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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 16886.13-2017

**Biological evaluation of medical devices-Part 13:Identification
and quantification of degradation products from polymeric
medical devices**

医疗器械生物学评价 第13部分：聚合物医疗器械降解产物的定性与定量
(English Translation)

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Foreword

GB/T 16886 "Biological Evaluation of Medical Devices" consists of the following parts.

- Part 1. Evaluation and testing in the risk management process;
- Part 2. Animal welfare requirements;
- Part 3. Genotoxicity, carcinogenicity and reproductive toxicity test;
- Part 4. Test options for interaction with blood;
- Part 5. In vitro cytotoxicity test;
- Part 6. Post-implantation local reaction test;
- Part 7. Ethylene oxide sterilization residue;
- Part 9. Qualitative and quantitative frameworks for potential degradation products;
- Part 10. Stimulation and skin sensitization test;
- Part 11. Systemic toxicity test;
- Part 12. Sample preparation and reference materials;
- Part 13. Qualitative and quantitative determination of degradation products of polymer medical devices;
- Part 14. Qualitative and quantitative determination of ceramic degradation products;
- Part 15. Qualitative and quantitative determination of metal and alloy degradation products;
- Part 16. Design of toxicokinetics of degradation products and solubles;
- Part 17. The establishment of a limitable amount of leachables;

---Part 18. Chemical characterization of materials;

---Part 19. Physical chemistry, morphological and surface characterization of materials;

--- Part 20. Principles and methods for immunological toxicology testing of medical devices.

This part is the 13th part of GB/T 16886.

This part is drafted in accordance with the rules given in GB/T 1.1-2009.

This part replaces GB/T 16886.13-2001 "Medical evaluation of medical devices - Part 13. Degradation products of polymer medical devices Qualitative and quantitative. The main technical changes compared with GB/T 16886.13-2001 are as follows.

--- Revised scope (see Chapter 1);

--- Modified "4 degradation test method";

--- Modified "5 test steps";

--- Added Appendix B polymer environmental stress cracking.

This section uses the translation method equivalent to ISO 10993-13:2010 "Medical Device Biology Evaluation Part 13. Polymer Medical Devices Qualitative and Quantitative Analysis of Mechanical Degradation Products.

The documents of our country that have a consistent correspondence with the international documents referenced in this part are as follows.

---GB/T 6682-2008 Analytical laboratory water specifications and test methods (ISO 3696:1987, MOD);

--- GB/T 16886.1-2011 Biological evaluation of medical devices - Part 1. Evaluation and testing in the process of risk management (ISO 10993-1:2009, IDT);

--- GB/T 16886.9-2017 Biological evaluation of medical devices - Part 9. Qualitative and quantitative framework for potential degradation products (ISO 10993-9:2009, IDT);

--- GB/T 16886.12-2017 Medical Device Biology Evaluation Part 12. Sample Preparation and Reference Samples (ISO 10993-12:2012, IDT);

--- GB/T 16886.16-2003 Biological evaluation of medical devices - Part 16. The toxic kinetics of degradation products and solubles Research design (ISO 10993-16:1997, IDT);

--- GB/T 16886.17-2005 Biological evaluation of medical devices - Part 17. Establishment of leaching allowances (ISO 10993-17:2005, IDT).

Introduction

The degradation products included in this part of GB/T 16886 mainly refer to hydrolysis and/or oxidation in aqueous environments (such as humans).

The process leads to degradation products formed by chemical bond cleavage. It is generally believed that other biological factors such as enzymes, proteins and cellular activities may change.

Degradation rate and degradation properties.

It should be noted that polymer devices may contain residues such as monomers, oligomers, solvents, catalysts, additives, fillers and processing aids.

Residues and leachables. If these ingredients are present, they may interfere with the characterization and quantification of the degradation products, which need to be considered and explained. What it is recognized that the residual monomer may be the same as the degradation product produced by the polymer itself. Readers only pay attention to further biological evaluation the results of the degradation test are used in the test, and no distinction is made between the leachables and the degradation products. If this is the case, it may not be necessary to produce from degradation.

The leachables were separated from the material.

Due to the general characteristics of this part of GB/T 16886, there are product standards that describe degradation products under more relevant conditions of use.

When forming, consider replacing this part. This section applies to screening new polymer materials and/or improvements with unknown degradation behavior after contact with in vivo.

Polymer material. This section does not involve degradation caused by in vivo testing. Users of this section may consider other in vivo degradation monographs.

Degradation test described.

Long-term implants may not degrade within the test time range given in this section. The purpose of this section is to assist in the identification of medical devices.

Biological hazards of degradation products of mechanical polymer parts. As noted above, those degradation products may result from various degradation mechanisms. This section does not A comprehensive analysis of the degradation of medical devices and their performance, users can refer to the relevant product standards. Qualitative degradation products and quantification, which is the basis for biological evaluation according to GB/T 16886.1, and is based on GB/T 16886.17 for risk assessment and appropriate time.

Basis for toxicokinetic studies in accordance with GB/T 16886.16.

Medical device biology evaluation Part 13. Degradation products of polymer medical devices Qualitative and quantitative