
**Traditional Chinese medicine — Safety
controls for cupping devices**

*Médecine traditionnelle chinoise — Contrôles de sécurité pour les
ventouses*

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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).

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).

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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*.

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.

Introduction

Cupping therapy is one of the most widely used traditional medical practices. It involves creating a partial vacuum in cups placed on the skin for air suction or to extract the blood through various techniques. Even though cupping devices are marketed and used in many countries, there is no International Standard for safety controls for cupping devices. Such controls are needed to ensure the safety of cupping devices, which touch the skin or come into contact with open wounds during bleeding for wet cupping. These controls require the risk management of manufacturing, packaging and labelling and the presentation, storage, reuse, servicing and disposal of cupping devices to protect cupping practitioners and patients from the risks of misuse and infections.

Traditional Chinese medicine — Safety controls for cupping devices

1 Scope

This document specifies safety controls for cupping devices used for air suction or discharge.

It applies to cupping devices that contain cups made of manufactured materials, such as plastic, glass, rubber, ceramic or silicone.

It does not apply to cupping devices that contain cups made from natural materials (e.g. bamboo) or those that include additional features, such as magnetism or infrared.

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 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 17664-2, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 19611, *Traditional Chinese medicine — Air extraction cupping device*

ISO 22213, *Traditional Chinese medicine — Glass cupping device*

3 Terms and definitions

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

ISO and IEC maintain terminology 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

dry cupping

therapeutic method involving the placement of suction cup(s) on intact skin, creating negative pressure (suction) inside the suction cup for the prevention or treatment of diseases

3.2

wet cupping

therapeutic method involving placement of suction cup(s) on intact skin after pricking the skin to extract blood using a scalpel, needle, three-edge needle, automatic pricking tool or other for the prevention or treatment of diseases