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Traditional Chinese medicine — General requirements of moxibustion devices

Médecine traditionnelle chinoise — Exigences générales concernant les dispositifs de moxibustion

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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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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.

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.

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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.

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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.

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3.2
moxibustion material
combustible material comprising mainly moxa floss and used in moxibustion

3.3
body of moxibustion device
part of the moxibustion device that is used to hold moxibustion materials and remains on or over the human body throughout the moxibustion process

3.4
moxibustion temperature
temperature at the human body surface when using the moxibustion device

3.5
moxa floss
cotton-like material for moxibustion made from mugwort leaves

3.6
moxa stick
round long stick made of moxa floss, also called moxa roll

Note 1 to entry: Moxa sticks can be in the form of a pure moxa stick, a medicinal moxa stick (with additives) or a smokeless moxa stick.

3.7
medicinal moxa stick
moxibustion with the moxa roll made of moxa and various substances

3.8
fineness of moxa floss
weight of the starting material (mugwort leaves) to the weight of the final product (moxa floss) presented in the form of a ratio

4 Configuration

4.1 Structure

4.1.1 Size and shape

The size and shape of moxibustion devices can vary according to the intended use, such as on a specific point or an area of the human body surface.

4.1.2 Visual inspection

When inspected by normal or corrected-to-normal vision:

a) the surface of the moxibustion device shall not have any obvious defects such as breakages, protrusions, dents or rust that can cause accidental cuts or injuries to the user;

b) moxibustion devices for repeated use shall have a temperature-adjusting mechanism or other appropriate arrangement to maintain moxibustion at an appropriate temperature;

c) except for moxibustion with tube, the body of the moxibustion device shall ensure that the removal of ash is easy and shall be well ventilated to facilitate combustion; it should also contain:

   1) a mounting base or support that can hold the stick (s) firmly;

   2) a barrier or other safety arrangement to prevent ash or ember from falling onto the surface of the human body.

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