ICS 11.040.01

C 30

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

中华人民共和国国家标准

GB/T 16886.1-2011/ISO 10993-1: 2009

Replace GB/T 16886.1-2001

Biological evaluation of medical devices— Part 1: Evaluation and testing within a risk management process

医疗器械生物学评价 第 1 部分：风险管理过程中的评价与试验

(ISO 10993-1: 2009, IDT)

Issued on June 16, 2011 **Implemented on November 01, 2011**

Issued by **General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China**

Standardization Administration of the People's Republic of China

Contents

Foreword

GB/T 16886 *Biological evaluation of medical devices* consists of following parts:

— Part 1: Evaluation and testing within a risk management process;

— Part 2: Animal welfare requirements;

— Part 3: Tests for genotoxicity carcinogenicity and reproductive toxicity;

— Part 4: Selection of tests for interactions with blood;

— Part 5: Test for in vitro cytotoxicity;

— Part 6: Tests for local effects after implantation;

— Part 7: Ethylene oxide sterilization residuals;

— Part 9: Framework for identification and quantification of potential degradation products;

— Part 10:Tests for irritation and delayed-type hypersensitivity;

— Part 11:Tests for systemic toxicity;

— Part 12:Sample preparation and reference materials;

— Part 13: Identification and quantification of degradation products from polymeric medical devices;

— Part 14: Identification and quantificaton of degradation products from ceramics;

— Part 15: Inentificatoin and quantificatoin of degradation products from metals and alloys;

— Part 16: Toxicokinetic study design for degradation products and leachables;

— Part 17: Estabilishment of allowable limits for leachable substances;

This Part is Part 1 of GB/T 16886.

There are other standards for biological tests in other aspects.

This Part is drafted according to the rules specified in GB/T 1.1-2009.

This Part replaces GB/T16886.1-2001 *Biological Evaluation of Medical Devices - Part 1: Evaluation and Test*, compared with GB/T 16886.1-2001, the main content modified are as follows:

— Modified the name of the Standard;

— Modified the "Introduction";

— Modified the "Scope";

Introduction

The primary aim of this part of GB/T 16886/ISO 10993 is the protection of humans from potential biological risks arising from the use of medical devices. It is compiled from numerous International and National Standards and Guidelines concerning the biological evaluation of medical devices. It is intended to be a guidance document for the biological evaluation of medical devices within a risk management process, as part of the overall evaluation and development of each device. This approach combines the review and evaluation of existing data from all sources with, where necessary, the selection and application of additional tests, thus enabling a full evaluation to be made of the biological responses to each medical device, relevant to its safety in use. It must be appreciated that the term “medical device” is wide-ranging and, at one extreme, consists of a single material, which may exist in more than one physical form, and at the other extreme, of a complex instrument or piece of apparatus, consisting of numerous components made of more than one material.

GB/T 16886/ISO 10993 addresses the determination of the effects of medical devices on tissues, mostly in a general way, rather than in a specific device-type situation. Thus, for a complete biological safety evaluation, it classifies medical devices according to the nature and duration of their anticipated contact with human tissues when in use and indicates, in matrices, the biological data sets that are thought to be relevant in the consideration of each device category.

The range of biological hazards is wide and complex. The tissue interaction with a constituent material alone cannot be considered in isolation from the overall device design. Thus, in designing a device, the choice of the best material with respect to its tissue interaction might result in a less functional device, tissue interaction being only one of a number of characteristics to be considered in making that choice. Where a material is intended to interact with tissue in order to perform its function, the biological evaluation needs to address this.

Tissue interactions that are regarded as adverse, caused by a material in one application, might not be regarded as such in a different situation. Biological testing is based upon,

among other things, in vitro and ex vivo test methods and upon animal models, so that the anticipated behaviour when a device is used in humans can be adjudged only with caution, as it cannot be unequivocally concluded that the same tissue reactions will also occur in this species. In addition, differences in the manner of response to the same material among individuals indicate that some patients can have adverse reactions, even to well-established materials.

The role of this part is to serve as a framework in which to plan a biological evaluation which, as scientific knowledge advances our understanding of the basic mechanisms of tissue responses, minimizes the number and exposure of test animals by giving preference to chemical constituent testing and in vitro models, in situations where these methods yield equally relevant information to that obtained from in vivo models.

It is not intended that GB/T 16886/ISO 10993 provide a rigid set of test methods, including pass/fail criteria, as this might result in either an unnecessary constraint on the development and use of novel medical devices, or a false sense of security in the general use of medical devices. Where a particular application warrants it, experts in the product or in the area of application concerned can choose to establish specific tests and criteria, described in a product-specific vertical standard.

This part is intended for use by professionals, appropriately qualified by training and experience, who are able to interpret its requirements and judge the outcome of the evaluation for each medical device, taking into consideration all the factors relevant to the device, its intended use and the current knowledge of the medical device provided by review of the scientific literature and previous clinical experience.

Annex A contains an informative table that is generally helpful in identifying biological data sets recommended in the evaluation of medical devices, according to their category of body contact and duration of clinical exposure. Annex B contains guidance for the application of the risk management process to medical devices which encompasses biological evaluation.

Biological evaluation of medical devices—

Part 1: Evaluation and testing within a risk management process

1 Scope

This part of GB/T 16886 describes:

— the general principles governing the biological evaluation of medical devices within a risk management process;

— the general categorization of devices based on the nature and duration of their contact with the body;

— the evaluation of existing relevant data from all sources;

— the identification of gaps in the available data set on the basis of a risk analysis;

— the identification of additional data sets necessary to analyse the biological safety of the medical device;

— the assessment of the biological safety of the medical device.

This part does not cover testing of materials and devices that do not come into direct or indirect contact with the patient's body, nor does it cover biological hazards arising from any mechanical failure. Other parts of GB/T 16886 cover specific tests, as indicated in the Foreword.

2 Normative references

The articles contained in the following documents have become this standard when they are quoted herein. For the dated documents so quoted, all the modifications (Including all corrections) or revisions made thereafter shall be applicable to this Standard.

ISO 10993-2 Biological evaluation of medical devices — Part 2: Animal welfare requirements

ISO 10993-3 Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

完整版本请在线下单

或咨询：

TEL: 400-678-1309

QQ: 19315219

Email：info@lancarver.com

http://www.lancarver.com

线下付款方式：

1. 对公账户：

单位名称：北京文心雕语翻译有限公司

开 户 行：中国工商银行北京清河镇支行

账　　号：0200 1486 0900 0006 131

2. 支付宝账户：info@lancarver.com

注: 付款成功后，请预留电邮，完整版本将在一个工作日内通过电子 PDF 或 Word 形式发送至您的预留邮箱，如需索取发票，下单成功后的三个工作日内安排开具并寄出，预祝合作愉快！