INTERNATIONAL STANDARD

ISO 21291

First edition
2019-05

Traditional Chinese medicine — Therapeutic fumigation devices

Médecine traditionnelle chinoise — Dispositifs de fumigation thérapeutique

Reference number
ISO 21291:2019(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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).

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).

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.

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.

Traditional Chinese medicine — Therapeutic fumigation devices

1 Scope

This document specifies the requirements and test methods for therapeutic fumigation devices, hereafter referred to as the device.

This document does not apply to decoction pieces.

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*

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*

IEC 60601-2-52, *Medical electrical equipment — Part 2-52: Particular requirements for the basic safety and essential performance of medical beds*

IEC 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

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

— IECElectropedia: available at http://www.electropedia.org/

3.1
therapeutic fumigation device
device that heats liquid decoction pieces to form steam

Note 1 to entry: The steam is used therapeutically.

3.2
closed therapeutic fumigation device
therapeutic fumigation device which uses an enclosed capsule for treatment

Note 1 to entry: During treatment, the steam and areas of the patient's body undergoing therapeutic fumigation are predominantly isolated from the surrounding environment.

3.3
open therapeutic fumigation device
therapeutic fumigation device which does not use an enclosed capsule for treatment

Note 1 to entry: During treatment, both the steam and areas of the patient's body undergoing therapeutic fumigation are exposed to the surrounding environment.

4 Classification and components

4.1 Classification

The device is classified according to the body area being treated and the fumigation method being applied.

a) Local type and full-body type can be classified by body area being treated (see Figure 1 and Figure 3).

b) Open therapeutic fumigation devices and closed therapeutic fumigation devices, hereinafter referred to as open devices and closed devices, can be classified by the exposure to the environment (see Figure 1 and Figure 2).

4.2 Components

The device consists of a heating unit, decoction container, steam outlet temperature-sensing unit, control unit, steam pathway and output unit with steam outlet.

For open devices, a skin temperature-sensing unit is also included.

For closed devices, a treatment capsule and a capsule steam temperature-sensing unit are also included. For closed devices involving therapeutic fumigation of the whole body, a support system for the treatment capsule is also included (see Figures 1 to 3).