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GB/T 16886.14-2003 / ISO 10993-14:2001

Biological Evaluation of Medical Devices - Part 14: Identification and Quantification of Degradation Products from Ceramics

(ISO 10993-14:2001, IDT)

医疗器械生物学评价

第 14 部分：陶瓷降解产物的定性与定量

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Foreword

This Part of GB/T 16886 equivalently adopts the international standard ISO 10993-14:2001 *Biological Evaluation of Medical Devices – Part 14: Identification and Quantification of Degradation Products from Ceramics*.

The general title of GB/T 16886 is *Biological Evaluation of Medical Devices*, which consists of the 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: Tests 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 Sensitization;

--- Part 11: Tests for Systemic Toxicity;

--- Part 12: Sample Preparation and Reference Materials;

--- Part 13: Identification and Quantification of Degradation products form Polymeric Medical Devices;

--- Part 14: Identification and Quantification of Degradation Products from Ceramics;

--- Part 15: Identification and Quantification of Degradation Products from Metals and Alloys;

--- Part 16: Toxicokinetic Study Design for Degradation Products and Leachable Substances

For other aspects of biological tests, there shall be other parts of standard.

This Standard was proposed by China Food and Drug Administration.

Biological Evaluation of Medical Devices - Part 14: Identification and Quantification of Degradation Products from Ceramics

1 Scope

This Part of GB/T 16886 specifies two methods of obtaining solutions of degradation products from ceramics (including glasses) for the purposes of quantification. It also gives guidance on the analysis of these solutions in order to identify the degradation products. Because of the generalized nature of this Part of GB/T 16886, product specific standards, when available, that address degradation product formation under more relevant conditions of use, should be considered first.

This Part of GB/T 16886 considers only those degradation products generated by a chemical dissociation of ceramics during in vitro testing. No degradation induced by mechanical stress or external energy is covered. It is noted that while ISO 6872 and ISO 9693 cover chemical degradation tests, they do not address the analysis of degradation products.

Because of the range of ceramics used in medical devices and the different requirements for accuracy and precision of the results, no specific analytical techniques are identified. Further, this Part of GB/T 16886 provides no specific requirements for acceptable levels of degradation products.

Although these materials are intended for biomedical applications, the biological activity of these degradation products is not addressed in this Part of GB/T 16886.

2 Normative References

The provisions in following documents become the provisions of this Standard through reference in this Part of GB/T 16886. For dated references, the subsequent amendments (excluding corrigendum) or revisions do not apply to this Part, however, parties who reach an agreement based on this Part are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document applies.

GB/T 6682 Water for Laboratory Use – Specifications (GB/T 6682-1992, neq ISO

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