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

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Traditional Chinese medical device - Gua Sha instruments

中医器械 刮痧器具

(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 20308:2017 "Gua Sha tools in Traditional Chinese Medicine".

Compared with ISO 20308:2017, this document has undergone many structural adjustments. Appendix A lists the differences between this document and ISO 5840-1.

A list of chapter and section numbers for 2021.

This document differs significantly from ISO 20308:2017. The relevant clauses are indicated in vertical margins.

Single lines (|) are indicated. A summary of these technical differences and their causes can be found in Appendix B.

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";

---Added sources for terms, informative references to GB/T 21709.22-2013, and references;

---The phrase "other forms of gua sha tools" has been removed from the scope;

---Note added in version 3.2;

---The recommended sizes for triangular, comb-shaped, and fish-shaped gua sha tools have been changed (see Tables C.4, C.5, and C.6).

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 U8).

1 Scope

This document specifies the requirements for scraping tools and describes the corresponding test methods.

This document applies to gua sha tools.

This document does not apply to electronic gua sha 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 6566-2010 Limits of Radionuclides in Building Materials GB/T 9966.5 Test methods for natural stone - Part 5: Hardness test 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) 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.

Gua Sha

Using specially designed scraping tools, based on the theory of meridians and acupoints in traditional Chinese medicine, appropriate scraping techniques are applied to the body surface to prevent and treat diseases.

[Source. GB/T 21709.22-2013, 3.1] 3.2 Gua Sha instruments Plate-shaped tools made of hard materials such as ox horn, Bian stone, ceramics, and jade are the main tools for Gua Sha.

[Source. GB/T 21709.22-2013, 3.2, with modifications] Note. For the materials, shapes and

sizes of common gua sha tools, please refer to Appendix C.

4.1 Appearance

The appearance of gua sha tools should meet the following requirements.

- a) The surface of the scraping tool should be flat, smooth, and free of particles and foreign matter;
- b) No part of the scraping tool should have sharp corners and edges, cracks, or obvious deformation or damage.