

INTERNATIONAL  
STANDARD

ISO  
22213

First edition  
2020-08

---

---

**Traditional Chinese medicine — Glass  
cupping device**

*Médecine traditionnelle chinoise — Ventouses en verre*



Reference number  
ISO 22213:2020(E)

© ISO 2020



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

	Page
<b>Foreword</b>	<b>iv</b>
<b>Introduction</b>	<b>v</b>
<b>1 Scope</b>	<b>1</b>
<b>2 Normative references</b>	<b>1</b>
<b>3 Terms and definitions</b>	<b>1</b>
<b>4 Specification</b>	<b>2</b>
4.1 Configuration	2
4.2 Dimensions and parameters	2
4.2.1 General	2
4.2.2 Volume of the inner cavity	3
4.2.3 Glass thickness	3
4.3 Material	3
<b>5 Requirements</b>	<b>3</b>
5.1 Biological compatibility	3
5.2 Surface smoothness	3
5.3 Glass quality	3
5.4 Performance	4
5.4.1 Negative pressure resistance	4
5.4.2 Pressure maintenance	4
5.4.3 Test methods	4
5.5 Sterilization and disinfection	4
<b>6 Package</b>	<b>4</b>
6.1 Primary package	4
6.2 Secondary package	4
<b>7 Labelling</b>	<b>4</b>
7.1 General	4
7.2 Primary package	5
7.3 Secondary package	5
7.4 Storage and transit package	5
<b>Annex A (informative) Test methods for a glass cupping device</b>	<b>6</b>
<b>Bibliography</b>	<b>8</b>

## 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](http://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](http://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](http://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](http://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