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Traditional Chinese medicine — Herbal decoction apparatus

Médecine traditionnelle chinoise — Appareil décoction herbe-médicinale

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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).

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).

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.

This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

This second edition cancels and replaces the first edition (ISO 18665:2015), of which it constitutes a minor revision. The changes are as follows:

— General: 'this International Standard' changed to 'this document';

— Clause 2: IEC 60204-1 updated to the 2016 edition;

— Clause 3: addition of the introductory text according to ISO/IEC Directives, Part 2;

— 3.2: “hemetic” changed to “airtight” in definition;

— 3.3: “non-hemetic” changed to “non-airtight” in definition;

— 4.3.4: “dependable without leakage” changed to “watertight”;

— 4.5.1: “give” changed to “generate”;

— 4.5.5: “put on” changed to “attached to”;

— minor editorial changes.

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.

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Introduction

This document has been developed in response to worldwide demand for herbal decoction apparatus traded internationally. There is a wide variety of herbal decoction apparatus currently available commercially, but there are no standards guiding its manufacture. Increased use of decoctions as a means of administering herbal medicine, as well as growing patient expectations and concerns regarding safety and quality, have given rise to the need to improve the safety and quality of herbal decoction apparatus through implementation of an International Standard.

There are two main types of herbal decoction apparatus in common use. According to the structure of herbal decoction apparatus, it can be divided into hermetic decoction apparatus and non-hermetic decoction apparatus

The primary aim of this document is to ensure the safety and quality of both non-hermetic decoction apparatus and hermetic decoction apparatus.

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Traditional Chinese medicine — Herbal decoction apparatus

1 Scope

This document specifies the general requirements of herbal decoction apparatus with design pressures less than 0,1MPa. It includes both hermetic and non-hermetic decoction apparatus.

This document is applicable to herbal decoction apparatus for individual herbal formula prescriptions and for commercial use as well as private use. It also applies to the decocting part of the integrated apparatus of decoction and package.

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/IEC Guide 37:2012, *Instructions for use of products by consumers*

ISO 780, *Packaging — Distribution packaging — Graphical symbols for handling and storage of packages*

ISO 16528-1:2007, *Boilers and pressure vessels — Part 1: Performance requirements*

ISO 16528-2:2007, *Boilers and pressure vessels — Part 2: Procedures for fulfilling the requirements of ISO 16528-1*

ISO 21469:2006, *Safety of machinery — Lubricants with incidental product contact — Hygiene requirements*

IEC 60204-1:2016, *Safety of machinery — Electrical equipment of machines — Part 1: General requirements*

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 https://www.electropedia.org/

3.1
herbal decoction apparatus
device that produces the herbal liquid by extracting medicinal herb pieces with water and heat

3.2
hermetic decoction apparatus
container that is airtight during decoction with the decoction pressure higher than the atmospheric pressure

3.3
non-hermetic decoction apparatus
container that is non-airtight and open to the atmosphere with decoction pressure equal to atmospheric pressure

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