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Traditional Chinese medicine — Safety controls for cupping devices

Médecine traditionnelle chinoise — Contrôles de sécurité pour les ventouses

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Foreword

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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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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.

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

3.3
cupping device
device used to perform dry or wet cupping, which includes suction cups and means of air suction or discharge, such as a suction pump, fire, twist rotary or rubber suction bulb

4 Requirements

4.1 Safety controls before use

4.1.1 Design and manufacture of cupping devices

Cupping devices shall be designed and manufactured to be safe for both practitioner and patient and in accordance with ISO 19611 and ISO 22213.

4.1.2 Restrictions of reuse

Cupping devices used for wet cupping shall be used only once. They may be reused when used for dry cupping if cleaned and disinfected.

4.1.3 Sterility of cupping devices used for wet cupping

Cupping devices used for wet cupping shall be sterilized before use. If the sterility is compromised, the devices shall be resterilised in the appropriate facility in accordance with ISO 14937 either inside or outside of the clinic.

4.1.4 Cleaning and disinfection of cupping devices used for dry cupping

Cupping devices used for dry cupping shall be cleaned and disinfected before use. Cleaning and disinfection shall comply with the recommendations provided by the manufacturer in accordance with ISO 17664-2.

4.1.5 Visual test

A sample of cupping devices shall be taken according to the accredited sampling criteria and visually tested to ensure it is free from damages or defects.

4.1.6 Checking package, label, user manual and attached leaflets

4.1.6.1 Package integrity shall be inspected in accordance with ISO 11607-1.

4.1.6.2 The label, user manual and instructions for use shall be checked before using the device. In particular, the following information shall be verified:

a) product name (e.g. cupping device for professional or personal use, massage or face cupping set);

b) name, address and trademark of the manufacturer;

c) lot number, preceded by the word 'LOT' and/or the date of manufacture;

d) sterilization method and expiry date of pre-sterilized cupping device;

e) information for disinfection of cupping devices used for dry cupping in accordance with ISO 17664-2;

f) information for handling, storage and transportation.

4.1.6.3 The scientific evidence for all medical claims indicated in the user manual or in the attached leaflets shall be verified to ensure its credibility.

4.2 Safety controls after use

4.2.1 Disposal of cupping devices used for wet cupping

Cupping devices used for wet cupping shall be disposed of in a medical waste container immediately after use.

4.2.2 Cleaning and disinfection of cupping devices used for dry cupping

Cupping devices used for dry cupping shall be placed in a dedicated container immediately after use. They shall be cleaned and disinfected before reuse following the recommendation of the manufacturer in accordance with ISO 17664-2.

5 Safety control verification

Safety controls for cupping devices should be verified by the cupping practitioner to ensure the safe use of cupping devices. See Annex A for additional information.

Annex A
(informative)

Checklist for safety control verification

#	Item	Status
1	Cupping devices designed and manufactured in accordance with ISO 19611 and ISO 22213	
2a	Sterility of cupping devices used for wet cupping	
2b	Cleanliness of cupping devices used for dry cupping	
3	Cupping devices are free from damages or defects	
4	Packaging integrity	
5	Labels, user manual and instructions for use contain the following information:	
	a) product name	
	b) name, address and trademark of the manufacturer	
	c) lot number or the date of manufacture	
	d) sterilization method and expiry date for pre-sterilized cupping devices	
	e) information for handling, storage and transportation	
6	Scientific evidence cited for all medical claims	
7a	Cupping devices used for wet cupping disposed of in a medical waste container immediately after use	
7b	Cupping devices used for dry cupping placed in a dedicated container immediately after use	
7c	Cupping devices used for dry cupping cleaned and disinfected before reuse	