TECHNICAL SPECIFICATION

ISO/TS 16791

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Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers

Informatique de santé — Exigences pour une identification internationale, lisible par capture automatique, des produits médicinaux

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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 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 215, *Health informatics*.

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Introduction

Globally, healthcare regulators, medicinal product suppliers, and healthcare providers, among others, are facing increased pressure to ensure a more secure and safer supply chain for medicinal products. The primary objective is to ensure optimal patient safety outcomes. International organizations such as the World Health Organization (WHO) and the Council of Europe, along with many other healthcare organizations are also seeking robust systems that will deliver outcomes to enhance overall supply chain integrity, to prevent product falsification and to improve patient safety, especially at the point of care.

Machine readable coding is a technology capable of achieving these stated outcomes. Therefore, the core purpose of this Technical Specification is to provide guidance for machine-readable coding based on globally harmonized and interoperable standards for wide scale international implementation.

This Technical Specification outlines the requirements to implement international machine-readable coding on medicinal product packages in the healthcare supply chain. It assists all stakeholders implement, use, and optimize Automatic Identification and Data Capture Identification (AIDC) technologies in their respective enterprises with a particular attention to Health Informatics. In that respect, it complements ISO 11615.

As AIDC offers a wide spectrum of potential solutions, particularly for data carriers such as barcodes, it has highlighted the importance of properly defining data structures to prevent ambiguity when information is encoded and captured.

Furthermore, the semantics of data carried can be defined by a number of organizations (also called "issuing agencies"), some with commercial activities, some with a national emphasis, and others with a standard development organizations' objective. This particular specification focuses on the GS1 System of Standards[1)].

The majority of supplies (such as processed food, office supplies, apparels, medical devices and equipment, medicinal products, etc.) in healthcare around the world use the GS1 System of Standards for AIDC as it is multi-sectorial and a globally implemented system of standards. Interoperability along the supply chain is easier to achieve once a single system of standards is used in any market, including healthcare.

This Technical Specification is intended to guide healthcare packaging designers, regulatory affairs specialists, logistics operators, and others to implement AIDC solutions for healthcare.

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1 Scope

This Technical Specification provides guidance on identification and labelling of medicinal products from the point of manufacture of packaged medicinal product to the point of dispensing the product.

This Technical Specification outlines best practice for AIDC barcoding solutions for applications. Users can, however, consider the coding interoperability requirements for other AIDC technologies e.g. Radio Frequency Identification (RFID).

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 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*

ISO/IEC 15415, *Information technology — Automatic identification and data capture techniques — Bar code symbol print quality test specification — Two-dimensional symbols*

ISO/IEC 15416, *Information technology — Automatic identification and data capture techniques — Bar code print quality test specification — Linear symbols*

ISO 28219, *Packaging — Labelling and direct product marking with linear bar code and two-dimensional symbols*

ISO 22742, *Packaging — Linear bar code and two-dimensional symbols for product packaging*

3 Terms and definitions

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

3.1 Terms

3.1.1
application identifier
AI
GS1[2)] prefix that defines the meaning and purpose of the data element that follows, as defined in ISO/IEC 15418 and GS1 General Specifications

[SOURCE: ISO 19762-1:2008, 01.01.94]

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