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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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Traditional Chinese medical device - Glass cupping device

中医器械 玻璃拔罐器

(English Translation)

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is modified to adopt ISO 22213:2020 "Glass cupping devices for traditional Chinese medicine".

Compared with ISO 22213:2020, this document has undergone the following structural adjustments.

---Added sections 5.1 and 5.2, corresponding to sections 5.2 and 5.3 in ISO 22213:2020. Section 5.3 corresponds to sections 4.3 and 5.6 in ISO 22213:2020.

This corresponds to section 5.1 of ISO 22213:2020;

---A new chapter, Test Methods, has been added, with 6.4.1 and 6.4.2 corresponding to 5.4.3 in ISO 22213:2020.

The technical differences between this document and ISO 22213:2020, and the reasons therefor, are as follows.

---ISO 10993-1 (see 5.6, 6.6) has been replaced with the normatively referenced GB/T 16886.1 to adapt to my country's technical conditions.

High operability;

---ISO 3585 (see 5.3, 6.3) has been replaced with the normatively referenced GB/T 34843 to adapt to my country's technical conditions and improve reliability.

Operability;

---ISO 17664 (see 5.5, 6.5) has been replaced with the normatively referenced YY/T 0802 to adapt to my country's technical conditions and improve reliability.

Operability;

---ISO 10993-4, ISO 10993-10, ISO 10993-18, ISO/T S10993-19, and ISO 15223-1 have been removed to suit my needs.

The actual situation in the country;

---The term "cupping" has been removed from the terms and definitions; it does not need to be defined in this document.

---The terminology and description of instantaneous pressure in "resistance to negative pressure" have been changed to instantaneous negative pressure (see 3.3, 5.4.1), and the definition has been revised, resulting in a more accurate description.

For accuracy;

---The recommended models by volume have been removed, replaced with examples of commonly used models named alphabetically, and the phrase "can also be specified by the manufacturer" has been added.

The designation (see 4.2.1) ensures that the tank number matches the internal volume, avoiding ambiguity and adapting to my country's actual situation.

---The requirement for content volume size has been removed, replaced with a common size example, and "can also be specified by the manufacturer" (see 4.2.2) has been added, allowing...

The difference was changed to $\pm 10\%$, and the internal volume of the XS size was changed to 80 mL (see Table 1) to adapt to the actual situation in my country;

---The tank glass wall thickness value has been removed to better suit my country's specific circumstances and improve operability;

---Dimensional requirements and test methods have been added (see 5.1, 6.1) to improve the standardization of glass cupping sets;

---Added requirements for the appearance of glass cupping sets with other internal volumes, which are now specified by the manufacturer (see 5.2), to adapt to the actual situation in our country.

Condition;

---The instantaneous pressure during negative pressure maintenance is changed to the initial negative pressure value (see 5.4.2) to improve operability;

---The packaging has been removed (see Chapter 6 of ISO 22213:2020) to suit my country's specific circumstances;

---The symbol has been removed (see Chapter 7 of ISO 22213:2020) to adapt to the actual situation in my country;

---The test methods for resistance to negative pressure and maintenance of negative pressure in Appendix A have been moved to Chapter 6 (see 6.4.1, 6.4.2) to improve operability.

Acting.

The following editorial changes have been made to this document.

---The term "Traditional Chinese Medicine" in the standard name has been changed to "Traditional Chinese Medicine Instruments";

---The phrases "glass cupping devices operate by generating negative pressure through a heat source placed inside the cup" and "single and repeated" have been removed from the scope.

The phrase "use" should be changed from "vacuum cupping devices as defined in ISO 19611" to "manual or electric negative pressure cupping devices".

---Note added to definition 3.2;

---The content of Figure A.1 has been changed;

---References have been removed.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the Standardization Technical Unit for Traditional Chinese Medicine Instruments (SMD/T U008).

1 Scope

This document specifies the specifications and requirements for glass cupping sets and describes the corresponding test methods.

This document applies to glass cupping devices.

This document does not apply to manual or electric negative pressure cupping devices.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included.

For references to documents, only the version corresponding to that date applies to this

document; for undated references, the latest version (including all amendments) applies.

This document.

GB/T 16886.1 Biological evaluation of medical devices - Part 1: Evaluation and testing in the risk management process (GB/T 16886.1-2022, ISO 10993-1:2018, IDT) GB/T 34843.3 Properties of borosilicate glass (GB/T 34843-2017, ISO 3585:1998, MOD) YY/T 0802 Handling of Medical Devices - Information provided by medical device manufacturers (YY/T 0802-2020, ISO 17664.

2017, MOD)

3 Terms and Definitions

The following terms and definitions apply to this document.

glass cupping device Glassware used in cupping therapy.

negative pressure

Gas pressure below ambient atmospheric pressure.

Note: The negative pressure value in this document represents the difference between the air pressure inside the glass cupping device and the atmospheric pressure.

The short-term negative pressure generated inside the glass cupping device.

4.1 Structural Form

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