ICS 11.100.20
CCS C30

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0771.1-2020

Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management

动物源医疗器械 第1部分：风险管理应用

Issued on: September 1, 2025 **Implemented on: April 1, 2021**

Issued by: National Medical Products Administration

Table of Contents

Foreword

YY/T 0771 "Medical Devices of Animal Origin" consists of the following parts.

--- Part 1. Risk management applications;

--- Part 2. Control of source, collection and disposal;

--- Part 3. Confirmation of the elimination and inactivation of viral and transmissible spongiform encephalopathy (TSE) factors;

--- Part 4. Principles of elimination and/or inactivation of factors of transmissible spongiform encephalopathy (TSE) and its process confirmation analysis. This part is part 1 of YY/T 0771. This section was drafted in accordance with the rules given in GB/T 1.1-2009. This part replaces YY/T 0771.1-2009 "Medical Devices of Animal Origin Part

1 Risk Management Application", and YY/T 0771.1- Compared with.2009, in addition to editorial changes, the main changes are as follows:

--- Revised "Appendix DTSE Risk Management Related Information". This part uses the redrafting method to modify and adopt ISO 22442-1..2015 "Medical Devices of Animal Origin Part 1. Risk Management use". The technical differences between this part and ISO 22442-1..2015 and the reasons are as follows:

--- On the normative reference documents, according to GB/T 1.1-2009 and GB/T.20000.2-2009, this part is made technical The adjustment of the difference to adapt to the technical conditions of our country, the adjustment is concentrated in Chapter 2 "Regulatory Reference Documents", specific Adjust as follows: - Replace ISO 10993-1 with GB/T 16886.1 equivalent to international standards; - Replaced ISO 14971 with YY/T 0316-2016 which is equivalent to adopting international standards; - Replaced ISO 22442-2..2015 with YY/T 0771.2-2020 which adopted international standards - Replaced ISO 22442-3 with YY/T 0771.3 equivalent to the international standard. Please note that some content of this document may involve patents. The issuer of this document does not assume responsibility for identifying these patents. This part is proposed by the State Drug Administration. This part is under the jurisdiction of the National Medical Device Biological

Evaluation Standardization Technical Committee (SAC/TC248). This section was drafted. Shandong Medical Device Product Quality Inspection Center. The main drafters of this section. Liu Chenghu, Shi Yanping, Liu Jia. The previous versions of the standards replaced by this part are as follows:

--- YY/T 0771.1-2009.

Some medical devices use materials of animal origin. Animal tissue and its derivatives are used in the design and manufacture of medical devices to provide properties that are superior to non-animal matrix materials. Medical treatment The range of materials and types of materials derived from animals in the device is very wide, and these materials can constitute the main part of the device (such as cattle/porcine heart valves, Osseous or orthopedic bone substitutes, hemostatic devices), product coating or infiltration (e.g. collagen, gelatin, heparin) or used in device manufacturing processes (Such as animal fat derivatives such as oleate and stearate, fetal bovine serum, enzymes, culture medium). YY/T 0316-2016 is a general standard that stipulates that manufacturers identify hazards associated with medical devices (including in vitro medical devices) (Source) and the process of dangerous situations, used to estimate and evaluate these dangerous risks, control these risks and monitor Effectiveness. This part of YY/T 0771 gives additional requirements and guidelines for evaluating the use of inanimate or inanimate animal organizations Or medical devices made from derivatives thereof. This part of YY/T 0771 is expected to cover medical devices including active implanted medical devices (such as implantable infusion pumps). This part of YY/T 0771 does not apply to in vitro diagnostic devices. This part of YY/T 0771 is not an "independent" standard and can only be used with YY/T 0316-2016. Application of this part For guidance, see Appendix A, and for the risk management flowchart of medical devices using animal materials, see Appendix B, TSE factors for specific animal materials The special requirements for risk management are in accordance with the provisions of Appendix C. For information on TSE risk management, see Appendix D. Meeting the requirements of this part can be regarded as complying with this part of YY/T 0771. The guidelines given in the notes and informative appendix are Material information is not a checklist provided to auditors. Medical devices of animal origin Part 1. Risk management applications

1 Scope

YY/T 0771.1 is Part 1 of the Chinese series on medical devices made from animal tissue, and it covers the application of risk management to them. Animal-derived devices, from bovine pericardium heart valves to porcine dermal matrices to collagen and heparin, carry a hazard no synthetic material has: the possibility of transmitting an infectious agent, including the transmissible spongiform encephalopathy agents that reshaped this whole regulatory area. Risk management here therefore begins with sourcing, the country and herd the tissue came from, and runs through the processing steps that inactivate or remove

agents. For a manufacturer of any animal-derived device seeking Chinese registration, this is the framework the risk file has to follow.

This part of YY/T 0771 specifies the identification and use of animal-derived materials (inactive or rendered inactive) for medical devices Equipment-related hazards (sources) and hazardous situations, the estimation, evaluation and control of the resulting risks, and procedures for monitoring the effectiveness of these controls (Combined with YY/T 0316-2016). This section applies to medical devices manufactured from animal-derived materials (inactive or rendered inactive), excluding in vitro diagnostic medicine Therapeutic equipment. This section does not apply to medical devices that use human tissue. This section does not specify a quality management system for the control of the entire production stage of medical devices. In addition, taking into account the residual risk defined in YY/T 0316-2016 and weighing the expected medical comparison with other alternatives Treatment benefit, this section gives the judgment process of the acceptability of residual risk, as well as medical devices manufactured using animal tissue or its derivatives Requirements and guidelines for risk management of hazards (sources) .These hazards (sources) include.

a) Bacterial, mold or yeast contamination;

b) virus contamination;

c) Contaminated Spongiform Spongiform Encephalopathy (TSE) factors;

d) Unwanted pyrogenic, immunological or toxicological reactions caused by the material. Similar principles apply to parasites or other unclassified pathogens.

Note 1. The operation of a comprehensive quality management system during the production process is not a requirement of this part. See the quality management system for the control of all stages of medical device production or reprocessing For the standard, see YY/T 0287.

Note 2. Refer to Appendix A for application guidance in this section.

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 the cited documents without 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 process of risk management (GB/T 16886.1- 2011, ISO 10993-1..2009, IDT)

YY/T 0316-2016 Application of medical device risk management to medical devices (ISO 14971..2007, IDT)

YY/T 0771.2-2020 Medical devices of animal origin Part 2. Control of source, collection and

disposal (ISO 22442-2..2015, MOD)

YY/T 0771.3 Medical Devices of Animal Origin Part 3. Virus and Transmissible Spongiform Encephalopathy (TSE) Factor Elimination and Inactivation Confirmation (YY/T 0771.3-2009, ISO 22442-3..2007, IDT)

3 Terms and definitions

The terms and definitions defined in YY/T 0316-2016 and the following apply to this document.