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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 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.

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 60204-1:2009, *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

4 Requirements

4.1 Material

4.1.1 Any material that is in direct contact with the decoction shall be non-toxic, corrosion-resistant, non-shedding and high-temperature-resistant, and shall not cause chemical reactions, absorption with the decoction or release of substances. It shall be in accordance with the corresponding hygienic standard.

4.1.2 The lubricant shall be in accordance with the rules given in ISO 21469:2006, Clause 5.

4.2 Surface quality

4.2.1 The outside surface of the decoction apparatus shall be neat and easy to clean. The surface coating after the anti-corrosion treatment of the parts shall be neat, smooth and non-shedding.

4.2.2 The surface roughness of the metal parts that are in contact with the decoction shall be less than 0,8 μm .

4.2.3 The surface of any non-metal decoction container that comes into contact with the decoction, as well as that of the sealing elements, shall be bright and clean, smooth and free of bubbles.

4.2.4 The material name and flow direction in the pipeline shall be marked where the external pipelines connect.

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4.3 Performance

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4.3.1 The performance of the hermetic container of the herbal decoction apparatus shall be in accordance with the rules given in ISO 16528-1:2007, 7.4 and 7.5 and ISO 16528-2:2007, Clause 5.

4.3.2 The pipeline system, easy to clean and dismantle and with a flexible valves switch, shall have no blind pipe. The residues shall be less than 20 ml.

4.3.3 The minimum diameter for the pipe from decoction container to decoction outlet shall not be less than 15 mm.

4.3.4 The seal of the lubricating device of the decoction apparatus shall be watertight.

4.3.5 The decocting time can be set with the timing error values no greater than 1 %.

4.3.6 The decocting temperature of the herbal decoction apparatus can be free set, automatically controlled and displayed with the measuring error values less than ± 1 °C.

4.4 Electrical safety

4.4.1 The continuity of the protective grounding circuit of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, 8.2.3.

4.4.2 The insulation resistance of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, 18.3.

4.4.3 The voltage of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, 18.4.

4.4.4 The push buttons of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, 10.2.

4.4.5 The indicator lights and displays of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, 10.3.

4.4.6 The wiring of the electrical system shall be in accordance with the rules given in IEC 60204-1:2009, Clause 13.

4.4.7 The marking, warning signs and reference designations shall be in accordance with the rules given in IEC 60204-1:2009, Clause 16.

4.5 Machinery safety

4.5.1 The hermetic decoction apparatus shall generate an alarm and stop heating automatically when the decocting temperature reaches 120 °C.

4.5.2 For the hermetic decoction apparatus, a safety valve shall be located on the top of the decoction container with the set pressure not higher than 1,05 times the maximum working pressure.

4.5.3 For the hermetic decoction apparatus, the hydraulic testing pressure of the decoction container shall be no less than 1,25 times the design pressure.

4.5.4 For the non-hermetic decoction apparatus, a full water test shall be performed.

4.5.5 A warning sign to indicate the presence of a hot surface, as specified in ISO 7010:2011, Table 2, W017, shall be attached to the outside surface of the herbal decoction apparatus. See [Figure 1](#).



Figure 1 — ISO 7010-W017: Warning; Hot surface

5 Test methods

5.1 Material test

5.1.1 Check the certificate of conformity of the material. When there is no certificate, the material shall be tested in accordance with the testing methods given in the corresponding material standard.

5.1.2 Check the certificate of conformity of the lubricant.

5.2 Surface quality test

5.2.1 Confirm with the naked eye that the outside surface quality meets the requirements in [4.2.1](#).

5.2.2 Test with the surface roughness measuring instrument to control that the surface roughness of the metal parts that are in contact with the decoction are less than 0,8 µm ([4.2.2](#)).

5.2.3 Confirm that the surfaces of the non-metal parts that are in contact with the decoction meet the requirements in [4.2.3](#).

5.2.4 Confirm with the naked eye that the marking of the externally connected pipelines meets the requirements of [4.2.4](#).

5.3 Performance test

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5.3.1 Hermetic container test

The hermetic container test shall be in accordance with the rules given in ISO 16528-1:2007, 7.4 and 7.5 and ISO 16528-2:2007, Clause 5.

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5.3.2 Pipeline system and valve test

Check the pipeline installation and the easy dismantling conditions. Place the herbal decoction apparatus on level ground and connect it to one end of the pipeline of the packaging component. Place the other end of the pipeline lower than the decoction outlet.

Add a nominal capacity of water to the decoction container, then perform the valve switch test. Open the valve to let the water flow until no more water comes out. Place a bowl at the outlet and then incline the herbal decoction apparatus more than 10 degrees towards the outlet.

Measure the water volume in the bowl with a 50 ml measuring cup and compare this value with the specified value.

5.3.3 Pipeline diameter test

Measure the minimum bore diameter in the pipeline.

5.3.4 Loading test

Add 50 % of nominal capacity of drinking water to the decoction container. With the decocting temperature in the hermetic condition set at the maximum working temperature, and the decocting time set at 40 min, start the apparatus. Conduct the loading test in accordance with [5.3.6](#), [5.3.7](#), [5.5.1](#) and [5.5.2](#).