
**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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 249, *Traditional Chinese medicine*.

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Introduction

This International Standard 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 their manufacture. Increased use of decoctions as a means of administering herbal medicine, as well as growing patients' 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 International Standard 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 International Standard specifies the general requirements of herbal decoction apparatus with design pressures less than 0,1MPa. It includes both hermetic and non-hermetic decoction apparatus.

It is applicable to the 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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.

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 hermetic during decoction with the decoction pressure higher than the atmospheric pressure

3.3

non-hermetic decoction apparatus

container that is non-hermetic 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, 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 a non-metal decoction container that is contact with the decoction as well as 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.

4.3 Performance

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 as well as with 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 dependable with no leakage.

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 $\pm 1^\circ\text{C}$.

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 in IEC 60204-1:2009, Clause 16.

4.5 Machinery safety

4.5.1 The hermetic decoction apparatus shall give 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 of 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 7010:2011¹⁾, Table 2, W017, shall be put on the outside surface of the herbal decoction apparatus. See [Figure 1](#).



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

1) This sign is available at <https://www.iso.org/obp/ui/#iso:grs:7010:2:W017>.