



**NSAI**  
Standards

Irish Standard  
I.S. EN 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 (

## I.S. EN ISO 11239:2012

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation - recommendation based on the consensus of an expert panel and subject to public consultation.

SWIFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

*This document replaces:*

*This document is based on:*  
EN ISO 11239:2012

*Published:*  
15 November, 2012

This document was published under the authority of the NSAI and comes into effect on:  
15 November, 2012

**ICS number:**

35.240.80

**NSAI**  
1 Swift Square,  
Northwood, Santry  
Dublin 9

T +353 1 807 3800  
F +353 1 807 3838  
E standards@nsai.ie  
W NSAI.ie

**Sales:**  
T +353 1 857 6730  
F +353 1 857 6729  
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

**Management Centre: Avenue Marnix 17, B-1000 Brussels**

**Contents**

Page

**Foreword.....3**

## **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.

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

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

### **Endorsement notice**

The text of ISO 11239:2012 has been approved by CEN as a EN ISO 11239:2012 without any modification.

*This page is intentionally left BLANK.*

I.S. EN ISO 11239:2012  
**INTERNATIONAL  
STANDARD**

**ISO  
11239**

First edition  
2012-11-01

---

---

**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**

*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*



Reference number  
ISO 11239:2012(E)

© ISO 2012



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2012

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland



# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms, definitions and abbreviations</b> .....	<b>1</b>
<b>3.1 Terms and definitions</b> .....	<b>1</b>
<b>3.2 Abbreviations</b> .....	<b>5</b>
<b>4 Requirements</b> .....	<b>6</b>
<b>4.1 General requirements for controlled vocabularies</b> .....	<b>6</b>
<b>4.2 Requirements for use within the IDMP set of standards</b> .....	<b>7</b>
<b>5 Schema</b> .....	<b>7</b>
<b>5.1 General</b> .....	<b>7</b>
<b>5.2 Conceptual models — Supporting concepts</b> .....	<b>8</b>
<b>5.3 Conceptual models — High-level concepts</b> .....	<b>10</b>
<b>Annex A (informative) Examples of controlled vocabularies</b> .....	<b>17</b>
<b>Annex B (informative) Examples of controlled vocabularies to describe medicinal products</b> .....	<b>23</b>
<b>Bibliography</b> .....	<b>28</b>

## **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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 11239 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

## 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.

**ISO 11239:2012(E)**

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).

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

- 
- [Looking for additional Standards? Visit Intertek Inform Infostore](#)
  - [Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation](#)
-