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BSI Standards Publication

Traditional Chinese medicine — Herbal decoction apparatus



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National foreword

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Traditional Chinese medicine — Herbal decoction apparatus

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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*.

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.

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 — Part1: 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