

5 September 2025

Original: English

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Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

- 1. Notifying Member: CHINA
 - If applicable, name of local government involved (Articles 3.2 and 7.2):
- 2. Agency responsible:

State Administration for Market Regulation (Standardization Administration of the P.R.C.)

- 3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], Other:
- 4. Products covered (HS codes or national tariff lines. ICS numbers may be provided in addition, where applicable): Ophthalmic instruments, including instruments to measure axial distances in the eye, corneal topographers, endoilluminators, direct ophthalmoscopes, retinoscopes, fundus cameras, indirect ophthalmoscopes, slit-lamp microscopes, perimeters, synoptophores, eye refractometers, ophthalmometers, optical coherence of the human eye, operation microscopes used in ocular surgery, etc. (HS code(s): 901850); (ICS code(s): 11.040.70)
- **5.** Details of notified document(s) (title, number of pages and languages, means of access): National Standard of the P.R.C., Ophthalmic instruments—Fundamental requirements and test methods—Part 2: Light hazard protection; (55 page(s), in Chinese)

Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request:

https://members.wto.org/crnattachments/2025/TBT/CHN/25 05850 00 x.pdf

6. Description of content: This document specifies fundamental requirements for optical radiation safety for ophthalmic instruments and describes the corresponding test methods.

This document applies to all ophthalmic instruments that direct optical radiation into or at the eye. It also applies to those portions of therapeutic or surgical systems that direct optical radiation into or at the eye for diagnostic, illumination, measurement, imaging or alignment purposes and applicable to the treatment beams of therapeutic devices for non-target tissues.

- 7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
- 8. Relevant documents:

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9. Proposed date of adoption: To be determined

Proposed date of entry into force: 36 months after approval

10. Provision of comments

Final date for comments: 4 November 2025

[X] 60 days from notification

Contact details of agency or authority designated to handle comments regarding the notification:

WTO/TBT National Notification and Enquiry Center of the People's Republic of China

Tel: +86 10 57954633/ 57954627

E_mail: tbt@customs.gov.cn