SLOVENSKI STANDARD
SIST EN ISO 11238:2018

01-oktober-2018

Nadomešča:
SIST EN ISO 11238:2013

Zdravstvena informatika - Identifikacija medicinskih izdelkov - Elementi in zgradba podatkov za enotno identifikacijo in izmenjavo predpisanih informacij o substancah (ISO 11238:2018)

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on substances (ISO 11238:2018)

Medizinische Informatik - Identifikation von Arzneimitteln - Datenelemente und Strukturen zur eindeutigen Identifikation und zum Austausch von vorgeschriebenen Informationen zu Stoffen (ISO 11238:2018)

Informatique de santé - Identification des médicaments - Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les substances (ISO 11238:2018)

Ta slovenski standard je istoveten z: **EN ISO 11238:2018**

ICS:

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

SIST EN ISO 11238:2018 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11238

August 2018

ICS 35.240.80

Supersedes EN ISO 11238:2012

English Version

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on substances (ISO 11238:2018)

Informatique de santé - Identification des produits médicaux - Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les substances (ISO 11238:2018)

Medizinische Informatik - Identifikation von Arzneimitteln - Datenelemente und Strukturen zur eindeutigen Identifikation und zum Austausch von vorgeschriebenen Informationen zu Stoffen (ISO 11238:2018)

This European Standard was approved by CEN on 24 July 2018.

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

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European foreword

This document (EN ISO 11238:2018) 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 February 2019, and conflicting national standards shall be withdrawn at the latest by February 2019.

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 11238:2018 has been approved by CEN as EN ISO 11238:2018 without any modification.

INTERNATIONAL STANDARD

ISO 11238

Second edition
2018-07

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

Informatique de santé — Identification des produits médicaux — Eléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les substances

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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. www.iso.org/directives

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

This document was prepared by ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition ISO 11238:2012[2], which has been technically revised.

Introduction

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

ISO 11615[3], *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*

ISO 11616[4], *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[5], *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[6], *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement*

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

ISO/TS 20440[7], *Health informatics — Identification of Medicinal Products — Implementation guide 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[8], *Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11615 data elements and structures for the unique identification and exchange of regulated Medicinal Product information*

ISO/TS 20451[9], *Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

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 reliable manner. The IDMP standards therefore support the following interactions:

— between one medicine regulatory agency and another, e.g. European Medicines Agency to the US Food and Drug Administration (FDA), or vice versa; and between the European Medicines Agency and the National Competent Authorities in the EU, vice versa;

— between pharmaceutical companies and medicine regulatory agencies, e.g. "Pharma Company A" to Health Canada;

— between the sponsor of a clinical trial to a medicine regulatory agency, e.g. "University X" to the Austrian Agency for Health and Food Safety (AGES);

— between a medicine regulatory agency and other stakeholders, e.g. UK Medicines and Health Care Products Regulatory Agency (MHRA) to the National Health Service (NHS);

— between medicine regulatory agencies and worldwide-maintained data sources, e.g. the Pharmaceutical and Medical Device Agency (PMDA) and the organization responsible for assigning substance identifiers.

Unique identifiers produced in conformance with the IDMP standards will support applications for which it is necessary to reliably identify and trace the use of medicinal products and the ingredients within medicinal products.

This document provides a structure that enables the assignment and maintenance of unique identifiers for all substances in medicinal products. This document sets out the general rules for defining and distinguishing substances, and provides a high-level model for substances and specified substances to support the organization and capturing of data.

It is anticipated that implementation will use the ISO/TS 19844 and HL7 messaging (see 5.8) to deliver a strong, non-semantic unique identifier for every substance present in a medicinal product. It is anticipated that a single maintenance organization will be responsible for the generation of global identifiers for every substance and that such an organization would retain the defining elements upon which the substance identifier was based. At the specified substance level, a more regional approach may be necessary because of the proprietary nature of much of the information.

The use of the identifier is essential for the description of substances in medicinal products on a global scale. This document does not involve developing nomenclature for substances or specified substances, but common and official substance names in current use can be mapped to each identifier.

Ingredients used in medicinal products range from simple chemicals to gene-modified cells to animal tissues. To unambiguously define these substances is particularly challenging. This document defines substances based on their scientific identity (i.e. what they are) rather than on their use or method of production. Molecular structure or other immutable properties, such as taxonomic, anatomical and/or fractionation information, are used to define substances. This document contains five single substance types and a mixture substance class that are sufficient to define all substances. Although it is certainly possible to define or classify substances in other ways, this document uses a minimalistic structured scientific concept approach focusing on the critical elements necessary to distinguish two substances from one another. There are frequently interactions between substances when they are mixed together, but this document has intentionally not included these supramolecular interactions at the substance level because of the variable nature and strength of such interactions. This document also allows for the capture of multiple terms which refer to a given substance and a variety of reference information that could be used to classify substances or relate one substance to another.

In addition to the substance level, this document also provides elements for the capture of further information on substances that make up the defining characteristics of specified substances, such as grade, manufacturer, manufacturing information and specifications, and also to capture information on substances that are frequently combined together in commerce but are not strictly a medicinal product. At the specified substance level, four groups of elements provide information essential to the tracking and description of substances in medicinal products.

The basic concepts in the regulatory and pharmaceutical standards development domain use a wide variety of terms in various contexts. The information models presented in this document depict elements and the relationship between elements that are necessary to define substances. The terms and definitions described in this document are to be applied for the concepts that are required to uniquely identify, characterize and exchange information on substances in regulated medicinal products.

The terms and definitions adopted in this document 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 this document, "% (V/V)" is used in place of "% volume fraction".

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

CAUTION — This document uses colour. This should be taken into consideration when printing.

1 Scope

This document provides an information model to define and identify substances within medicinal products or substances used for medicinal purposes, including dietary supplements, foods and cosmetics. The information model can be used in the human and veterinary domain since the principles are transferrable. Other standards and external terminological resources are referenced that are applicable to 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/TS 19844:2018, *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*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
adjuvant
component that potentiates the immune response to an antigen and/or modulates it towards the desired immune response

3.2
active marker
constituent or groups of constituents of a (herbal) Substance (fresh), Herbal Drug, Herbal preparation or herbal medicinal product which are of interest for control purposes and are generally accepted to contribute to therapeutic activity

Note 1 to entry: Active markers are not equivalent to analytical or signature markers that serve solely for identification or control purposes.