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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