SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 20451:2026

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Nadomešča:
SIST-TS CEN ISO/TS 20451:2018

Zdravstvena informatika - Identifikacija medicinskih izdelkov - Uporaba ISO 11616 podatkovnih elementov in struktur za enotno identifikacijo in izmenjavo predpisanih informacij o farmacevtskih izdelkih (ISO/TS 20451:2026)

Health informatics - Identification of medicinal products - Implementation for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (ISO/TS 20451:2026)

Medizinische Informatik - Identifikation von Arzneimitteln - Implementierungsleitfaden für ISO 11616 Datenelemente und Strukturen zur eindeutigen Identifikation und zum Austausch von vorgeschriebenen pharmazeutischen Produktkennzeichen (ISO/TS 20451:2026)

Informatique de santé - Identification des médicaments - Implémentation des éléments de données et structures ISO 11616 pour l'identification unique et l'échange d'informations réglementées sur les produits pharmaceutiques (ISO/TS 20451:2026)

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35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

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ICS 35.240.80

Supersedes CEN ISO/TS 20451:2018

English Version

Health informatics - Identification of medicinal products - Implementation for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (ISO/TS 20451:2026)

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Ref. No. CEN ISO/TS 20451:2026 E

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European foreword

This document (CEN ISO/TS 20451:2026) 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.

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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Endorsement notice

The text of ISO/TS 20451:2026 has been approved by CEN as CEN ISO/TS 20451:2026 without any modification.

Technical Specification

ISO/TS 20451

Health informatics — Identification of medicinal products — Implementation for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

Informatique de santé — Identification des médicaments — Implémentation des éléments de données et structures ISO 11616 pour l'identification unique et l'échange d'informations réglementées sur les produits pharmaceutiques

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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 20451:2017 [1]), which has been technically revised.

The main changes are as follows:

— alignment with the changes done in the first revision of ISO 11616 [2];

— addition of the concept for global PhPID (gPhPID).

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

This document provides guidelines and requirements for implementing ISO 11616 [2], one of the five ISO standards on the identification of medicinal products (IDMP)[1]. The five ISO standards on IDMP and the corresponding four ISO Technical Specifications, when used together, provide the basis for exchanging data elements that will support the unique and unambiguous identification of medicinal products. The primary purpose of this document is to provide technical guidance to software implementers; short descriptions of business rationale are also included, where relevant, to provide context. Thus, this document focuses on business and technical considerations for implementation that will construct and parse well-formed, transmittable IDMP messages. Following transmission of required data elements, unique identifiers are to be produced in conformance with the standards to support applications where it is necessary to reliably identify and trace regulated biopharmaceutical products. However, this document does not include extensive information on creation or maintenance of identifier repositories. Reference is made to either regional guidance or implementation guides to support practical implementation within either a region or a jurisdiction. ISO/TR 14872 [7] describes the general core principles and proposed service delivery model for supporting implementation and ongoing maintenance of IDMP terminologies.

1) ISO 11615 [3], ISO 11616 [2], ISO 11238 [4], ISO 11239 [5], ISO 11240 [6].

Health informatics — Identification of medicinal products — Implementation for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

1 Scope

This document provides requirements and recommendations related to the concepts required to associate pharmaceutical products or groups of pharmaceutical products with an appropriate set of PhPID(s) in accordance with ISO 11616 [2].

Pharmaceutical product identifiers and the related elements are intended to represent pharmaceutical products as defined within a medicinal product by a medicines regulatory authority. While the ISO standards on IDMP can be applied to off-label usage of medicinal products, such applications are currently outside of the scope of this document.

Reference to ISO 11238 [4], ISO 11239 [5], ISO 11240 [6], ISO 11615 [3], HL7 V3 messaging standards (HL7 Reference Information Model (RIM)[8], HL7 Common Product Model (CPM)[9] and HL7 V3 Structured Product Labelling (SPL)[10], and HL7 FHIR[11] can be applied for pharmaceutical product information in the context of this document.

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 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*

ISO 11239, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*

ISO 11240, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement*

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

ISO 11616, *Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated pharmaceutical product information*

ISO/TS 19844, *Health informatics — Identification of medicinal products (IDMP) — Implementation guidelines for ISO 11238 for data elements and structures for the unique identification and exchange of regulated information on substances*

ISO/TS 20440, *Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11239 data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*

ISO/TS 20443, *Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information*

ISO 21090, *Health informatics — Harmonized data types for information interchange*

3 Terms and definitions

No terms and definitions are listed in this document.

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/

4 Conformance

— Mandatory: Defining elements necessary for the unique identification of Medicinal Products per the ISO IDMP standards and technical specifications.

— Conditional: Applies to the "within category" data elements, as applicable, when there are alternative data sources for a given data element(s) to identify medicinal and pharmaceutical products. Regional implementation of the ISO IDMP standards and technical specifications may elevate the conditional conformance categories to "mandatory" per regional requirements.

— Optional: When listed at the category level (e.g. specified substance), optional corresponds to ISO categories or data elements that are not absolutely necessary for the unique identification of medicinal or pharmaceutical products according to the ISO IDMP standards and technical specifications. Regional implementation of the ISO IDMP standards and technical specifications may elevate the optional conformance categories to "mandatory" or "conditional" per regional requirements.

5 Concepts required for the unique identification of pharmaceutical products

5.1 General considerations for elements required for the unique identification of pharmaceutical products

Clause 5, along with Annex A and Annex B, describes the elements and messaging required to uniquely identify and characterize a pharmaceutical product. It provides the requirements to support pharmaceutical product identification. Examples are given in Annex C.

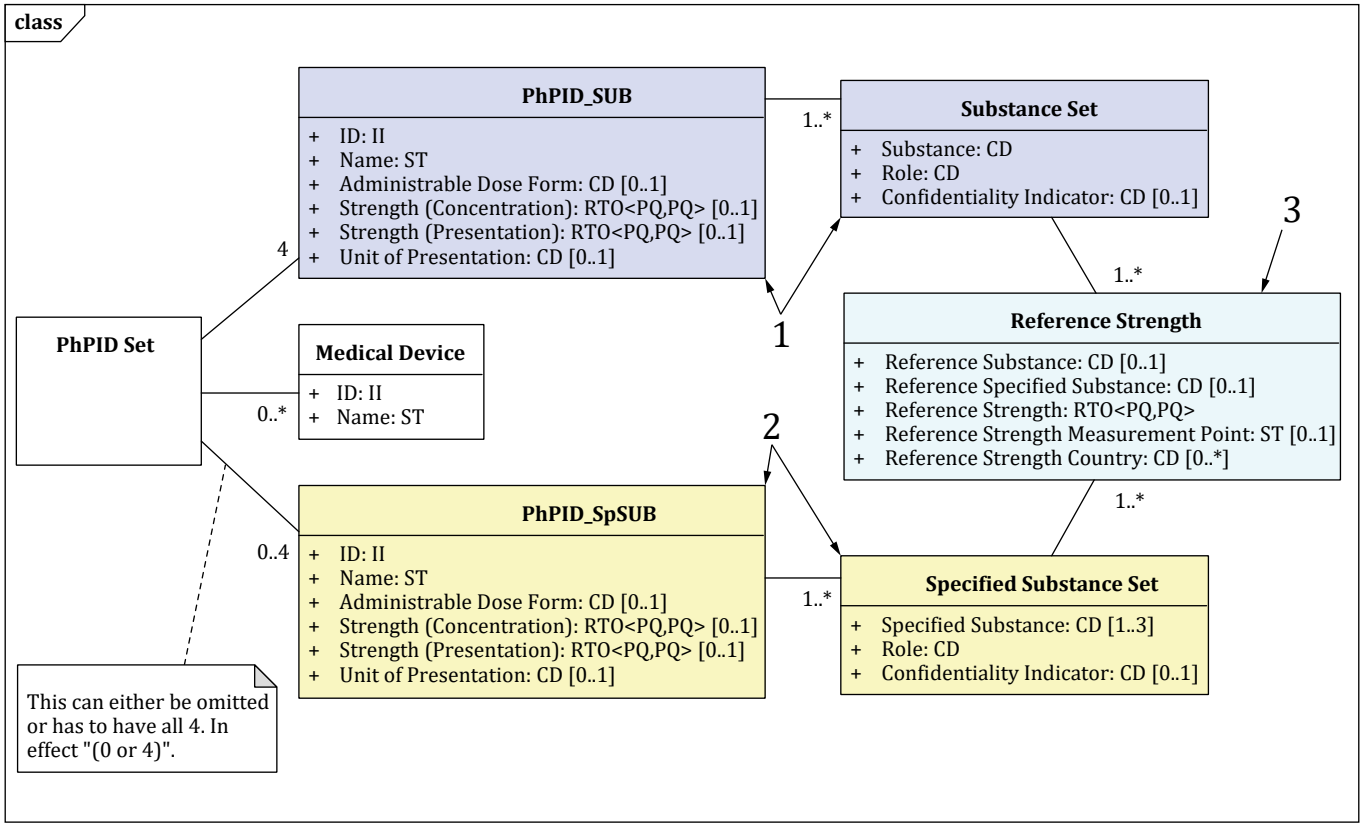
The information modelling in this document uses the Unified Modelling Language (UML)[2], which is maintained by OMG (Object Management Group)[3].

Figure 1 shows the pharmaceutical product identification (PhPID) detailed model.

Pharmaceutical product identification (PhPID) shall be based on the following subset of elements that describe the pharmaceutical product.

2) https://www.uml.org/

3) https://www.omg.org/about/omg-standards-introduction.htm



Key

1 substance stratum
2 specified substance stratum
3 strengths

Figure 1 — Pharmaceutical product identification (PhPID) detailed model

a) active substance(s) or specified substance(s);

NOTE The substance(s) within the ingredient role “active” and “adjuvant” are utilised to define PhPID.

b) strength(s), strength units (units of measurement or unit of presentation, or both);

c) reference strength(s) includes reference substance(s) (i.e. active moiety and its corresponding strength);

d) administrable dose form;

e) medical device, when it is a component of a Medicinal Product.

5.2 Principles required for the unique identification of a pharmaceutical product

The following principles for the unique identification of a pharmaceutical product shall apply:

a) a medicinal product may relate to one or more pharmaceutical products as part of a treatment regime [e.g. a kit, which might be a combination pack containing vaginal tablets (500 mg) and an external vaginal cream (10 %)];

b) the characterization of the pharmaceutical product(s) based on the active substance(s) or specified substance(s), the (reference) strength thereof, the administrable dose form(s), and the medical device (e.g. a scaffolding for cell-based products) being part of the Medicinal Product (e.g. drug-device combination);