

---

---

**Traditional Chinese medicine —  
General requirements of moxibustion  
devices**

*Médecine traditionnelle chinoise — Exigences générales concernant  
les dispositifs de moxibustion*



This document is a preview generated by EUS



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

# Contents

Page

<b>Foreword</b>	<b>iv</b>
<b>Introduction</b>	<b>v</b>
<b>1 Scope</b>	<b>1</b>
<b>2 Normative references</b>	<b>1</b>
<b>3 Terms and definitions</b>	<b>1</b>
<b>4 Configuration</b>	<b>2</b>
4.1 Structure	2
4.1.1 Size and shape	2
4.1.2 Visual inspection	2
4.2 Expression of dimensions	3
<b>5 Materials</b>	<b>3</b>
5.1 General	3
5.2 Body of moxibustion devices	3
5.3 Moxibustion materials	3
5.3.1 Moxa floss	3
5.3.2 Moxa sticks	3
<b>6 Moxibustion temperature</b>	<b>4</b>
6.1 General	4
6.2 Moxibustion with tube	4
6.3 Moxibustion devices other than moxibustion with tube	4
6.4 Moxibustion devices for repeated use	4
<b>7 Safety requirements</b>	<b>4</b>
7.1 General	4
7.2 Environmental protection	4
<b>8 Packaging</b>	<b>5</b>
8.1 Primary packaging	5
8.2 Secondary packaging	5
<b>9 Labelling</b>	<b>5</b>
9.1 Primary label	5
9.2 Secondary label	5
<b>10 Transport and storage</b>	<b>6</b>
<b>11 Instructions for use</b>	<b>6</b>
<b>Annex A (informative) Test methods to determine the moxibustion temperature</b>	<b>7</b>
<b>Annex B (informative) Method of artificial drying of mugwort leaves by heat</b>	<b>10</b>
<b>Bibliography</b>	<b>11</b>

## 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](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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

This second edition cancels and replaces the first edition (ISO 18666:2015), of which it constitutes a minor revision. The changes to the previous edition are as follows:

- Introduction: the term 'International Standard' changed to 'document' in the first and third paragraphs; improvement of English expression to 'increasing expectations and concerns by patients' and the term 'ensure' changed to 'guide' in the second and third paragraphs;
- Scope: the term 'International Standard' changed to 'document' in the first and third paragraphs; minor editorial change of the term 'uses' to 'use' in the second paragraph;
- [Clause 3](#): addition of the introductory text according to ISO/IEC Directives, Part 2;
- [3.4](#): deletion of the phrase 'during treatment';
- [4.1.1](#): improvement of English expression for clarity;
- minor editorial changes.

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](http://www.iso.org/members.html).

## Introduction

This document specifies the general requirements for safety and quality of moxibustion devices, including the moxibustion materials used in such devices. The safety and quality of both moxibustion devices and materials are closely related to moxibustion safety and quality.

There is a wide variety of moxibustion devices and materials currently available commercially, but there are no standards guiding their manufacture and finishing. Increased interest and use of moxibustion, as well as increasing expectations and concerns by patients regarding moxibustion safety and quality, have given rise to the need to improve safety and quality of moxibustion through implementation of an International Standard.

The primary aim of this document is to guide the safety and quality of moxibustion devices and materials.

[Annex A](#) gives guidance on the methods that can be used to determine the moxibustion temperature at the human body surface during treatment using the moxibustion device.

[Annex B](#) gives guidance on the method of artificial drying of mugwort leaves by heat.



# Traditional Chinese medicine — General requirements of moxibustion devices

## 1 Scope

This document specifies the general requirements for configuration, materials, performance and safety requirements of moxibustion devices. It also specifies the minimum requirements for moxibustion materials used in moxibustion devices.

It is applicable across a wide range of moxibustion devices that use moxa floss as the main combustion material and can remain on or over the body throughout the moxibustion process. It is applicable to moxibustion devices for both single and repeated usage.

This document does not apply to devices that imitate moxibustion, such as electro-moxibustion and infrared moxibustion devices that do not involve the use of moxa floss. It also does not apply to moxa floss used in direct moxibustion.

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

ISO/TS 10993-19, *Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

## 3 Terms and definitions

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

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

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

### 3.1

#### **moxibustion device**

apparatus that uses moxa floss as the main combustion material and is intended for single or repeated usage

**EXAMPLE** Moxibustion with tube, such as a short moxa roll with a cardboard base and a moxa tube (made of cardboard) that is single-use and developed as an alternative to direct moxibustion.

Note 1 to entry: Moxibustion devices include those accessories as defined by the manufacturers that are necessary to enable the normal use of the moxibustion device.