

# SVENSK STANDARD

## SS-EN ISO 11615:2017



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**Hälsa- och sjukvårdsinformatik – Identifiering av läkemedel –  
Dataelement och strukturer för identifiering och utbyte av  
information på reglerade medicinska produkter (ISO 11615:2017)**

**Health informatics – Identification of medicinal products –  
Data elements and structures for the unique identification and  
exchange of regulated medicinal product information  
(ISO 11615:2017)**

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Denna standard ersätter SS-EN ISO 11615:2012, utgåva 1.

The European Standard EN ISO 11615:2017 has the status of a Swedish Standard. This document contains the official version of EN ISO 11615:2017.

This standard supersedes the Swedish Standard SS-EN ISO 11615:2012, edition 1.

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EUROPEAN STANDARD

EN ISO 11615

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2017

ICS 35.240.80

Supersedes EN ISO 11615:2012

English Version

Health informatics - Identification of medicinal products -  
Data elements and structures for the unique identification  
and exchange of regulated medicinal product information  
(ISO 11615:2017)

Informatique de santé - Identification des médicaments  
- Éléments de données et structures pour  
l'identification unique et l'échange d'informations sur  
les médicaments contrôlés (ISO 11615:2017)

Medizinische Informatik - Identifikation von  
Arzneimitteln - Datenelemente und -strukturen zur  
Identifikation von Arzneimitteln für den Austausch von  
behördlich genehmigten Arzneimittelinformationen  
(ISO 11615:2017)

This European Standard was approved by CEN on 17 November 2017.

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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
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**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

**SS-EN ISO 11615:2017 (E)**

<b>Contents</b>		Page
European foreword .....		vi
Introduction .....		vii
<b>1</b>	<b>Scope</b> .....	<b>1</b>
<b>2</b>	<b>Normative references</b> .....	<b>1</b>
<b>3</b>	<b>Terms, definitions and abbreviated terms</b> .....	<b>2</b>
<b>4</b>	<b>Message exchange format</b> .....	<b>13</b>
<b>5</b>	<b>Conformance terminology and context as it relates to the ISO IDMP standards and corresponding IDMP technical specifications</b> .....	<b>14</b>
<b>6</b>	<b>Concepts required for the unique identification of Medicinal Products</b> .....	<b>14</b>
6.1	General considerations .....	14
6.2	Authorised Medicinal Products .....	14
6.3	Investigational Medicinal Products .....	15
6.4	Concepts required for the unique identification of a Medicinal Product and the association with PhPID(s) .....	15
6.5	Concepts required for the unique identification of Medicinal Products and the association with the marketing authorisation number .....	15
6.6	Concepts required for the unique identification of Medicinal Products and the association with data carrier identifiers .....	16
<b>7</b>	<b>Description of the information modelling principles and practices</b> .....	<b>17</b>
7.1	General considerations .....	17
7.2	Conceptual overview diagrams .....	17
7.3	High-level diagrams .....	18
7.4	Detailed description diagrams .....	18
7.4.1	General .....	18
7.4.2	Relationships between classes .....	19
7.4.3	Attributes of classes .....	20
7.4.4	Generalised classes and patterns .....	20
7.4.5	Translation and language .....	20
<b>8</b>	<b>Identifying characteristics for authorised Medicinal Products</b> .....	<b>20</b>
8.1	Primary identifiers — General considerations .....	20
8.2	Medicinal Product Identifier (MPID) .....	21
8.2.1	General considerations .....	21
8.2.2	MPID code segments .....	21
8.3	Packaged Medicinal Product Identifier (PCID) .....	22
8.3.1	General considerations .....	22
8.3.2	Package description (PCID) code segment .....	23
8.4	Medicinal Product Batch Identifier (BAID1) .....	23
8.5	Medicinal Product Batch Identifier (BAID2) .....	23
<b>9</b>	<b>Information for an authorised Medicinal Product</b> .....	<b>24</b>
9.1	Authorised Medicinal Product — Information overview .....	24
9.1.1	General .....	24
9.1.2	Medicinal Product .....	24
9.1.3	Medicinal Product name .....	24
9.1.4	Header .....	25
9.1.5	Manufacturer/Establishment (organisation) .....	25
9.1.6	Marketing authorisation .....	25
9.1.7	Packaged Medicinal Product .....	25
9.1.8	Pharmaceutical product .....	25
9.1.9	Ingredient .....	25
9.1.10	Clinical particulars .....	25
9.2	Medicinal Product .....	25

9.2.1	General.....	25
9.2.2	Detailed description of Medicinal Product information.....	26
9.3	Marketing authorisation.....	32
9.3.1	General.....	32
9.3.2	Detailed description of marketing authorisation information.....	33
9.4	Organisation.....	38
9.4.1	General.....	38
9.4.2	Detailed description of organisation information.....	38
9.5	Manufacturer/Establishment (organisation).....	41
9.5.1	General.....	41
9.5.2	Detailed description of manufacturer/establishment (organisation) information.....	41
9.6	Packaged Medicinal Product, including manufactured item and device.....	42
9.6.1	General.....	42
9.6.2	Detailed description of Packaged Medicinal Product information.....	43
9.7	Ingredient, substance and strength.....	52
9.7.1	General.....	52
9.7.2	Detailed description of ingredients, substance and strength information.....	52
9.8	Pharmaceutical product and device.....	55
9.8.1	General.....	55
9.8.2	Detailed description of pharmaceutical product and device information.....	55
9.9	Clinical particulars.....	57
9.9.1	General.....	57
9.9.2	Detailed description for clinical particulars information.....	58
<b>10</b>	<b>Identifying characteristics for Investigational Medicinal Products.....</b>	<b>62</b>
10.1	General.....	62
10.2	Primary identifiers.....	62
10.2.1	General considerations.....	62
10.3	Investigational Medicinal Product Identifier (IMPID).....	63
10.3.1	General considerations.....	63
10.3.2	IMPID code segments.....	63
10.4	Investigational Medicinal Product Package Identifier (IPCID).....	64
10.4.1	General provisions.....	64
10.4.2	Package description code segment.....	64
10.5	Investigational Medicinal Product Batch Identifier (BAID1).....	65
10.6	Investigational Medicinal Product Batch Identifier (BAID2).....	65
<b>11</b>	<b>Information for an Investigational Medicinal Product.....</b>	<b>65</b>
11.1	General.....	65
11.2	Conceptual overview of the information for an Investigational Medicinal Product.....	65
11.2.1	General.....	65
11.2.2	Investigational Medicinal Product.....	66
11.2.3	Investigational Medicinal Product name.....	66
11.2.4	Header.....	66
11.2.5	Manufacturer/Establishment (organisation).....	66
11.2.6	Clinical trial authorisation.....	67
11.2.7	Investigational Packaged Medicinal Product.....	67
11.2.8	Pharmaceutical product.....	67
11.2.9	Ingredient.....	67
11.2.10	Clinical particulars.....	67
11.3	Investigational Medicinal Product.....	67
11.3.1	General.....	67
11.3.2	Detailed description of Investigational Medicinal Product information.....	67
11.4	Clinical trial authorisation.....	70
11.4.1	General.....	70
11.4.2	Detailed description of clinical trial authorisation information.....	70
11.5	Manufacturer/Establishment (organisation).....	72
11.6	Investigational Packaged Medicinal Product.....	72

**SS-EN ISO 11615:2017 (E)**

11.7	Pharmaceutical product.....	72
11.7.1	General.....	72
11.7.2	Pharmaceutical product.....	73
11.7.3	Dosing and route of administration.....	73
11.8	Ingredient.....	73
11.9	Clinical particulars.....	74
11.10	PhPID sets.....	74
11.11	Device nomenclature.....	74
11.12	Device batch identifier.....	74
11.13	Physical characteristics.....	74
11.14	Other characteristics.....	74
<b>Annex A (normative) Full model — Authorised Medicinal Products detailed diagram.....</b>		<b>75</b>
<b>Annex B (normative) Full model — Investigational Medicinal Products detailed diagram.....</b>		<b>76</b>
<b>Bibliography.....</b>		<b>77</b>



## **European foreword**

This document (EN ISO 11615:2017) 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 June 2018, and conflicting national standards shall be withdrawn at the latest by June 2018.

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.

This document supersedes EN ISO 11615:2012.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

### **Endorsement notice**

The text of ISO 11615:2017 has been approved by CEN as EN ISO 11615:2017 without any modification.



## Introduction

This document was developed in response to a worldwide demand for internationally harmonised specifications for Medicinal Products. It is part of a set of five ISO Standards and four ISO Technical Specifications which together provide the basis for the unique Identification of Medicinal Products (IDMP).

These sets of standards and technical specifications comprise:

- ISO 11615
- ISO/TS 20443;
- ISO 11616;
- ISO/TS 20451;
- ISO 11238;
- ISO/TS 19844;
- ISO 11239;
- ISO/TS 20440;
- ISO 11240.

These standards and technical specifications for the identification of Medicinal Products (IDMP) support the activities of medicines regulatory agencies worldwide by region. 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:

- regulatory medicines authority to regulatory medicines authority;
- pharmaceutical company to regulatory medicines authority;
- sponsor of a clinical trial to regulatory medicines authority;
- regulatory medicines authority to other stakeholders (as applicable);
- regulatory medicines authority 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 document are to be applied for the concepts which are required to uniquely identify, characterise and exchange regulated Medicinal Products and associated information.

The terms and definitions adopted in this document are intended to facilitate the interpretation and application of legal and regulatory requirements.

This document has been developed in conjunction with the Common Product Model (CPM) and Structured Product Labelling (SPL) in HL7.