INTERNATIONAL STANDARD

ISO 23963-2

First edition
2022-08

Traditional Chinese medicine — Requirements for process traceability system of Chinese materia medica and decoction pieces —

Part 2: Electronic labelling

Médecine traditionnelle chinoise — Exigences relatives au système de traçabilité du processus pour la Materia Medica chinoise et les décoctions —

Partie 2: Étiquetage électronique

Reference number
ISO 23963-2:2022(E)

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Published in Switzerland

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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*.

A list of all parts in the ISO 23963 series can be found on the ISO website.

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

Chinese medicine (medicinal plants, animals and minerals) originates from a wide variety of different sources of supply. The production documentation is handled differently by each company and important manufacturing steps are usually not fully documented. Several companies are usually involved in the manufacturing process of Chinese medicine and relevant information is often not passed on fully from one company to the other. This makes it very difficult for manufacturers and consumers to retrace the entire production process (e.g. cultivation, harvesting, processing, storage and logistics) and to assess the quality and safety of the Chinese medicine. The lack of transparency in the manufacturing process slows down to a certain extent the further development and internationalization of traditional Chinese medicine. Therefore, a supply chain traceability system is needed which ensures that the documentation of all product-relevant information is standardized and available at all times. Such a system will enable companies to better evaluate their suppliers and to convince end users of the quality and safety of their products.

This document is consistent with ISO 18668-1, ISO 18668-2, ISO 18668-3 and ISO 20333. It includes the application of these documents and provides a solution to improve the management of all processes relating to Chinese medicine, contributes to the establishment of the traditional Chinese medicine supply chain traceability system and quality-investigating mechanism, enhances product quality and competitiveness, protects consumers' rights and ensures safe and effective application in clinical use.

This document can promote the process of standardization, informatization and modernization for traditional Chinese medicine.

Traditional Chinese medicine — Requirements for process traceability system of Chinese materia medica and decoction pieces —

Part 2:
Electronic labelling

1 Scope

This document specifies the content of electronic labelling in the form of QR codes on the outer packing of Chinese materia medica and decoction pieces. This document is applicable to the cultivation, production, sales, use units and consumers of Chinese materia medica and decoction pieces.

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 18668-2, *Traditional Chinese medicine — Coding system for Chinese medicines — Part 2: Codes for decoction pieces*

ISO 18668-3, *Traditional Chinese medicine — Coding system for Chinese medicines — Part 3: Codes for Chinese Materia Medica*

ISO 20333, *Traditional Chinese medicine — Coding rules for Chinese medicines in supply chain management*

ISO 22217, *Traditional Chinese medicine —Storage requirements for raw materials and decoction pieces*

ISO 23963-1, *Traditional Chinese medicine — Requirements for process traceability system of Chinese materia medica and decoction pieces — Part 1: Components*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology 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
QR code
two-dimensional bar code
error-correcting matrix symbology, consisting of an array of nominally square modules arranged in an overall square pattern, including a unique finder pattern located at three corners of the symbol and intended to assist in easy location of its position, size and inclination

[SOURCE: ISO 22742:2010, 3.33, modified — Notes to entry removed.]

3.2
electronic labelling
text, graphics, symbols and all instructions presented on the terminal device after scanning the QR code

3.3
licence
legally binding agreement which permits an organisation to manufacture or distribute a traditional Chinese medicine product

3.4
trusted third-party platform
entity that facilitates interaction between two parties, both of which trust the third party

4 Requirements of electronic labelling

4.1 The content of electronic labelling shall be based on ISO 23963-1.

4.2 The organization providing the electronic labelling services shall be a trusted third-party platform which is independent from all companies involved in the supply chain.

4.3 The content of the electronic labelling shall be fixed and the user has no right to modify it. The revision of the content of the electronic labelling is carried out by a trusted third-party platform.

4.4 Each batch of Chinese materia medica or decoction pieces shall correspond to a unique electronic labelling.

4.5 If there is more than one distributor, its information can be added according to 5.3.

4.6 The language for electronic labelling shall be in the official language of the country in which the products will be sold.

4.7 If the QR code can be scanned accurately and quickly, the size of the QR code can be determined according to the area of the product package.

5 Content of electronic labelling

5.1 Basic information

5.1.1 Product name

The specification of Chinese materia medica and decoction pieces shall be provided according to ISO 18668-2 and ISO 18668-3.

5.1.2 Barcode

Provide a barcode according to ISO 20333.

5.1.3 Code

Provide 17 bits of code for Chinese materia medica and decoction pieces, according to ISO 18668-2 and ISO 18668-3.

5.1.4 Brand

The trademark and brand registered by the manufacturer.

5.1.5 Place of origin

The origin is accurate to the county level, according to ISO 20333.

5.1.6 Harvest time

Harvest time of specific batches of Chinese materia medica. Specific to the month. The format is YYYY-MM-DD, e.g. 2022-01-30.

5.1.7 Processing method

Processing method of a specific batch of decoction pieces.

5.1.8 Specification

The unit is g/pack, e.g. 1 g/pack, 3 g/pack, 5 g/pack, 6 g/pack, 9 g/pack, 10 g/pack, 12 g/pack, 15 g/pack, 30 g/pack.

5.1.9 Efficacy

The efficacy of Chinese materia medica and decoction pieces by law.

5.1.10 Adverse reaction

Describe the adverse reaction of Chinese materia medica and decoction pieces. If none, describe this as "not clear yet."

5.1.11 Contraindication

Describe the contraindications of Chinese materia medica and decoction pieces. If none, describe these as "not clear yet."

5.2 Manufacturer information

5.2.1 Manufacturer

The name of the manufacturer, which is registered.

5.2.2 Address

The address of manufacturer, accurate to the door number.

5.2.3 Telephone number

The manufacturer's contact number: country code – area code – telephone number.

5.2.4 Website

The manufacturer's website is required. The format is www.***.com/cn/jp/co.kr, e.g. www.iso.org.

5.2.5 Product time

The date of planting, harvesting, processing and production is required. The format is YYYY-MM-DD, e.g. 2022-01-30.

5.3 Distributor information

5.3.1 Distributor

The name of the distributor, which is registered.

5.3.2 Address

The address of the distributor, accurate to the door number.

5.3.3 Telephone number

The distributor's contact number: country code – area code – telephone number.

5.3.4 Website

The distributor's website is required. The format is www.***.com/cn/jp/co.kr, e.g. www.iso.org.

5.3.5 Packing time

The date of packing is required. The format is YYYY-MM-DD, e.g. 2022-01-30.

5.4 Additional information

5.4.1 Storage method

Implement the provisions of ISO 22217.

5.4.2 Applied standards

The documents implemented, such as ISO 18668-2 and ISO 18668-3.

5.4.3 Picture

A picture of decoction piece samples shall be provided by the manufacturer.

5.4.4 Decocting method

— A stainless steel casserole is recommended for decocting, followed by stainless-steel pots or ceramic pots. Iron, aluminium or copper pots shall not be used.

— Decoction pieces shall be soaked for 20 min to 30 min before decoction. Adjust the soaking time according to local temperature, humidity and the texture of the decoction pieces.

— The amount of water can be 2 cm to 3 cm higher than the decoction pieces in the pot.

— Generally, first use a high heat to decoct, then use a low heat to maintain the state of boiling.

— Special decoction pieces or decoction pieces for the elderly and children shall be decocted according to doctors' instructions.