



**International
Standard**

ISO 21366

**Traditional Chinese medicine —
General requirements for
smokeless moxibustion devices**

*Médecine traditionnelle chinoise — Exigences générales relatives
à la moxibustion sans fumée*

**Second edition
2026-09**

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 249, *Traditional medicine*, Subcommittee SC 1, *Traditional Chinese medicine*.

This second edition cancels and replaces the first edition (ISO 21366:2019), which has been technically revised.

The main changes are as follows:

- Changed limit value of smoke density for the statement of 'smokeless' from 200 to 50.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Moxibustion is one of the major traditional medical therapies. Smokeless moxibustion is an emerging form of the moxibustion therapy. Smokeless moxibustion devices have different forms or are composed of the materials used in conventional moxibustion without additional materials or processing for their safe use.

The standardization of smokeless moxibustion devices can enhance the efficacy and improve the quality and safety of moxibustion treatments using smokeless moxibustion devices, especially in regard to biocompatibility with the human body and indoor air quality.

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Traditional Chinese medicine — General requirements for smokeless moxibustion devices

1 Scope

This document specifies general requirements for the performance and safety of smokeless moxibustion devices. It covers smoke density, moxibustion temperature, noxious gas and test methods for smokeless moxibustion devices.

This document is applicable to any combustion-type device that claims to provide smokeless moxibustion.

This document does not apply to devices that imitate moxibustion, such as electro moxibustion and infrared moxibustion devices.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 2248, *Packaging — Complete, filled transport packages — Vertical impact test by dropping*

ISO 7240-2, *Fire detection and alarm systems — Part 2: Fire detection control and indicating equipment*

ISO/TS 7240-9, *Fire detection and alarm systems — Part 9: Test fires for fire detectors*

ISO 15011-2, *Health and safety in welding and allied processes — Laboratory method for sampling fume and gases — Part 2: Determination of the emission rates of carbon monoxide (CO), carbon dioxide (CO₂), nitrogen monoxide (NO) and nitrogen dioxide (NO₂) during arc welding, cutting and gouging*

ISO 16000-4, *Indoor air — Part 4: Determination of formaldehyde — Diffusive sampling method*

ISO 16000-6, *Indoor air — Part 6: Determination of organic compounds (VVOC, VOC, SVOC) in indoor and test chamber air by active sampling on sorbent tubes, thermal desorption and gas chromatography using MS or MS FID*

ISO 18666, *Traditional Chinese medicine — General requirements of moxibustion devices*

ISO 18666:2021, *Traditional Chinese medicine — General requirements of moxibustion devices*

ISO 15011-2, *Health and safety in welding and allied processes — Laboratory method for sampling fume and gases — Part 2: Determination of the emission rates of carbon monoxide (CO), carbon dioxide (CO₂), nitrogen monoxide (NO) and nitrogen dioxide (NO₂) during arc welding, cutting and gouging*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>