

ICS 11.100



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

GB/T 16886.7-2015

**Biological evaluation of medical devices-Part 7: Ethylene oxide
sterilization residuals**

医疗器械生物学评价 第7部分：环氧乙烷灭菌残留量

(English Translation)

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Table of Contents

Foreword	1
Scope	2
Normative references	3
Terms and definitions	4
Requirements	5
Product release	6

Foreword

GB/T 16886 "Biological evaluation of medical devices" 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 8: Selection and limitation of reference materials for biological tests;
- 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 from 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 leachables;
- Part 17: Establishment of allowable limits for leachable substances;

- Part 18: Chemical characterization of materials;
- Part 19: Physico-chemical, morphological and topographical characterization of materials;
- Part 20: Principles and methods for immunotoxicology testing of medical devices.

This Part is Part 7 of GB/T 16886.

This Part was drafted in accordance with the rules given in GB/T 1.1-2009.

This Part replaces GB/T 16886.7-2001 "Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals". Compared with GB/T 16886.7-2001, the main changes are as follows.

- modified the introduction;
 - modified 4.1 General;
 - modified 4.3 Allowable limits. adding the overview; modifying the amounts of allowable limit for ethylene oxide (EO) and 2-chloroethanol (ECH);
- adding the tolerable contact limits for surface contact devices and implants;
- modifying the average daily exposure dose for special devices EO and ECH;
- modified 4.4.3 Product sampling;
 - modified 4.4.6 Product extraction;
 - modified Annex A Evaluation of gas chromatograms;
 - modified Annex B Gas chromatographic determination for EO and ECH.
- integrating EO and ECH standard preparation, instrumentation, reagents and product leaching into Annex J and Annex K; adding the determination of precision, linearity, method detection limit and limit of quantitation;
- deleting Gas chromatographic conditions recommended by Table B.2;
- added Flowchart and guidance for the application of this Part of GB/T 16886 series of standards to the determination of EO and ECH residuals in medical devices;
 - modified previous Annex A (present Annex E) Extraction conditions for determination of residual EO;
 - modified description of previous Annex E (present Annex F). modifying the name as "Rationale for the provisions of this Part of GB/T 16886";
- integrating the determination of EO and ECH allowable limits into Annex G and Annex H respectively; completing and improving;
- added Annex G Establishment of allowable limits for EO;

-- added Annex H Establishment of allowable limits for ECH;

-- added Annex I Establishment of allowable limits for EG;

-- added Annex J Preparation of EO and ECH standards;

-- added Annex K Ethylene oxide residue measuring methods.

This Part uses translation method to identically adopt ISO 10993-7:2008 "Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals".

The Chinese documents which have consistency with the international normative references in this Part are as follows.

GB/T 16886.1-2001, Biological evaluation of medical devices - Part 1.

Evaluation and testing (ISO 10993-1:1997, IDT) GB/T 16886.3-2008, Biological evaluation of medical devices - Part 3: Tests for genotoxicity carcinogenicity and reproductive toxicity (ISO 10993-3:2003, IDT) GB/T 16886.10-2005, Biological evaluation of medical devices - Part 10.

Tests for irritation and delayed-type hypersensitivity (ISO 10993-10:2002, IDT) GB/T 16886.12-2005, Biological evaluation of medical devices - Part 12.

Sample preparation and reference materials (ISO 10993-12:2002, IDT) GB/T 16886.17-2005, Biological evaluation of medical devices - Part 17.

Establishment of allowable limits for leachable substances (ISO 10993-17:2002, IDT) this Part was proposed by China Food and Drug Administration.

This Part shall be under the jurisdiction of National Technical Committee on Medical Device Biology Evaluation of Standardization Administration of China (SAC/TC 248).

The drafting organization of this Part. China Food and Drug Administration Jinan Medical Device Quality Supervision and Inspection Center.

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Versions of standard substituted by this Part is.

-- GB/T 16886.7-2001.

1 Scope

This Part of GB/T 16886 specifies allowable limits for residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) in individual EO-sterilized medical devices, procedures for the measurement of EO and ECH, and methods for determining compliance so that devices may be released.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

3 Terms and definitions

For the purposes of this document, the terms and definitions defined in ISO 10993-1 and ISO 10993-17 as well as the followings apply.

extraction until the amount of EO or ECH in a subsequent extraction is less than 10 % of that detected in the first extraction, or until there is no analytically significant increase in the cumulative residue levels detected

4 Requirements

In establishing the maximum daily doses of EO and ECH that a medical device is allowed to deliver to patients, devices shall be categorized according to the duration of contact.

Devices shall be placed into one of three exposure categories in accordance with ISO 10993-1, 5.3.

5 Product release

Dissipation curves are used to estimate the post-sterilization time required for products, or families of similar products, to reach residue limits, principally for EO, in compliance with 4.3.