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Biological evaluation of medical devices - Part 10: Tests for skin sensitization

医疗器械生物学评价 第10部分：皮肤致敏试验

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Foreword

This Document was drafted as per the rules specified in GB/T 1.1-2020 Directives for Standardization - Part

1.Rules for the Structure and Drafting of Standardizing Documents. This Document is Part 10 of GB/T (Z) 16886 Biological Evaluation of Medical Devices. GB/T (Z) 16886 consists of the following parts.

1.Evaluation and Testing within a Risk Management Process;

2.Animal Welfare Requirements;

3.Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity;

4.Selection of Tests for Interactions with Blood;

5.Tests for in Vitro Cytotoxicity;

6.Tests for Local Effects after Implantation;

7.Ethylene Oxide Sterilization Residuals;

9.Framework for Identification and Quantification of Potential Degradation Products;

10.Tests for Skin Sensitization;

11.Tests for Systemic Toxicity;

12.Sample Preparation and Reference Materials;

13.Identification and Quantification of Degradation Products from Polymeric Medical Devices;

1 Scope

GB/T 16886.10-2024 is the skin sensitization part of the Chinese biological evaluation series for medical devices, the Chinese adoption of ISO 10993-10. Sensitization is the endpoint that has to be assessed for essentially every device that touches a patient, so this is one of the most frequently applied biocompatibility tests there is. The 2024 edition matters because of how it has changed: the international standard has moved decisively away from the guinea pig maximisation and Buehler tests toward the murine local lymph node assay and, increasingly, toward the in chemico and in vitro methods of the defined approaches, and this edition brings that into the Chinese system. The document sets out the general principles and the selection of the test method for a given device and material, the sample preparation and the extraction conditions, the procedures for each accepted method with the vehicle, the dosing, the induction and challenge phases and the scoring, the interpretation of the results, and the reporting. The 2024 edition replaces GB/T 16886.10-2017. For a device manufacturer or a testing laboratory working on the Chinese market, this is the governing method.

This Document specifies the procedure for the assessment of medical devices and their constituent materials with regard to their potential to induce skin sensitization.

2 Normative References

The provisions in following documents become the essential provisions of this Document through reference in this Document. For the dated documents, only the versions with the dates indicated are applicable to this Document; for the undated documents, only the latest version (including all the amendments) is applicable to this Document.

GB/T 16886.1-2022 Biological evaluation of medical devices - Part

3 Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 10993-1 and the following apply. ISO and IEC maintain terminology databases for use in standardization at the following addresses.

3.1 Allergen; Sensitizer Substance or material that is capable of inducing a specific hypersensitivity reaction upon repeated contact with that substance or material.

3.2 Allergic contact dermatitis Clinical diagnosis based on an observed immunologically-mediated cutaneous reaction to a substance.

4 General Principles - Step-Wise Approach

The available methods for testing sensitization were developed specifically to detect skin sensitization potential. Other types of adverse effects are generally not predicted by these tests. This document requires a step-wise approach, considering that any stage can result in the conclusion that further testing for skin sensitization is not necessary.

5 Pretest Considerations

5.1 General It is important to emphasize that pretest considerations can result in the conclusion that testing for skin sensitization is not necessary. The requirements given in GB/T 16886.1-2022, Clause 5, and the following apply. In vivo, non-sterile samples shall be investigated by topical investigation only, as the possibility of microbial contamination of the test sample can confound the final assay interpretation.