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

GB/T 44876-2024

**Implants for surgery - Cleanliness of orthopedic implants -
General requirements**

外科植入物 骨科植入物的清洁度 通用要求

(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document is modified to adopt ISO 19227:2018 "Implants for surgery - General requirements for cleanliness of orthopaedic implants".

The technical differences between this document and ISO 19227:2018 and their reasons are as follows.

--- The normative reference GB/T 16886.1 replaces ISO 10993-1 (see 4.4) to adapt to my country's technical conditions and improve the reliability of the product.

operability;

--- ISO 10993-5 (see 5.8) has been replaced by the normative reference GB/T 16886.5 to adapt to my country's technical conditions and improve the reliability of the product.

operability;

--- The normative reference GB/T 19973.1 replaces ISO 11737-1 (see 5.3) to adapt to my country's technical conditions and improve the reliability of the product.

operability;

--- Replaced the European Pharmacopoeia and the United States Pharmacopoeia (see 5.4 and 5.5.3) with the four volumes of the Pharmacopoeia of the People's Republic of China (2020 edition) to suit Adapt to my country's technical conditions and improve operability.

The following editorial changes have been made to this document.

--- GB/T 16886.12 replaces the informative reference ISO 10993-12 (see 5.5.2 and 5.6);

--- GB/T 16886.17 replaces the informative reference ISO 10993-17 (see 5.6);

--- GB/T 25915 (all parts) replaces the informative reference ISO 14644 (all parts);

--- GB/T 27025 replaces the informative reference ISO/IEC 17025 (see 4.7);

--- GB/T 42061 replaces the informative reference ISO 13485 (see 4.1);

--- GB/T 42062 replaces the informative reference ISO 14971 (see 4.2);

--- YY/T 0618 replaces the informative reference AAMIST 72 (see 5.4).

Introduction

Cleaning of orthopedic implants is a critical step in achieving their biocompatibility and controlling the microbial load to meet sterilization process requirements.

The safe use of orthopedic implants is related to the materials they are composed of, as well as to the contaminants they release or remain on their surfaces.

Degree of protection is a key factor in ensuring the biocompatibility of implants. Where appropriate, cleaning is the removal of contaminants generated during the previous manufacturing process.

However, the cleaning method should not interact with the material and should not impair the biocompatibility and performance of the implant.

Cleaning agents should be effectively removed unless it has been demonstrated that they will not impair the biocompatibility and performance of the implant.

This is related to the biological evaluation of implants in GB/T 16886.1.

Orthopedic implants can be delivered sterile or non-sterile. In both cases, the manufacturer is responsible for cleaning the implant to remove Contaminants during the manufacturing process.

The purpose of cleaning validation is to demonstrate the effectiveness of the cleaning process to reduce physical, chemical, and microbiological contaminants to below specified

levels.

Evaluation and validation of cleaning methods is a difficult task that requires detailed knowledge of the orthopedic implant manufacturing process to identify potential contaminants, Potential interactions between the cleaning process, implant materials, and the environment (e.g., how the implant is handled after cleaning, the environment, and subsequent packaging) the cleanliness of the implant can be controlled by producing and cleaning the implant in a clean environment to replace the final Cleaning. In this case, the implant does not need to be cleaned prior to packaging, but the cleanliness requirements defined in this document may apply.

Cleanliness of surgical implants and orthopedic implants General requirements

1 Scope

This document specifies the cleanliness requirements for orthopedic implants (hereinafter referred to as implants) and the cleaning procedures for orthopedic implants based on a risk management process.

Requirements for test methods for process validation and control.

This document does not specify packaging and sterilization requirements, which are specified in other documents.

This document applies to both process cleaning and final cleaning.

This document does not apply to liquid and gas implants.

This document does not apply to cleaning processes that are performed or are the responsibility of the user.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to this document.

GB/T 16886.1 Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process (GB/T 16886.1-2022,ISO 10993-1:2018,IDT) GB/T 16886.5 Biological evaluation of medical devices Part 5: In vitro cytotoxicity test (GB/T 16886.5-2017, ISO 10993-5:2009, IDT) GB/T 19973.1 Microbiological methods for sterilization of health care products Part 1: Determination of the total number of microorganisms on the product (GB/T 19973.1-2023,ISO 11737-1:2018,IDT) ISO 9377-2 Water quality - Determination of hydrocarbon oil index - Part 2: Method using solvent

extraction and gas chromatography ASTM D7066-04 Infrared determination of dimers/trimers of chlorotrifluoroethylene (S-316) in recycled grease and non-polar materials

3 Terms and Definitions

The following terms and definitions apply to this document.

The URLs for terminology databases used for standardization maintained by ISO and IEC are as follows.

cleaning

To remove contaminants (3.4) from an article to the extent necessary for further processing or for its intended use

NOTE: Contaminants (3.4) can be removed from implant surfaces using mechanical, physical and/or chemical methods. The ability of an implant to be cleaned depends on many factors, particularly the chemical properties of the implant surface, the chemical properties of the contaminants, the cleaning process (3.3), the design of the implant (e.g., components that reduce its ability to be cleaned), surface, blind pores, micropores and macropores), surface morphology and porosity of the implant.