TECHNICAL SPECIFICATION

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CEN ISO/TS 16791

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English Version

Health informatics - Requirements for international machine-readable coding of medicinal product package identifiers (ISO/TS 16791:2020)

Informatique de santé - Exigences pour une identification internationale, lisible par capture automatique, des produits médicinaux (ISO/TS 16791:2020)

Medizinische Informatik - Anforderungen für internationale maschinenlesbare Kodierungen von Identifikatoren für Arzneimittelpackungen (ISO/TS 16791:2020)

This Technical Specification (CEN/TS) was approved by CEN on 7 September 2020 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (CEN ISO/TS 16791:2020) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes CEN ISO/TS 16791:2015.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO/TS 16791:2020 has been approved by CEN as CEN ISO/TS 16791:2020 without any modification.

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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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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 215, *Health informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO/TS 16791:2014), which has been technically revised.

The main changes to the previous edition are as follows:

— adjustment of definitions to the latest IDMP standard (ISO 11615), adding definition for aggregation;

— improvement of 5.2.1.4;

— improvement of 5.3 with a clear distinction between product authentication and supply chain integrity;

— improvement of Annex D;

— Addition of Annex E.

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

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. Organizations such as the World Health Organization (WHO), the European Union and the US Congress, 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 document is to provide guidelines for machine-readable coding based on globally harmonized and interoperable standards for wide scale international implementation.

This document outlines the requirements to implement international machine-readable coding on medicinal product packages in the healthcare supply chain; this process cannot be isolated from more general identification practice with medical devices or other categories of products. It assists all stakeholders implement, use, and optimize Automatic Identification and Data Capture (AIDC) technologies in their respective enterprises with a particular attention to Health Informatics. In that respect, this document 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®[1)] System of Standards.

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

NOTE 1 See Reference [39].

NOTE 2 See Reference [40].

1) GS1® is a registered trademark. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO.

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

1 Scope

This document provides guidelines on identification and labelling of medicinal products from the point of manufacture of packaged medicinal product to the point of dispensing the product.

This document 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 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 11615:2017, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*

ISO/TS 19256, *Health informatics — Requirements for medicinal product dictionary systems for health care*

3 Terms, definitions and abbreviated terms

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 http://www.electropedia.org/

3.1 Terms and definitions

3.1.1
aggregation
aggregated packaging
hierarchical, parent-child relationship between a containing object (i.e. parent) and one or more objects (i.e. children) which are contained

Note 1 to entry: When the content of a delivery is not homogeneous, aggregation shall be provided by using a univocal identification of the delivery, such as with a Serial Shipping Container code (SSCC); see Annex C.

3.1.2
application identifier
AI
GS1® 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/IEC 19762:2016, 01.01.82]