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Traditional Chinese medicine — Glass cupping device

Médecine traditionnelle chinoise — Ventouses en verre

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Foreword

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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 has been widely used since ancient times. The glass cupping device is one of the most commonly used types of cupping devices. The quality of the glass cupping device has a direct impact on its safe use and influences the therapeutic efficacy. This document was developed to improve the safety and quality of the glass cupping device.

Traditional Chinese medicine — Glass cupping device

1 Scope

This document specifies the requirements for the glass cupping device applying negative pressure created by a heat source placed in its inner cavity.

This document includes the requirements for configuration, material, performance, packaging and labelling, as well as appropriate test methods.

This document applies to single-use and multiple-use glass cupping devices.

This document does not apply to the air extraction cupping device covered by ISO 19611.

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 3585, *Borosilicate glass 3.3 — Properties*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

ISO 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process*

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

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

ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

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 http://www.electropedia.org/

3.1
cupping
placing cups on the skin to create localized negative pressure by means of heat or suction pump, thereby affecting the body surface or increasing bloodletting as a result of the *negative pressure* (3.3) within the cups

3.2
glass cupping device
device made of glass which is used for *cupping* (3.1)

3.3
negative pressure
pressure less than that of the ambient atmosphere

Note 1 to entry: The method of creating negative pressure shall be stated when this term is used.

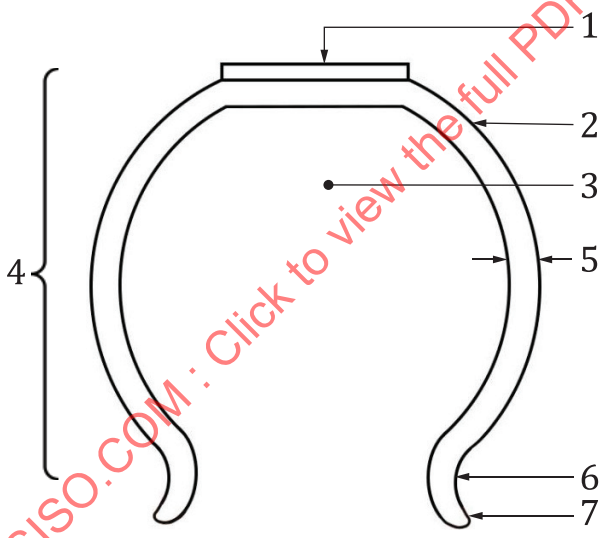
[SOURCE: ISO 4135:2001, 3.3.10]

3.4
instantaneous pressure
pressure produced inside a *glass cupping device* (3.2) at the instant moment of *cupping* (3.1)

4 Specification

4.1 Configuration

The typical shape and structure of a glass cupping device are shown in Figure 1.



Key
1 top of glass cupping device
2 external surface
3 inner cavity
4 glass cupping device body
5 glass thickness of device body (δ)
6 chamfer of glass cupping device
7 lip of glass cupping device

Figure 1 — Typical shape and structure of a glass cupping device

4.2 Dimensions and parameters

4.2.1 General

The glass cupping device should be made in one of five sizes numerically coded from 1 to 5.

4.2.2 Volume of the inner cavity

The volume of the inner cavity for each numerically coded cup shall be specified as shown in Table 1.

Table 1 — Volume of inner cavity

Dimensions in millilitres

Cup number	Inner volume
1	340 ± 17
2	260 ± 13
3	180 ± 9
4	130 ± 6,5
5	95 ± 4,8

4.2.3 Glass thickness

The glass thickness shall be specified as shown in Table 2.

Table 2 — Glass thickness

Dimensions in millimetres

Cup number	Glass thickness δ
1	7,50 ± 0,4
2	6,40 ± 0,3
3	6,30 ± 0,3
4	5,90 ± 0,3
5	4,70 ± 0,2

4.3 Material

The glass cupping device shall be made from borosilicate glass that conforms with ISO 3585.

5 Requirements

5.1 Biological compatibility

The glass cupping device shall be evaluated and documented in accordance with the guidance and principles given in ISO 10993-1, ISO 10993-4, ISO 10993-10, ISO 10993-18 and ISO/TS 10993-19.

5.2 Surface smoothness

The external surface, the lip and the top of the glass cupping device shall be smooth, without cracks or burrs.

5.3 Glass quality

The glass cupping device shall have no more than one impurity with a diameter of ≥ 1,0 mm. There shall be no more than three impurities with a diameter of ≥ 0,5 mm to < 1,0 mm. Cup numbers 1, 2 and 3 shall have no more than two bubbles with a diameter of ≥ 5,0 mm. Cup number 4 and cup number 5 shall have no more than three bubbles with a diameter of ≥ 3,0 mm. No bubble with a diameter of > 5,0 mm is allowed.

5.4 Performance

5.4.1 Negative pressure resistance

The glass cupping device shall resist the instantaneous pressure of ≥ −91,50 kPa without cracking or breaking.

5.4.2 Pressure maintenance

Pressure loss between the glass cupping device body and skin shall not be more than 10 % of the instantaneous pressure when being tested for 10 min.

5.4.3 Test methods

See Annex A.

5.5 Sterilization and disinfection

The sterilization and disinfection of the glass cupping device shall conform to ISO 17664.

6 Package

6.1 Primary package

The glass cupping device shall be sealed in a primary package. There shall be no foreign matter within the primary package under visual inspection.

The material and design of the primary package shall have no detrimental effects on the contents. The material and design of the primary package shall ensure:

a) that contents remain clean and disinfected under dry, clean and adequately ventilated storage conditions;

b) the minimal risk of contamination of the contents during removal from the package;

c) adequate protection of the contents during normal handling, transit and storage;

d) that once opened, the package cannot be resealed without it being evident that it has already been opened.

NOTE The requirements of materials, sterile barrier systems and packaging systems for terminally disinfected medical devices are provided in ISO 11607-1.

6.2 Secondary package

One or more primary packages shall be packaged in a secondary package.

The secondary package shall be sufficiently robust to protect the contents during handling, transit and storage.

One or more secondary packages may be packaged in a storage package, a transit package or both.

7 Labelling

7.1 General

The symbols used on the package shall conform to ISO 15223-1.

7.2 Primary package

The primary package shall be marked with at least the following information:

a) name and address of the manufacturer;

b) product name;

c) product size (following 4.2.2);

d) specification and quantity;

e) product registration number for certification purposes;

f) date of manufacture;

g) a warning to check the integrity of each primary package before use, such as "Do not use if package is damaged" or the appropriate symbol.

7.3 Secondary package

The secondary package shall be marked with at least the following information:

a) name and address of the manufacturer;

b) product name;

c) specification and quantity;

d) net weight and gross weight;

e) product registration number for certification;

f) date of manufacture;

g) a warning to check the integrity of the secondary package before use, such as "Do not use if package is damaged" or the appropriate symbol.

7.4 Storage and transit package

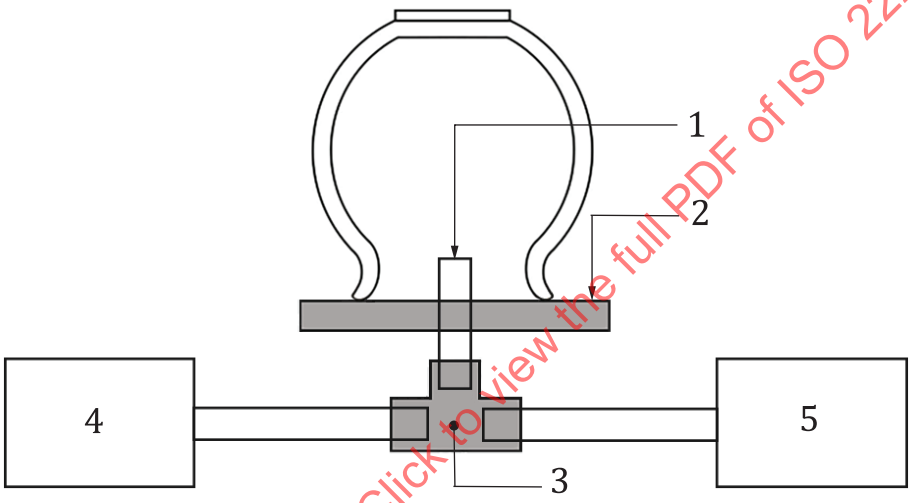
Storage and transit package shall have the sign "Fragile" and the appropriate symbol. Words and signs shall be legible and durable throughout transportation.

Annex A
(informative)

Test methods for a glass cupping device

A.1 General

To measure internal negative pressure of a glass cupping device, the T-shape valve shall be strongly connected to a suction pump, a manometer and a tube through a silicon plate. The glass cupping device shall be placed on the silicon plate with the tube into the inner cavity at standard atmosphere (see ISO 2533). The experimental setup is shown in Figure A.1.



Key

1 tube
2 silicon plate (thickness: 3 mm)
3 T-shape valve
4 suction pump
5 manometer

Figure A.1 — Experimental setup to measure negative pressure

A.2 Negative pressure resistance

Negative pressure resistance of a glass cupping device should be tested by measuring the negative pressure, which is instantaneous maximum pressure (−95,10 kPa), created by a suction pump. The glass cupping device shall maintain the instantaneous maximum pressure for 3 s. The performance of the glass cupping device and its appearance shall remain intact after the negative pressure resistance test.

A.3 Pressure maintenance

Pressure maintenance of a glass cupping device should be tested by measuring the negative pressure, which should be within the range of −54,57 kPa to −62,38 kPa, created by a suction pump. Pressure loss between the glass cupping device body and the silicon plate shall not be more than 10 % for 10 min.