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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Biological evaluation of medical devices - Part 22: Guidance on nanomaterials

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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 22 of GB/T (Z) 16886 "Biological Evaluation of Medical Devices". GB/T (Z) 16886 has issued the following

part.

--- Part 1.Evaluation and testing in the risk management process;

--- Part 2.Animal welfare requirements;

--- Part 3.Genotoxicity, carcinogenicity and reproductive toxicity tests;

--- Part 4.Selection of blood interaction tests;

--- Part 5.In vitro cytotoxicity test;

--- Part 6.Local reaction test after implantation;

--- Part 7.Ethylene oxide sterilization residues;

--- Part 9.Qualitative and quantitative framework for potential degradation products;

--- Part 10.Irritation and skin sensitization test;

--- Part 11.Systemic toxicity test;

--- Part 12.Sample preparation and reference materials;

--- Part 13.Qualification and quantification of degradation products of polymer medical devices;

--- Part 14.Qualitative and quantitative of ceramic degradation products;

--- Part 15.Qualitative and quantitative analysis of metal and alloy degradation products;

--- Part 16.Toxicokinetic study design of degradation products and leachable substances;

--- Part 17.Establishment of allowable leachable limits;

--- Part 18.Chemical characterization of medical device materials in the risk management process;

--- Part 19.Characterization of physical chemistry, morphology and surface properties of materials;

--- Part 20.Principles and methods of medical device immunotoxicology testing;

--- Part 22.Nanomaterials Guidelines.

This document is equivalent to ISO /T R10993-22.2017 "Biological Evaluation of Medical Devices Part 22.Guidelines for Nanomaterials", document

The type is adjusted from the ISO technical report to my country's national standardization guiding technical document.

Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents.

Introduction

This document is intended to provide guidance for the biological evaluation of medical devices that contain, result from, or consist of nanomaterials. How many nanomaterial terms

kind of definition. This document will use the ISO definition. When a material has external and internal dimensions on the nanometer scale, that is, when its dimensions or

When the structure composition is between 1nm and 100nm, it is considered as a nanomaterial (ISO /T S80004-1.2015). For regulatory purposes,

It is advisable to check the applicable regulatory definitions for a particular country. Other features (such as nano-specific properties) can also be included in such

in the definition of.

Morphological structures formed on the surface of medical devices may also have nanoscale dimensions. Therefore, the impact of this structure on the biological response of the device

Possible impacts also need to be considered.

Nano-objects with a length ranging from 1 nm to 100 nm may be produced during the life cycle of a medical device.

Evaluation of adverse effects that may be caused by nano-objects produced by medical devices in any link of preparation, use, wear or degradation. This applies to

Medical devices manufactured using nanomaterials, and medical devices not manufactured using nanomaterials, but which may generate nanoscale abrasive or degrading particles

medical equipment. For the biological evaluation of medical devices, knowledge of the potential generation and/or release of nanoobjects from such materials is essential.

need.

The procedures described in GB/T (Z) 16886 for the biological evaluation of medical devices can be used for those medical devices containing nano-objects,

But these nanoobjects will not be released from the device, because they are an integral part of the device. However, when nanoobjects may be released

When, it is also necessary to conduct a safety evaluation of the released nano-objects. In addition to the evaluation of medical devices, it is also possible to evaluate the composition or composition of nanomaterials

be evaluated individually.

This document provides trained professionals with a general approach to the biological evaluation of nanomaterials in the context of medical device evaluation,

It also discusses how to use other parts of GB/T (Z) 16886 when evaluating nanomaterials. Various tests described in GB/T (Z) 16886

Certain methods may not always be applicable to the testing of nanomaterials. Nanomaterials themselves can exist in the form of powders or colloidal dispersions, but

It can also be present in medical devices as nanostructured materials or materials and/or medical device surface structures when combined with a matrix. usually,

The nanomaterial itself needs to be evaluated, not the leach solution typically used when testing biological materials or medical devices.

price. Nanomaterials present particular challenges when performing test systems and interpretation of test results commonly used in medical device evaluation.

Nanotechnology, the development of nanomaterials, and the evaluation of the potential toxicity of such materials are emerging fields, and this document represents only the

time knowledge. Although appropriate tools and methods for evaluating nanomaterials are

still being developed, consideration is given to risk/benefit analyses, providing relevant

Characterization of nanomaterials and data on biological effects to address safety issues in their application in the field of medical devices.

This document addresses how medical devices containing, produced, or composed of nanomaterials are

Guidance is provided for biological evaluation of machinery.

GB/T (Z) 16886 "Biological Evaluation of Medical Devices" is proposed to be composed of 21 parts.

--- Part 1.Evaluation and testing in the risk management process. The purpose is to protect human beings from potential

In the biological risk, and describe the biological evaluation of the medical device in the risk management process, as the overall evaluation of the medical device and

An integral part of the development process.

--- Part 2.Animal welfare requirements. The purpose is to maximize the use of scientifically sound non-animal tests to ensure that they are used to evaluate medical

Animal tests on the biological performance of materials used in devices comply with recognized ethical and scientific principles.

--- Part 3.Genotoxicity, carcinogenicity and reproductive toxicity tests. The purpose is to determine the potential genotoxicity, carcinogenicity

or reproductive toxicity medical devices to provide evaluation guidelines and methods.

--- Part 4.Test selection for interaction with blood. The purpose is to provide a general basis for the evaluation of the interaction between medical devices and blood

Require.

--- Part 5.In vitro cytotoxicity test. The purpose is to provide a test method for evaluating the cytotoxicity of medical devices in vitro.

--- Part 6.Local reaction test after implantation. The purpose is to provide a basis for evaluating local reactions after implantation of biomaterials used in medical devices.

experiment method.

--- Part 7.Ethylene oxide sterilization residues. The purpose is to apply EO and

The allowable limit of 2-chloroethanol (ECH) residues, EO and ECH residues provide testing steps and determine whether the device can

The factory provides detection methods.