

SVENSK STANDARD

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**Hälsa- och sjukvårdsinformatik – Identifiering av läkemedel –
Dataelement och strukturer för identifiering och utbyte av
obligatorisk information om läkemedels dosformer,
enhetspresentation, administreringsvägar och förpackningar
(ISO 11239:2012)**

**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 11239:2012)**

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EUROPEAN STANDARD

EN ISO 11239

NORME EUROPÉENNE

EUROPÄISCHE NORM

November 2012

ICS 35.240.80

English Version

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 11239:2012)

Informatique de santé - Identification des médicaments - Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les formes des doses pharmaceutiques, les unités de présentation, les voies d'administration et les emballages (ISO 11239:2012)

Medizinische Informatik - Identifikation von Arzneimitteln - Struktur und kontrollierte Vokabularien zur Identifikation von pharmazeutischen Darreichungsformen, pharmazeutischen Konventionseinheiten, Anwendungsarten und Verpackungen (ISO 11239:2012)

This European Standard was approved by CEN on 24 May 2012.

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COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (EN ISO 11239:2012) 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of an identical text or by endorsement, at the latest by May 2013, and conflicting national standards shall be withdrawn at the latest by May 2013.

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SS-EN ISO 11239:2012 (E)

Introduction

This International Standard was developed in response to a worldwide demand for internationally harmonized specifications for medicinal products. It is one of a group of five standards which together provide the basis for the unique identification of medicinal products. The group of standards comprises:

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 the unique identification and exchange of regulated pharmaceutical product information;*

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.*

These standards for the identification of medicinal products (IDMP) support the activities of medicines regulatory agencies worldwide by jurisdiction. These include a variety of regulatory activities related to development, registration and life cycle management of medicinal products, as well as pharmacovigilance and risk management.

To meet the primary objectives of the regulation of medicines and pharmacovigilance it is necessary to exchange medicinal product information in a robust and reliable manner. The IDMP standards therefore support the following interactions (this is not an exhaustive list):

- regulator to regulator;
- pharmaceutical company to regulator;
- sponsor of clinical trial to regulator;
- regulator to other stakeholders;
- regulator to worldwide-maintained data sources.

The necessary messaging specifications are included as an integral part of the IDMP standards to secure the interactions above.

Unique identifiers produced in conformance with the IDMP standards are aimed at supporting applications where it is necessary to reliably identify and trace the use of medicinal products.

There are many terms in use to describe basic concepts in the regulatory, pharmaceutical and healthcare standards development domain for different purposes and in different contexts. The terms and definitions described in this International Standard are to be applied for the concepts which are required in order to uniquely identify, characterize and exchange regulated medicinal products and associated information.

The terms and definitions adopted in this International Standard are intended to facilitate the interpretation and application of legal and regulatory requirements but they are without prejudice to any legally binding document. In case of doubt or potential conflict, the terms and definitions contained in legally binding documents prevail.

In the context of identification of pharmaceutical dose forms, units of presentation, routes of administration and packaging, this International Standard describes the essential elements for the specification, translation and versioning of the specified controlled terms. Also described are recommendations concerning the mapping of terms that are already used by stakeholders to the concepts arising from the implementation of this International Standard.

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The high-level concepts defined consist of:

- pharmaceutical dose form;
- unit of presentation;
- route of administration;
- packaging.

The supporting, more mechanical, components are described separately from the high-level clinical concepts. The supporting concepts consist of:

- a) terms and codes;
- b) translations;
- c) versioning;
- d) mapping.

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

1 Scope

This International Standard specifies:

- the data elements, structures and relationships between the data elements required for the exchange of information, which uniquely and with certainty identify pharmaceutical dose forms, units of presentation, routes of administration and packaging items (containers, closures and administration devices) related to medicinal products;
- a mechanism for the association of translations of a single concept into different languages, which is an integral part of the information exchange;
- a mechanism for the versioning of the concepts in order to track their evolution;
- rules to allow regional authorities to map existing regional terms to the terms created using this International Standard, in a harmonized and meaningful way.

In addition, to support the successful application of this International Standard, references to standards concerned with identification of medicinal products (IDMP) and messaging for medicinal product information are provided as required.

2 Normative references

The following referenced documents are indispensable for the application 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 639 (all parts), *Codes for the representation of names of languages*

ISO 3166 (all parts), *Codes for the representation of names of countries and their subdivisions*

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

3 Terms, definitions and abbreviations

3.1 Terms and definitions

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

3.1.1

administrable dose form

pharmaceutical dose form for administration to the patient, after any necessary transformation of the manufactured dose form has been carried out

EXAMPLES Solution for injection, tablet for oral use, hard-capsule powder for inhalation.

NOTE The administrable dose form is identical to the manufactured dose form in cases where no transformation of the manufactured item is necessary (i.e. where the manufactured item is equal to the pharmaceutical product).