Chinastandards.org

ICS 11.020
CCS C 05

WS

INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

WS/T 654.1-2018

Safety management for medical devices

(English Translation)

Issued on: January 1, 1970 **Implemented on: May 1, 2020**

Issued by: National Health Commission

Preview: page 1 of 5 shown, 16 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/ws-t-654-1-2018

Chinastandards.org

Table of Contents

Foreword
Introduction
1 Scope
2 Normative references
3 Terms and definitions
4 Management requirements
4.1 Basic principles
4.2 Management organization
4.3 Management Responsibilities
4.4 Management System
4.5 Risk Management
4.6 Collection and analysis of safety information
4.7 Supervision and inspection of safety and performance control system
4.8 File management
5 Personnel requirements
6 Environment and facility control
6.1 Environment
6.2 Facilities
7 Process control
7.1 Safety confirmation before clinical use
7.2 Control during use
7.3 Emergency response to adverse events
8 Safety and performance testing
8.1 Testing laboratory
8.2 Testing standards and appliances
8.3 Detection cycle
8.4 Test records
9 Supplier Management
Appendix A (Normative Appendix) Safety and Performance Status Identification
Appendix B (informative) Classification of medical device risk levels
References

Preview: page 2 of 5 shown, 16 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/ws-t-654-1-2018

Foreword

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

This standard was drafted. Chinese People's Liberation Army Joint Logistics Support Army Drug Instrument Supervision and Inspection Station, Capital Medical University, Central Theater General Hospital, Third Medical Center of General Hospital of Chinese People's Liberation Army, China Medical Equipment Association.

Drafters of this standard. Sun Xiwen, Li Yongxue, Li Yiyong, Duan Xinan, Mi Yongwei, Peng Mingchen, Zhang Zhiqiang, and Meng Jianguo.

Introduction

With the rapid development of modern economic society in our country and the continuous progress of medical device technology, the scale and level of medical devices have become modern an important symbol of medical technology capabilities of medical institutions. The status and role of medical devices in the medical process are becoming more and more prominent.

Key supporting technologies for technological and medical development.

Many large, medium and high-risk medical devices have been widely used in medical institutions in China, not only in large tertiary hospitals, but also in second-tier hospitals.

Level hospitals, and even grassroots medical and health institutions, have become an important basic guarantee for promoting and improving the level of medical technology.

It is worth noting that any misalignment and deviation of the technical performance and status parameters of the medical device during clinical use may be different degrees this affects the quality of medical treatment, causing injuries and even death to personnel.

Strengthening and standardizing the safety management of clinical use of medical devices by medical institutions, reducing the risk of clinical use of medical devices, and improving medical treatment Quality, an important measure to ensure medical safety, is also the unshirkable responsibility of medical institutions. The standard preparation team is based on relevant national laws and regulations.

Study and analyze the actual situation of medical device safety management in clinical use in China's medical institutions, summarize practical experience, and solicit opinions from all parties See the basis of this standard.

Medical device safety management

Preview: page 3 of 5 shown, 16 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/ws-t-654-1-2018

1 Scope

This standard specifies the safety management requirements for active medical devices entering medical institutions before and during clinical use, including medical treatment.

The structure established by the organization's medical device management organization, the responsibilities of organizations at all levels, the elements of various management systems that should be established, and the methods of safety management Laws, etc .; also specifies technical requirements to ensure the safety and effective performance testing, operating specifications, maintenance, etc. of medical devices.

This standard applies to the safety management of active medical devices used clinically by medical institutions.

2 Normative references

The following documents are essential for the application of this document. For dated references, only the dated version applies to this article Pieces. For undated references, the latest version (including all amendments) applies to this document.

GB 16895.24 Electrical installations of buildings-Part 7-710. Requirements for special equipment and locations Medical facilities YY/T 0841 Periodic test and post-repair test of medical electrical equipment

3 Terms and definitions

The terms and definitions defined in GB 16895.24 and the following apply to this document.

Medical device

In order to achieve diagnosis, treatment, monitoring, remission, compensation for disease, injury or disability; research on anatomical or physiological processes, Replacement, regulation; control of pregnancy; the purpose of examining human samples, its effects on the human body and in vivo are not through pharmacology Obtained by scientific, immunological or metabolic means (but these means may be involved and play a certain auxiliary role), alone or in combination.

Generic term for instruments, equipment, appliances, materials or other items used in the human body, including the software required.

3.1.1

High risk medical device Medical devices with high potential hazards must be strictly controlled for their safety and effectiveness.

Note: This type of medical device corresponds to the third type of medical device in the Regulations on the Supervision and Administration of Medical Devices.

Preview: page 4 of 5 shown, 16 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/ws-t-654-1-2018

3.1.2

Medium risk medical device Medical devices that can ensure their safety and effectiveness through special controls.

Note: This type of medical device corresponds to the second type of medical device in the Regulations for the Supervision and Administration of Medical Devices.

3.1.3

Low risk medical device Medical devices whose safety and effectiveness can be guaranteed through routine control.

Note: This type of medical device corresponds to the first type of medical device in the Regulations for the Supervision and Administration of Medical Devices.

3.1.4 Active medical device

Need to use electric, pneumatic and other medical devices to drive their functions.

Medical venue

A place used to diagnose, treat, monitor and care for patients.

Note: To ensure that patients are protected from possible electrical hazards, additional protective measures are used in medical facilities. The type and performance of these hazards depends on the situation.

The treatment varies. Divide sites according to their different uses and different medical procedures.

3.2.1

Category of class 1

Medical sites that use active medical device components in the following ways.

-The active medical device parts are in contact with the outside of the body;

-Contact parts invade any part of the body.

3.2.2

Venue of class 2

Active medical device components are used in places such as cardiac diagnostics, operating rooms, and vital life-threatening treatments.

Medical engineering personnel Personnel with a medical engineering background, college degree or equivalent, and personnel engaged in medical device safety and quality technical assurance.

Preview: page 5 of 5 shown, 16 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/ws-t-654-1-2018