IDT)
- GB/T 16886.7-2001, *Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals* (ISO 10993-7:1995, IDT)
- GB/T 19974-2005, *Sterilization of health care products - General requirement for characterization of a sterilization agent and the development, validation and routine control of a sterilization process for medical devices* (ISO 14937:2000, IDT)

- YY/T 0297-1997, *Clinical investigation of medical devices* (ISO 14155:1996, IDT)

- YY 0970-2013, *Sterilization of single-use medical devices incorporating materials of animal origin - Validation and routine control of sterilization by liquid sterilants* (ISO 14160:1998, IDT)

- YY/T 0316-2008, *Medical devices - Application of risk management to medical devices* (ISO 14971:2007, IDT)

- YY/T 0567.1-2013, *Aseptic processing of health care products - Part 1: General requirements* (ISO 13408-1:2008, IDT)

- YY/T 0802-2010, *Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices* (ISO 17664:2004, IDT)

- YY/T 0771.1-2009, *Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management* (ISO 22442-1:2007, IDT)

- YY/T 0771.2-2009, *Medical devices utilizing animal tissues and their derivatives Part 2: Controls on sourcing, collection and handling* (ISO 22442-2:2007, IDT)

- YY/T 0771.3-2009, *Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management* (ISO 22442-3:2007, IDT)



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 State Food and Drug Administration.

This Standard shall be under the jurisdiction of National Technical Committee on Surgical Implants and Orthopedic Instruments of Standardization Administration of China (SAC/TC 110).

The drafting organizations of this Standard: Tianjin Medical Device Quality Supervision and Inspection Center, State Food and Drug Administration Medical Device Technical Review Center.

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Version of standard substituted by this Standard is:

- YY/T 0640-2008.