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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

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 249, *Traditional Chinese medicine*.

Introduction

This International Standard 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 growing patients' expectations and concerns 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 International Standard is to ensure 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 International Standard 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 uses 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 International Standard 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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

3 Terms and definitions

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

3.1
moxibustion device
apparatus that uses moxa floss as the main combustion material and intended for single or repeated usage

EXAMPLE Moxibustion with tube is a type of moxibustion device, 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 device includes those accessories as defined by the manufacturers that are necessary to enable the normal use of the moxibuston device.

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