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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 19974-2018

Replacing 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

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Table of Contents

Foreword
Introduction
1 Scope
1.1 Scope of application
1.2 Not applicable
2 Normative references
3 Terms and definitions
4 Quality management system elements
4.1 File
4.2 Management responsibilities

Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard replaces GB/T 19974-2005 "The characteristics of sterilization and sterilization factors for medical care products and the opening of medical device sterilization process

General requirements for hair, confirmation and general control. The main technical differences between this standard and GB/T 19974-2005 are as follows.

--- Added the definition of "Process Challenge Device (PCD)" (see 3.18).

This standard uses the translation method equivalent to ISO 14937.2009 "the characteristics of medical products sterilization and sterilization factors and medical devices

General requirements for the development, validation and routine control of bacterial processes.

The documents of our country that have a consistent correspondence with the international documents referenced in this standard are as follows.

Safety of electrical equipment for measurement, control and laboratory use - Part 4.

Special requirements for sterilizers and washer-disinfectors (idtIEC 61010-2-041.1995)

--- GB/T 16886.1-2011 Biological evaluation of medical devices - Part 1. Evaluation and testing in the process of risk management

(ISO 10993-1.2009, IDT)

--- GB/T 16886.17-2005 Biological evaluation of medical devices - Part 17. Establishment of leaching allowances

(ISO 10993-17.2002, IDT)

--- GB 18282.1-2015 Health care products - Sterilization of chemical indicators - Part 1. General (ISO 11140-1.2005,

IDT)

---GB/T 19022-2003 Measurement management system measurement process and measurement equipment requirements (ISO 10012.2003, IDT)

--- GB/T 19973.1-2015 Microwaveological methods for the sterilization of medical devices - Part 1

Ding (ISO 11737-1.2006, IDT)

--- GB/T 19973.2-2018 Sterilization of medical devices - Microbiological methods - Part 2

Aseptic testing for validation and maintenance (ISO 11737-2.2009, IDT)

Introduction

A sterile medical device is a device that has no living microorganisms. The standard specifies the requirements for confirmation and routine control of the sterilization process.

When the device is to be provided in a sterile form, all undesired microbial contamination should be minimized prior to sterilization. Even medical devices

The product is produced under standard manufacturing conditions that meet the requirements of the quality management system (eg YY/T 0287-2003) and will still be carried before sterilization.

There are a small number of microorganisms, and such devices are non-sterile devices. The purpose of sterilization is to inactivate microorganisms and convert non-sterile instruments into sterile

instrument.

The kinetics of inactivation of pure microbial culture using physical factors and/or chemical factors for sterilization of medical devices can generally be carried out using residual microorganisms.

The exponential relationship between quantity and degree of sterilization is well described. This means that microbial survival is inevitable regardless of the degree of sterilization.

The probability. For established treatment methods, the survival probability of residual microorganisms depends on the number of microorganisms, resistance and microorganisms during treatment.

The environment in which it exists. Therefore, any product in the batch product that has undergone the sterilization process cannot be guaranteed to be sterile and batch processed through the sterilization process.

Sterility of a product is defined as the probability of the presence of living microorganisms in the medical device.

If satisfied, the requirements described in this standard will provide a moist heat that is expected to be used in medical devices with appropriate microbicidal activity.

Sterilization process. Moreover, compliance with this standard ensures that sterilization is reliable and repeatable, so that there is reason to believe that microbes survive after sterilization.

The probability is relatively low. The probability of microbial survival to achieve sterility requirements is dictated by the standard. (eg EN556-1 and ANSI/AAMI)

ST67).

General requirements for quality management systems such as design and development, production, installation and service are listed in ISO 9001, Medical Device Production Quality Management

See YY/T 0287 for special requirements. These quality management system standards believe that some processes in manufacturing cannot be fully validated.

Verification of the continued product inspection and testing, sterilization is such a process. Therefore, before the implementation of the sterilization process, it should be confirmed that the sterilization process

The effectiveness of the inspection should be routinely monitored and equipment should be maintained.

Exposure to a properly identified and accurately controlled sterilization process is not the only factor that ensures the product is sterile and suitable for the intended use.

Therefore, we should also pay attention to the following aspects.

a) the microbiological status of incoming raw materials and/or components;

b) any confirmation and routine control of the cleaning and disinfection procedures for the product;

c) control of the manufacturing, assembly and packaging environment of the product;

d) control of equipment and processes;

e) control of personnel and their health;

f) the packaging method and packaging materials of the product;

g) Storage conditions of the product.

The type of contamination of the sterilized product affects the effectiveness of the sterilization process. It is recommended to use the medical institution and follow the manufacturer's instructions.

The book requirements (see ISO 17664) are reproducible medical devices as special cases. Despite cleaning, these products may still be widely available

Contaminated by microorganisms and residual organic and/or inorganic pollution. Therefore, special attention should be paid to the cleaning and disinfection process during repeated processing of the device.

Confirmation and control.

The requirements that this standard claims to meet are the normative part of this standard. The guidelines in Appendix E are not intended to be normative requirements, nor are they

The reviewer's review form is provided. The interpretations and methods given in the guide should be considered as necessary means of meeting the requirements of the standard. If it can also be satisfied

The requirements of this standard, methods not specified in the guide can also be used.

The development, validation, and routine control of the sterilization process involves several inconsistent but related activities such as calibration, maintenance, product definition, and

Process definition, installation qualification, operational qualification, and performance qualification. Although the activities specified in this standard are grouped and arranged in a specific order, this is not

These activities are required to be in the order in which they are presented in this standard. The required activities do not need to be in order because the development and validation in the process can

Can be repeated. The responsibilities for activities that implement the requirements of this standard vary from case to case. The requirements of this standard stipulate the duties of all parties

Responsibility (see 4.2), but does not stipulate who the specific responsibilities belong to. Appendix E provides guidance on the assignment of responsibilities.

This standard has three distinct uses.

--- Manufacturers of medical devices that will sterilize their products without specific standards;

--- for manufacturers and users of health care institutions without specific standards;

--- As a framework for the development and revision of specific sterilization process