

ICS 11.040



**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0290.5-2023

**Ophthalmic optics - Intraocular lenses - Part 5: Biocompatibility
(English Translation)**

Issued on: September 5, 2023

Implemented on: September 15, 2024

Issued by: National Medical Products Administration

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Foreword

This document was drafted in accordance with the rules given in GB/T 1.1-2020

"Directives for standardization - Part 1.Rules for the structure and drafting of standardizing documents".

This document is Part 5 of YY/T 0290 "Ophthalmic optics -- Intraocular lenses". The following parts of YY/T 0290 have been published.

- Part 1.Terminology;
- Part 2.Optical properties and test methods;
- Part 3.Mechanical properties and test methods;
- Part 4.Labeling and information;
- Part 5.Biocompatibility;
- Part 6.Shelf life and transportation stability;
- Part 8.Fundamental requirement;
- Part 9.Multifocal intraocular lenses;

- Part 10. Phakic intraocular lenses.

This document replaces YY/T 0290.5-2008 "Ophthalmic implants -- Intraocular lenses -- Part 5. Biocompatibility". Compared with YY/T 0290.5-2008, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

- Added Table 1 and Table 2 (see Chapter 4 of this Edition);
- Changed the overview of physical and chemical tests (see 5.1 of this Edition; 5.1 of Edition 2008);
- Added physical/chemical description (see 5.2 of this Edition);
- Changed the limit extraction test (see 5.3, Annex A of this Edition; 5.2, Annex A of Edition 2008);
- Changed the hydrolysis stability test (see 5.5, Annex C of this Edition; 5.4, Annex C of Edition 2008);
- Changed the light stability test (see 5.6, Annex D of this Edition; 5.5, Annex D of Edition 2008);
- Changed the Nd-YAG laser irradiation test (see 5.7, Annex E of this Edition; 5.6, Annex E of Edition 2008);
- Changed the detection limit of the insoluble inorganic test method (see 5.8 of this Edition; 5.7 of Edition 2008);
- Changed the overview of biological tests (see 6.1 of this Edition; 6.1 of Edition 2008);
- Added cytotoxicity tests (see 6.2 of this Edition);
- Changed the genotoxicity tests (see 6.4 of this Edition; 6.2 of Edition 2008);
- Added local reaction tests (see 6.5 of this Edition);
- Changed the additional conditions for the local reaction test after implantation (see Annex F of this Edition; Annex F of Edition 2008);
- Changed the eye implantation test (see Annex G of this Edition; Annex G of Edition 2008).

The modification of this document adopts ISO 11979-5:2020 "Ophthalmic implants --

Intraocular lenses -- Part 5.Biocompatibility".

The technical differences between this document and ISO 11979-5:2020 and their reasons are as follows.

- ISO 11979-1 was replaced by the normative reference YY/T 0290.1 (see Chapter

3 and Chapter 4) to adapt to China's national conditions and increase operability;

- ISO 11979-2 was replaced by the normative reference YY 0290.2 (see Annex B, Annex C, Annex D) to adapt to China's national conditions and increase operability;

- ISO 11979-3 was replaced by the normative reference YY 0290.3 (see Annex D) to adapt to China's national conditions and increase operability;

- ISO/TR 22979 was deleted as a normative reference;

- YY/T 1815 (see Chapter 4 and 5.1) was added as a normative reference to adapt to China's national conditions and increase operability;

- GB/T 11417.7 (see Annex A) to adapt to China's national conditions and increase operability;

- The normative reference document ISO 18369-4 was deleted to adapt to China's national conditions;

- The normative reference document ISO/TS 21726 was deleted to adapt to China's national conditions.

The following editorial changes were made to this document.

- To coordinate with the existing standards, the name of the standard was changed to "Ophthalmic optics -- Intraocular lenses -- Part 5.Biocompatibility".

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing authority shall not be held responsible for identifying any or all such patent rights.

This document was proposed by National Medical Products Administration.

This document shall be under the jurisdiction of Subcommittee on Medical Optics and

Instruments of National Technical Committee on Optics and Photonics of
Standardization Administration of China (SAC/TC 103/SC 1).

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Versions of standard substituted by this document are.

- It was first published in 1997 as YY 0290.5-1997. It was first revised in 2008;
- This is the second revision.

1 Scope

This document specifies the specific requirements for the biocompatibility evaluation
of intraocular lenses (Translator NOTE. it is referred as IOLs), including the
biocompatibility evaluation requirements of materials under production process
conditions, the evaluation of physicochemical properties related to biocompatibility,
and the test methods for ocular implantation.

This document applies to intraocular lenses.

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.

GB/T 11417.7, Ophthalmic optics -- Contact lenses -- Part 7. Physicochemical
properties test methods

3 Terms and definitions

The terms and definitions defined in YY/T 0290.1 apply to this document.