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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 44353.2-2024

Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling

动物源医疗器械 第2部分：来源、收集与处置的控制

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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 2 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.Source, collection and disposal control. This document is equivalent to ISO 22442-2.2020 "Medical devices of animal origin - Part

2.Control of source, collection and disposal". 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, Chongqing Municipal Drug Administration Technical Review and Inspection Center, Shanghai NewPulse Medical Technology Co., Ltd., and Beijing Bangsai Technology Co., Ltd. The main drafters of this document are: Sun Likui, Xu Huiwen, Fan Wei, Wen Xiantao, Nie Hongtao, Ruan Wenting, Liu Min, Yu Qifeng, and Zhang Hongwei.

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 varies. These materials may constitute a major part of the device (e.g., a bovine/porcine heart valve membranes, bone substitutes for dental or orthopedics, hemostatic devices), may be coatings or impregnations of the product (e.g. 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). The sources of tissues and derivatives used in medical devices are generally obtained by manufacturers from various animals, such as cattle, sheep, or commercially available farm animals. Some specialized factories also process animal-derived materials into finished products (such as gelatin) for use as raw materials in final medical devices. This document is intended to be used in conjunction with the other two parts of ISO 22442 while complying with my country's safety regulations. Manufacturers should refer to Information on the validation of elimination and/or inactivation of viruses and transmissible spongiform encephalopathies (TSE) agents in ISO 22442-3. This document only specifies the requirements for some elements of the quality management system and does not cover all the requirements of the quality management system. The standard for a quality management system (see ISO 13485) that controls all stages of the production or reprocessing of medical devices. The quality management system elements form part of a quality management system in accordance with ISO 13485. 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. Does 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 44353.2-2024 is the second part of the Chinese standard on medical devices made from animal tissue, and it covers the controls on where the material comes from and how it is obtained. Risk management, the subject of Part 1, decides what has to be controlled; this part specifies the controls themselves, and they sit at the beginning of the chain, before the manufacturer's own quality system has any hold on the material. The standard sets the requirements on the sourcing: the species and the geographical origin of the animals and the country's status in respect of transmissible spongiform encephalopathies, the age and the health of the animals and the veterinary control they were under, the tissue type and its infectivity category. It then sets the requirements on collection and handling: the establishments the animals are taken from and their approval, the ante-mortem and post-mortem inspection, the segregation from other material, the prevention of cross-contamination, the handling, storage and transport of the collected tissue, and the traceability and the documentation that has to accompany it back to the individual animal or herd. It is aligned with ISO 22442-2. For a manufacturer, a tissue supplier or an auditor in China, this is the control text.

This document specifies the origin, collection and handling (including storage and transportation) of animals and tissues for medical devices manufactured with animal-derived materials. The control requirements for in vitro diagnostic medical devices (e.g., transport, transmission, etc.) do not apply to in vitro diagnostic medical devices. The risk management process requirements given in ISO 22442-1 apply. NOTE. The choice of animal source is particularly important for TSE risk management (when using animal tissues from cattle, sheep, goats, deer, elk, mink, and cats). and/or its derivatives). This document is not applicable to medical devices that use human tissue. This document does not address the requirements for a quality management system to control all stages of the production of medical devices.

2 Normative references

The contents of the following documents constitute 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.

GB/T 44353.1-2024 Medical devices of animal origin Part

3 Terms and definitions

For the purposes of this document, the terms and definitions defined in ISO 22442-1 and the following apply. ISO and IEC maintain terminology databases for standardization at the following addresses.

3.1 Collection Remove tissue from the animal.

3.2 closed herd closedherd A herd managed through standard operating procedures (SOPs) that define criteria for limiting the admission of new animals to ensure that all introduced animals are The animals introduced are of equal or higher health standards than the original herd.

Note. Such SOPs typically include.

a) Veterinary monitoring process records;

b) Complete medical history records, including a complete record of the negligible TSE risk status of the herd with a documented history of TSE;

c) processes to prevent the use of proteins from mammalian sources, including fully documented feeding history, origin and traceability;

d) Complete breeding history records;

e) Complete record of veterinary drug and vaccine use history;

f) the traceability process for each animal;