PD CEN ISO/TS 16791:2020

BSI Standards Publication

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

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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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)

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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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.

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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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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

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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. 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].

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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]

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3.1.3
automatic identification and data capture
AIDC
methods or technologies for automatically identifying objects, collecting data about them, and entering that data directly into computer systems, eliminating manual entry

Note 1 to entry: The methods or technologies typically considered as part of AIDC include barcodes which can be linear or 2-dimensional symbols and Radio Frequency Identification (RFID) tags/chips.

3.1.4
authentication
comparing the attributes of the object itself to what is known about objects of that origin

Note 1 to entry: Attributes include unique identifier besides overt, covert, and/or forensic solutions.

3.1.5
medicinal product batch identifier 1
BAID1
unique identifier allocated to a specific batch of a medicinal product, which appears on the outer packaging of the medicinal product

Note 1 to entry: It is constructed by using the batch number assigned by the manufacturer and the expiration date. This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of a medicinal product at the package level.

[SOURCE: ISO 11615:2017, 3.1.51]

Note 2 to entry: BAID1 is market specific.

3.1.6
medicinal product batch identifier 2
BAID2
unique identifier allocated to a specific batch of a medicinal product, which appears on the immediate packaging, where this is not the outer packaging

Note 1 to entry: It is constructed by using the batch number assigned by the manufacturer and the expiration date. This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of a medicinal product based at the level of the immediate container.

[SOURCE: ISO 11615:2017, 3.1.52]

Note 2 to entry: 'immediate packaging' corresponds frequently to 'primary packaging'. See Annex B.

3.1.7
batch
lot
specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture

[SOURCE: ISO 11615:2017, 3.1.8 — modified, "lot" was added as a preferred term.]

3.1.8
batch number
lot number
identifier assigned to a specific batch of a medicinal product or item resulting from a manufacturing process at a specific point of time

[SOURCE: ISO 11615:2017, 3.1.9 — modified, "lot number" was added as a preferred term.]

Note 1 to entry: A batch number permits its manufacturing history to be traced.

Note 2 to entry: A batch number is made of series of ASCII characters.

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3.1.9
barcode
optical machine-readable representation of data, showing data about the object to which it attaches

Note 1 to entry: Originally, barcodes represented data by varying the widths and spacings of parallel lines, and can be referred to as linear or one-dimensional (1D). Later they evolved into rectangles, dots, hexagons, and other geometric patterns in two dimensions (2D). Although 2D systems use a variety of symbols, they are generally referred to as barcodes as well.

3.1.10
dispense medication
prepare and give out a medicinal product in accordance with a prescription

Note 1 to entry: This includes assessing the pharmaceutical appropriateness including decision support.

Note 2 to entry: See also ISO/TS 19293:2018.

3.1.11
global trade item number
GTIN®[2)]
number that is used for the unique identification of trade items worldwide

[SOURCE: ISO/IEC 15420:2009, 3.7 — modified, digit length removed.]

EXAMPLE 1 GS1® Identification Key which comprises a GS1® Company Prefix, an Item Reference and Check digit.

EXAMPLE 2 Used to identify trade items such as medicinal products and medical devices.

Note 1 to entry: See Annex A for the relationship between MPID, PCID, and GTIN®.

3.1.12
healthcare system
organization of people, institutions, and resources to deliver healthcare services to meet the health needs of target populations

3.1.13
identification
way information about an object, such as a trade item, can be found in IT systems, such as databases

Note 1 to entry: It refers to a sequence of characters (numerals and/or alpha characters). The identifier is intended to be a unique sequence structured according to a globally agreed architecture or syntax, and can or cannot contain inbuilt significance.

3.1.14
identification schema namespace
container for a set of identifiers that allows the disambiguation of homonym identifiers residing in different identification schema

3.1.15
identifier
ID
description that is sufficient to represent an object in a given environment identification schema

Note 1 to entry: This concept is generic and applies to all identifications mentioned in this document.

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

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3.1.16
machine-readable code
code, readable by a machine, that contains information used to establish a relationship between a physical object such as a medicinal product package and data sources such as medical, production, logistical and/or reimbursement coding systems

3.1.17
manufacturing
manufacture
process of production from the acquisition of all materials through all processing stages, including final packaging

3.1.18
marketing authorization
authorization issued from a medicines regulatory agency that allows a medicinal product to be placed on the market

[SOURCE: ISO 11615:2017, 3.1.40]

3.1.19
marketing authorization holder
organization that holds the authorization for marketing a medicinal product in a region or country

[SOURCE: ISO 11615:2017, 3.1.41— modified, "or country" added.]

3.1.20
medicinal product
pharmaceutical product or combination of pharmaceutical products that may be administered to human beings for treating or preventing disease, with the aim/purpose of making a medical diagnosis or to restore, correct or modify physiological functions

Note 1 to entry: The same definition applies for animal health.

[SOURCE: ISO 11615:2017, 3.1.50, — modified, “(or animals)” removed; notes to entry 1 and 2 removed and a new note 1 to entry added.]

3.1.21
medicinal product identifier
MPID
identifier allocated to a medicinal product supplementary to any existing authorization number as ascribed by a medicines regulatory agency in a region

[SOURCE: ISO 11615:2017, 3.1.53, — modified, “unique” removed; notes to entry removed.]

3.1.22
medicinal product package identifier
PCID
identifier allocated to a packaged medicinal product supplementary to any existing authorization number as ascribed by a medicines regulatory agency in a region

[SOURCE: ISO 11615:2017, 3.1.55, — modified, “unique” removed; note to entry removed.]

Note 1 to entry: See Annex D for relationship between MPID, PCID, and GTIN®.

3.1.23
object identifier
OID
globally unique value associated with an object to unambiguously identify it

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3.1.24
outer packaging
external container in which a medicinal product is supplied

[SOURCE: ISO 11615:2017, 3.1.57 — modified, note to entry removed.]

Note 1 to entry: Corresponds frequently to "secondary packaging" (see Annex B).

3.1.25
packaging hierarchy
relationship between a medicinal product package and its grouping in larger/smaller quantities

Note 1 to entry: See Annex B for illustration of "primary packaging", "secondary packaging", etc.

3.1.26
packaged medicinal product
medicinal product in a container being part of a package, representing the entirety that has been packaged for sale or supply

[SOURCE: ISO 11615:2017, 3.1.59]

Note 1 to entry: Corresponds frequently to "primary packaging" (see Annex B).

3.1.27
pharmaceutical product
qualitative and quantitative composition of a medicinal product in the dose form approved for administration in line with the regulated product information

[SOURCE: ISO 11615:2017, 3.1.60]

3.1.28
pharmaceutical product identifier
PhPID
identifier for a pharmaceutical product

[SOURCE: ISO 11615:2017, 3.1.61 — modified, "unique" removed.]

3.1.29
pharmacovigilance
science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem

[SOURCE: WHO, Reporting and learning systems for medication errors: the role of pharmacovigilance centres, 2014, Annex 1]

3.1.30
radio frequency identification
RFID
wireless non-contact system that uses radio-frequency electromagnetic fields to transfer data from a tag attached to an object, for the purposes of automatic identification and tracking

3.1.31
serialization
assigning a unique identifier (e.g. a number) to an item (e.g. pack, case or pallet)

Note 1 to entry: This identifier is stored on a database along with other information about the item (e.g. manufacturer, batch info, etc). Serialization typically includes randomly selected, encrypted, numerical or alpha-numeric serial number.

Note 2 to entry: According to Reference [51], 'unique identifier' is the safety feature which enables the verification of the authenticity and the identification of an individual pack of a medicinal product.

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3.1.32
traceability
ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application, or location of that which is under consideration

[SOURCE: Global Traceability Standard for Healthcare, GS1, 2013, 5.2]

3.1.33
univocal coding
unique identifier
identification that is unique to a specific instance and cannot be confused with another identification

3.1.34
verification
reading unique identifier numbers and checking these in a database

3.2 Abbreviated terms

IHE Integrating the Healthcare Enterprise

INN International Non-proprietary Name

NDC National Drug Code (from US FDA)

OCR Optical Character Recognition

4 Procedural background

4.1 General

Clause 4 specifies the distinctions between identification and data carriers (machine-readable coding and its international characters). It then focuses on medicinal product and the characteristics of their physical packaging in the marketplace.

Supply chain, traceability, and patient safety require appropriate labelling and the use of packaging identifiers (as described in ISO 11615). Since new processes are in development in many countries to fight against falsification, reimbursement fraud, etc., 4.7 addresses serialization, namely the unit (or instance) identification.

4.2 Identification

In this document, "identification" refers to a sequence of characters (numerals and/or alpha characters). This identifier shall be a unique sequence structured according to a globally agreed architecture or syntax and may or may not contain inbuilt significance.

EXAMPLE 1 The identifier for one pre-filled syringe of XYZ medication is: 7665431234887. The identifier for one telephone-service subscription is: 022 592 74 25.

Uniqueness of the identifier (also referred to as 'univocal coding') is the key to ensuring unambiguous identification. It is important to note that the same sequence of characters can identify different items or objects belonging to different domains (or contexts), but each unique object within a single domain (or context) shall also have an unambiguous identifier. Uniqueness is also governed by the selected identification schema (or namespace) and the domains (contexts) in which the schema applies. The identification schema rules are therefore paramount.

EXAMPLE 2 7665431234887 uniquely identifies the class pre-filled syringe of XYZ medication in the domain "GS1". 022 592 74 25 uniquely identifies a web conference access point in the domain "telephone-service subscription numbers, Switzerland".

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