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Traditional Chinese medicine — Infrared moxibustion-like instrument

Médecine traditionnelle chinoise — Instruments de moxibustion infrarouge

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Foreword

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

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

Moxibustion is a traditional Chinese medicine external therapy that uses moxa floss made from dried mugwort. It plays an important role in traditional Chinese medicine. The heating effect and infrared spectrum produced during the burning of mugwort has therapeutic effects due to the irradiation of the channels and acupuncture points sites.

Based on traditional Chinese medicine, the infrared moxibustion-like instrument is a medical device that simulates the heating effect and infrared spectrum of burning mugwort to irradiate the acupuncture points and surrounding area of a human body for the treatment of a variety of diseases.

At present, the infrared moxibustion-like instrument is used in many nations and is well known for its therapeutic effect.

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Traditional Chinese medicine — Infrared moxibustion-like instrument

1 Scope

This document specifies the requirements for infrared moxibustion-like instrument as a medical device.

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/IEC Guide 37, *Instructions for use of products by consumers*

ISO 780, *Packaging — Distribution packaging — Graphical symbols for handling and storage of packages*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

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 https://www.electropedia.org/

3.1
infrared moxibustion-like spectrum
specific radiation spectrum generated by the radiator which simulates the burning of mugwort

Note 1 to entry: It is primarily distributed in the wavelength range of 1 μm to 10 μm.

3.2
infrared moxibustion-like instrument
non-contact traditional Chinese medical device that uses infrared moxibustion-like radiation effects for acupuncture point and local region treatment

3.3
thermal response time
duration from the moment the device is energized, under indoor conditions to the moment it reaches the rated temperature with a level of stability

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