

**Meditsiiniinformaatika. Ravimite identifitseerimine.
Andmeelemendid ja andmestruktuur ravimi normitud
teabe üheseks identifitseerimiseks ning
andmevahetuseks (ISO 11615:2012)**

**Health informatics - Identification of medicinal products
- Data elements and structures for the unique
identification and exchange of regulated medicinal
product information (ISO 11615:2012)**

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11615:2012 sisaldab Euroopa standardi EN ISO 11615:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11615:2012 consists of the English text of the European standard EN ISO 11615:2012.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 01.11.2012.	Date of Availability of the European standard is 01.11.2012.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 35.240.80

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:
Aru 10, 10317 Tallinn, Eesti; www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:
Aru 10, 10317 Tallinn, Estonia; www.evs.ee; phone 605 5050; e-mail info@evs.ee

ICS 35.240.80

English Version

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated medicinal product information (ISO 11615:2012)

Informatique de santé - Identification des médicaments - Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les médicaments (ISO 11615:2012)

Medizinische Informatik - Identifikation von Arzneimitteln - Datenelemente und -strukturen zur Identifikation von Arzneimitteln für den Austausch von behördlich genehmigten Arzneimittelinformationen (ISO 11615:2012)

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

Foreword

This document (EN ISO 11615:2012) 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 11615:2012 has been approved by CEN as a EN ISO 11615:2012 without any modification.

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms, definitions and abbreviations	1
3.1 Terms and definitions	1
3.2 Abbreviations	12
4 Requirements	14
4.1 Concepts required for the unique Identification of Medicinal Products	14
5 Description of the information modelling principles and practices	17
5.1 General considerations	17
5.2 Conceptual overview diagrams	18
5.3 Section high-level diagrams	19
5.4 Detailed description diagrams	20
6 Identifying characteristics for authorized Medicinal Products	23
6.1 Primary identifiers	23
6.2 Medicinal Product Identifier (MPID)	23
6.3 Packaged Medicinal Product Identifier (PCID)	24
6.4 Medicinal Product Batch Identifier (BAID_1)	25
6.5 Medicinal Product Batch Identifier (BAID_2)	25
7 Information for an authorized Medicinal Product	25
7.1 Authorized Medicinal Product — Information overview	25
7.2 Medicinal Product	27
7.3 Marketing Authorization	32
7.4 Organization	38
7.5 Manufacturer/Establishment	40
7.6 Packaged Medicinal Product, including Manufactured Item and Device	41
7.7 Ingredient, Substance and Strength	50
7.8 Pharmaceutical Product and Device	54
7.9 Clinical Particulars	58
8 Identifying characteristics for Investigational Medicinal Products	66
8.1 General	66
8.2 Primary identifiers	66
8.3 Investigational Medicinal Product Identifier (IMPID)	67
8.4 Investigational Medicinal Product Package Identifier (IPCID)	68
8.5 Investigational Medicinal Product Batch Identifier (IBAID_1)	68
8.6 Investigational Medicinal Product Batch Identifier (IBAID_2)	68
9 Information for an Investigational Medicinal Product	69
9.1 Conceptual overview of the information for an Investigational Medicinal Product	69
9.2 Investigational Medicinal Product	70
9.3 Clinical Trial Authorization	72
9.4 Manufacturer/Establishment	75
9.5 Investigational Packaged Medicinal Product	75
9.6 Pharmaceutical Product	76
9.7 Ingredient	77
9.8 Clinical particulars	77
Annex A (informative) Full model — Authorized Medicinal Products conceptual level	78
Annex B (informative) Full model — Authorized Medicinal Products detailed diagram	79
Annex C (informative) Full model — Investigational Medicinal Products conceptual level	80

Annex D (informative) **Full Model — Investigational Medicinal Products detailed diagram** 81

Annex E (informative) **Worked example in tabular form** 82

Annex F (informative) **Class and attribute listing** 91

Annex G (informative) **Example implementation of Medicinal Product information** 105

Bibliography 113

Introduction

This International Standard was developed in response to a worldwide demand for internationally harmonized specifications for Medicinal Products. It is one 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 reliably exchange Medicinal Product information in a robust and consistent manner. The IDMP standards therefore support, at a minimum, the following interactions:

- regulator to regulator;
- pharmaceutical company to regulator;
- sponsor of clinical trial to regulator;
- regulator to other stakeholder;
- 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 given in this International Standard are to be applied for the concepts which are required 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.

This International Standard has been developed in conjunction with the Common Product Model in HL7. It is anticipated that implementation will use HL7 V3 messaging to transmit information between stakeholders.

In the context of exchange of regulatory information, the purpose of this International Standard is twofold:

- to specify data elements, structures and relationships between the data elements which are required to uniquely and with certainty identify Medicinal Products for human use;
- to specify definitions of terms for all data elements required to uniquely and with certainty identify Medicinal Products for human use.

In addition, reference to the use of other normative IDMP and messaging standards for Medicinal Product information is included in this International Standard in order to support successful related information exchange.

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

1 Scope

This International Standard establishes definitions and concepts and describes data elements and their structural relationships, which are required for the unique identification and the detailed description of Medicinal Products.

Taken together, the standards listed in the introduction define, characterize and uniquely identify regulated Medicinal Products for human use during their entire life cycle, i.e. from development to authorization, post-marketing and renewal or withdrawal from the market, where applicable.

Furthermore, to support successful information exchange in relation to the unique identification and characterization of Medicinal Products, the use of other normative IDMP messaging standards is included, which are to be applied in the context of this International Standard.

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 639-2, *Codes for the representation of names of languages — Part 2: Alpha-3 code*

ISO 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

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*

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

ISO/IEC 5218, *Information technology — Codes for the representation of human sexes*

3 Terms, definitions and abbreviations

3.1 Terms and definitions

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