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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 44353.1-2024

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

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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 Part 1 of GB/T 44353 "Medical devices of animal origin". GB/T 44353 has been published in the following parts.

1.Application of risk management;

2.Control of sources, collection and disposal. This document is equivalent to ISO 22442-1.2020 "Medical devices of animal origin - Part

1.Application of risk management". The following minimal editorial changes were made to this document.

--- Added Note 2 in 3.6. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Biological Evaluation of Medical Devices (SAC/TC248). This document was drafted by: Shandong Medical Device and Drug Packaging Inspection Institute, China Food and Drug Inspection Institute, Hangzhou Qiming Medical Medical Equipment Co., Ltd. and Shanghai Songli Biotechnology Co., Ltd. The main drafters of this document are. Sun Xiaoxia, Wan Min, Duan Xiaojie, Jin Linhe, He Hongbing, Chen Liang, Zhu Fuyu, Liu Meirong, and Chen Xingxing.

Some medical devices use materials of animal origin. The use of animal tissues and their derivatives in the design and manufacture of medical devices to provide properties that are superior to those of non-animal derived materials. The range and amount of animal-derived materials used in medical devices vary. These materials may constitute a major part of the device (e.g., bovine/porcine heart valve membranes, bone substitutes for dental or orthopedics, hemostatic devices), may be a coating or impregnation agent for the product (such as collagen, gelatin, heparin), or may Can be used in device manufacturing processes (such as animal fat derivatives such as oleate and stearate, fetal bovine serum, enzymes, culture media). ISO 14971 is a general standard that specifies the procedures for manufacturers to identify hazards and dangerous situations associated with medical devices, including in vitro medical devices. The process of estimating and evaluating the risks associated with these hazards, controlling these risks and monitoring the risk control throughout the life cycle of medical devices This document provides additional requirements and guidance for evaluating the effectiveness of products made from non-viable or inactivated animal tissues or their derivatives. Medical devices manufactured. This document is intended to cover medical devices including active implantable medical devices (such as implantable infusion pumps). This document does not apply to in vitro diagnostic devices. This document is not a "stand-alone" standard and should only be used in conjunction with ISO 14971.

Note. Meeting the specified requirements of this document is considered to be in compliance with this document. The guidance given in the notes and informative annexes is not normative and is not intended as a checklist. GB/T 44353 consists of four parts.

1.Application of risk management. The purpose is to specify the identification of medical products made with animal-derived materials (non-viable or inactivated). Hazards and hazardous situations associated with medical devices (excluding in vitro diagnostic medical devices), and the estimation, evaluation and control of the resulting risks controls, and procedures for monitoring the effectiveness of those controls.

2.Control of sources, collection and disposal. The purpose is to specify the animals and Control requirements for the source, collection and disposal (including storage and

transportation) of tissues.

3.Confirmation of removal and inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents. or products derived from animal tissues during the production of medical devices for the removal of viruses and transmissible spongiform encephalopathy agents and/or Inactivation confirmation.

4.Principles of removal and/or inactivation of transmissible spongiform encephalopathy (TSE) agents and process confirmation analysis. Can the processing of medical devices derived from non-viable animal tissue help reduce the nosocomial transmission of transmissible spongiform encephalopathies? Provide advice on the design and conduct of confirmation analyses for risks. Animal-derived medical devices Part

1 Scope

GB/T 44353.1-2024 is the first part of the Chinese standard on medical devices made from animal tissue, and it covers the application of risk management. Bovine pericardium in a heart valve, porcine intestine in a surgical mesh, bovine collagen in a dermal filler, equine tendon in a graft: these materials do things synthetic ones cannot, and they carry a hazard no synthetic material has, the transmission of a viral or a transmissible spongiform encephalopathy agent from the source animal to the patient. The risk cannot be tested out of a finished device, so it has to be managed through the whole chain, and this standard sets out how. It defines the risk management process as it applies to animal-sourced devices: the identification of the hazards arising from the species, the geographical origin, the tissue type and the age of the animal, the estimation and evaluation of the risk, the risk control measures available at sourcing, at collection, in the manufacturing process and in the inactivation and removal steps, the verification of their effectiveness, and the residual risk evaluation and the production and post-production information. It is aligned with ISO 22442-1. For a manufacturer or a notified body working in China, this is the framework the file is built on.

This document applies to medical devices manufactured with animal-derived materials (non-viable or inactivated), and does not apply to in vitro diagnostic medical devices. This document, in conjunction with ISO 14971, specifies the procedures for identifying the hazards and hazardous situations associated with such devices and for assessing the resulting risks. In addition, this document provides procedures for weighing the residuals defined in ISO 14971. This document provides guidance on the decision-making process for adopting dynamic devices and the acceptability of the residual risks when compared with the expected clinical benefits of existing devices. Requirements and guidance for risk management of typical hazards of medical devices manufactured from plant tissues or their derivatives, including.

a) Contamination by bacteria, mold or yeast;

b) Viral contamination;

c) contamination by transmissible spongiform encephalopathy (TSE) agents;

d) Undesirable pyrogenic, immunological or toxicological reactions caused by the material. Similar principles may apply to parasites or other unclassified pathogens. Except for some specific derivatives mentioned in Appendix C, this document does not give acceptance levels because these depend on many factors and it is impossible to Appendix C gives the values of animal fat derivatives, animal charcoal, milk and milk derivatives, wool derivatives and amino acids. Acceptable level of TSE risk. This document does not address the quality management system that controls all stages of the production of medical devices. This document does not cover medical devices that use human tissue. NOTE

1 It is not a requirement of this document to operate a comprehensive quality management system during production. For control of all stages of production or reprocessing of medical devices, see Quality Management. System standard (see ISO 13485). Note

2.Guidance on the application of this document is given in Appendix A.

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. ISO 10993-