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Health informatics - Requirements for international machine-readable coding of medicinal product package identifiers (ISO 16791:2026)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 05/26

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EN ISO 16791

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English Version

Health informatics - Requirements for international machine-readable coding of medicinal product package identifiers (ISO 16791:2026)

Informatique de santé - Exigences relatives au codage international lisible par machine des identifiants d'emballages de médicaments (ISO 16791:2026)

Medizinische Informatik - Anforderungen für internationale maschinenlesbare Kodierungen von Identifikatoren für Arzneimittelpackungen (ISO 16791:2026)

This European Standard was approved by CEN on 27 March 2026.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 16791:2026) 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.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2026, and conflicting national standards shall be withdrawn at the latest by October 2026.

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.

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Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: 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, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 16791:2026 has been approved by CEN as EN ISO 16791:2026 without any modification.

International Standard

ISO 16791

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

Informatique de santé — Exigences relatives au codage international lisible par machine des identifiants d'emballages de médicaments

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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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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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 third edition cancels and replaces the second edition (ISO/TS 16791:2020), which has been technically revised.

The main changes are as follows:

— addition of a definition on electronic product information;

— adjustment of 5.5.1 to reference ePL;

— addition of Annex F.

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 requirements for machine-readable coding based on globally harmonized and interoperable standards for wide scale international implementation, such as GS1 System or UDI for medical devices.

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; for example, it provides requirements regarding medicinal product package identifiers (PCID) and their relation with data carrier identifiers (DCID).

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 specified 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 document 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) 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 [34].

NOTE 2 See Reference [35].

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.

International Standard **ISO 16791:2026(en)**

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

1 Scope

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

This document outlines commonly accepted international practices for automatic identification and data capture (AIDC) barcoding solutions for applications and applies to manufacturers, distributors, healthcare facilities and all parties involved in labelling and distribution of packaged medicinal products. These users can, however, consider the coding interoperability requirements for other AIDC technologies, e.g. radio frequency identification (RFID); that technology is not addressed in this document except as for information.

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, *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*