

ICS 11.080.01

CCS C47



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

GB 18278.1-2015

**Sterilization of health care products-Moist heat-Part 1:
Requirements for the development, validation and routine
control of a sterilization process for medical devices**

医疗保健产品灭菌 湿热 第1部分：医疗器械灭菌过程的开发、确认和常规控制要求

(English Translation)

Issued on: December 10, 2015

Implemented on: January 1, 2017

**Issued by: General Administration of Quality Supervision, Inspection and
Quarantine of the People's Republic of China;
Standardization Administration of China**

Table of Contents

1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Quality Management System Elements	8
5 sterilization factor characterization	9
6 features described processes and equipment	9
7 Products OK	12
8 process determines	12
9 Confirm	13
10 Routine monitoring and control	15
11 sterilized product release	16
12 to maintain the effectiveness of the process	16
Appendix A (informative) Guide	18
Annex B (informative) based on the state of the natural microflora inactivation process determines (based on bioburden method)	22

Foreword

All technical content in this Part of GB 18278 is mandatory.

GB 18278 "Sterilization of health care products heat" is divided into the following two parts.

--- Part 1. Development of medical equipment sterilization process, validation and routine control requirements;

--- Part 2. Application guide.

This is part of the GB Part 118 278.

This section drafted in accordance with GB/T 1.1-2009 given rules.

This section and GB/T 18278.2 together instead of GB 18278-2000 "Sterilization of health care products for validation and routine control requirements

Confirmed that health care products Sterilization of health care institutions moist heat sterilization industrial heat sterilization "and GB/T 20367-2006" and conventional control

Claim". Compared with GB 18278-2000 and GB/T 20367-2006 main differences are as follows.

--- For industrial moist heat sterilization and heat sterilization two aspects of health care organizations;

--- Increasing the sterilization factor features, product definition, process definition, installation qualification, operational qualification, to maintain the effectiveness of the sterilization process technology

content.

This part identical with ISO 17665-1:2006 "developed heat sterilization of health care products for medical device sterilization process, indeed

Recognize and routine control. "

Consistency correspondence between this part of international documents and normative references of our files are as follows.

--- GB 18281.1-2015 Sterilization of health care products - Biological indicators - Part 1.General (ISO 11138-1:2006,

IDT);

--- GB 18281.3-2015 Sterilization of health care products - Biological indicators - Part 3.Biological indicators for moist heat sterilization

(ISO 11138-3:2006, IDT);

--- GB 18282.1-2015 Sterilization of health care products - Chemical indicators - Part 1.General (ISO 11140-1:2005,

IDT);

--- GB 18282.3-2009 Sterilization of health care products - Chemical indicators - Part 3.Class BD for steam penetration test

The Class 2 indicator systems (ISO 11140-3:2007, IDT);

--- GB 18282.4-2009 Sterilization of health care products - Chemical indicators - Part 4.BD used to replace steam penetration test

Examination II indicators (ISO 11140-4:2007, IDT);

--- GB 18282.5-2015 Sterilization of health care products chemical indicators - Part 5.Class of air exclusion measure for BD

Examination II indicators (ISO 11140-5:2007, IDT);

--- GB/T 19022-2003 Measurement management systems for measurement processes and measuring equipment (ISO 10012-2003, IDT);

--- GB/T 19633.1-2015 terminally sterilized medical device packaging - Part 1.materials,

sterile barrier systems and packaging systems

Requirements (ISO 11607-1:2006, IDT);

--- GB/T 19633.2-2015 terminally sterilized medical device packaging - Part 2. Confirm forming, sealing and assembly processes to

Demand (ISO 11607-2:2006, IDT);

Part 1 sterilization Microbiological Methods --- GB/T 19973.1-2015 medical devices. the total number of microorganisms on the product test

Set (ISO 11737-1:2006, IDT);

--- GB /sterilization Methodology Part 2 microbial T 19973.2-2005 Medical Devices. Confirm sterile test sterilization procedures

Test (ISO 11737-2:1998, IDT);

--- YY/T 0287-2003 medical device quality management system for regulatory requirements (ISO 13485:2003, IDT);

--- Processing YY/T 0802-2010 sterilization of medical equipment manufacturers to provide the information may be repeated sterilization of medical devices

(ISO 17664:2004, IDT).

This part made the following editorial changes.

--- According to GB/T 1.1 requirements of a number of editorial changes;

--- Deleted international standards foreword;

--- Introduction of international standards and references appear to replace the corresponding country standards.

Please note that some of the content of this document may involve patents. Issuer of this document does not assume responsibility for the identification of these patents.

This part is proposed by the China Food and Drug Administration.

This part of the National Standardization Technical Committee disinfection technology and equipment (SAC/TC200) centralized.

This section drafted by. Shandong Xinhua Medical Instrument Co., Ltd., Michael Di Jincheng Medical Devices Co., Ltd., the State Food and Drug

Goods Administration of Guangzhou Medical Device Quality Supervision and Inspection Center, Belimed Medical Equipment (Shanghai) Co., Ltd.

introduction

Sterile medical devices is a non-living micro-organisms products. International Standard specifies confirm the sterilization process and routine control of when

Medical devices must be provided in sterile form, it should be sterilized before its various unintended microbiological contamination to a minimum. Even medical devices

Mechanical products to meet the quality management system (for example. ISO 13485) requirements under standard production conditions produced before sterilization still with

A small amount of micro-organisms, such products shall be guilty of non-sterile products. Purpose of sterilization is to inactivate microorganisms, non-sterile products into sterile product.

Physical factors and/sterilization of medical devices using kinetic or chemical factors on pure cultures of microorganisms surviving microorganisms can be inactivated general

The number was exponential relationship between the degree of sterilization and be a good description. This means that regardless of the degree of sterilization, there must exist a microorganism

Live probability. For the treatment has been given, the remaining microorganism survival probability depends on the number of microbes, microbial resistance and processing

It was occurring environment. Therefore, sterilized products batch processing in any one of the products can not be guaranteed to be sterile, sterilized batch processing

Sterile product is defined as the amount of living micro-organisms present in the probability of the medical device.

If satisfied, the requirements of this standard will provide a description of the medical device intended to be used with appropriate antimicrobial activity of heat to kill off

Bacteria process. Moreover, to ensure compliance with this standard sterilization is reliable and repeatable, thus reason to believe that the probability of surviving microorganisms after sterilization

Rate relatively low. Sterility requirements for microbial survival probability by the regulatory requirements may vary by country (such as YY/T 0615.1).

General requirements for design and development, production, installation and services such as quality management system, see GB/T 19001, medical equipment production quality

Particular requirements for management systems see ISO 13485. These quality management system standard that some of the effectiveness of the process of manufacture can not be completely