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Meditsiiniinformaatika. Ravimite identifitseerimine. Andmeelemendid ja andmestruktuur aine normitud teabe üheseks identifitseerimiseks ning infovahetuseks (ISO11238:2012)

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on substances (ISO11238:2012)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11238:2012 sisaldab Euroopa standardi EN ISO 11238:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11238:2012 consists of the English text of the European standard EN ISO 11238:2012.
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.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11238

November 2012

ICS 35.240.80

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English Version

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on substances (ISO 11238:2012)

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 11238:2012)

Medizinische Informatik - Identifikation von Arzneimitteln - Struktur und kontrollierte Vokabularien zur Identifikation und Beschreibung von Substanzen und Inhaltsstoffen (ISO 11238:2012)

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

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

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Foreword

This document (EN ISO 11238:2012) 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.

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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 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;

— 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 Medicines Agency;

— 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.

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

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 materials within medicinal products.

This International Standard provides a structure that enables the assignment and maintenance of unique identifiers for all substances in medicinal products or in packaging materials in which medicinal products are contained. This International Standard sets out the general rules for defining and distinguishing substances, and provides a high-level model that structures substances and specified substances for the organization and capturing of data.

This International Standard has been developed using HL7’s Common Product Model, and detailed modelling of substances and specified substances has been undertaken in that domain. It is anticipated that implementation will use the HL7 substances implementation guide and messaging to deliver a strong, non-semantic unique identifier for every substance present in a medicinal product. It is anticipated that a single organization will be

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responsible for the generation of 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 International Standard 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.

Materials used in medicinal products range from simple chemicals to gene-modified cells to animal tissues. To unambiguously define these substances is particularly challenging. This International Standard 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 International Standard contains five groups of elements that are sufficient to define all substances. Although it is certainly possible to define or classify substances in other ways, this International Standard uses a minimalist 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 International Standard has intentionally not included these supramolecular interactions at the substance level because of the variable nature and strength of such interactions. This International Standard 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 International Standard also provides elements for the capture of further information on substances, such as grade, manufacturer, manufacturing 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 International Standard depict elements and the relationship between elements that are necessary to define substances. The terms and definitions described in this International Standard 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 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.

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

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1 Scope

This International Standard provides an information model to define and identify substances within medicinal products or substances used for medicinal purposes, including dietary supplements, foods and cosmetics. Other standards and external terminological resources are referenced that are applicable to this International Standard.

2 Terms, definitions, symbols and abbreviated terms

2.1 Terms and definitions

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

2.1.1
active marker
constituent, or groups of constituents, of an herbal substance, herbal preparation or herbal medicinal product which are of interest for control purposes and are generally accepted to contribute to therapeutic activity

NOTE Active markers are not equivalent to analytical or signature markers that serve solely for identification or control purposes.

2.1.2
analytical data
set of elements to describe and capture methods and reference material used to determine purity, potency or identity in a specified substance

2.1.3
chemical bond
condition that occurs when forces acting between two atoms or groups of atoms lead to the formation of a stable discrete molecular entity

2.1.4
chemical substance
type of substance that can be described as a stoichiometric or non-stoichiometric single molecular entity and is not a protein or nucleic acid substance

NOTE Chemical substances are generally considered “small” molecules which have associated salts, solvates or ions and may be described using a single definitive or representative structure.

2.1.5
chiral substance
substance whose molecular structure is not superimposable on its mirror image

2.1.6
component
intended constituent of a specified substance

EXAMPLE Dimethicone and silicon dioxide are components of simethicone. Human insulin protamine and zinc are the components in human insulin isophane.

NOTE Components are used to describe the substances and specified substances that form a multi-substance material.

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