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SWEDISH STANDARDS INSTITUTE

Hälso- och sjukvårdsinformatik – Identifiering av läkemedel – Dataelement och strukturer för unik identifiering och utbyte av måttenheter (ISO 11240:2012)

Health informatics – Identification of medicinal products – Data elements and structures for the unique identification and exchange of units of measurement (ISO 11240:2012)

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The European Standard EN ISO 11240:2012 has the status of a Swedish Standard. This document contains the official version of EN ISO 11240:2012.

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Denna standard är framtagen av kommittén för Hälso- och sjukvårdsinformatik, SIS/TK 334.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11240

November 2012

ICS 35.240.80

English Version

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of units of measurement (ISO 11240:2012)

Informatique de santé - Identification des médicaments - Éléments de données et structures pour l'identification unique et l'échange d'informations sur les unités de mesure (ISO 11240:2012)

Medizinische Informatik - Identifikation von Arzneimitteln - Datenelemente, Struktur und kontrolliertes Vokabular für Maßeinheiten (ISO 11240:2012)

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

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Foreword

This document (EN ISO 11240:2012) 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of an identical text or by endorsement, at the latest by May 2013, and conflicting national standards shall be withdrawn at the latest by May 2013.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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Endorsement notice

The text of ISO 11240:2012 has been approved by CEN as a EN ISO 11240:2012 without any modification.

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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 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 (this is not an exhaustive list):

— 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 to support 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.

In the context of measurement terminology, currently there are several alternative approaches possible for expressing units of measurement that can be used in a given instance. For purposes of electronic data exchange, it is therefore necessary to promote and encourage the adoption of a single standardized vocabulary that can be used as an international reference for:

— unit concepts,

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— concept definitions, where applicable, and

— concept identifiers.

This standardized vocabulary also needs to provide standardized structures that describe the mapping from and to the reference vocabulary, taking into consideration the various approaches currently being applied. This helps to ensure that terms and identifiers currently used to represent units of measurement in the drug regulatory, pharmacovigilance and healthcare environments are mapped in a standardized and traceable way to the underlying metrological concepts, especially to the SI system of units. This will help ease implementation of this International Standard without impacting on the unit terms currently in use.

The purpose of this International Standard is twofold:

a) to address the issues outlined above by connecting to existing unit vocabularies in current use;

b) to facilitate electronic information exchange and interoperability that enables the unique and categorical identification of a medicinal product.

Results of measurements are essential for the identification of medicinal products. However, often different ways are used to express these results. The situation is further complicated by differences in the ways they are expressed in national legislation and in local administration. From the many available conventions, a consensus should therefore be reached on how to express the results of measurements on medicinal products, particularly for exchange between information systems. Standardized structures are required in order to capture and exchange the terms representing the coded concepts for purposes of displaying and printing the concept representations in various languages suitable for human readability.

Universal principles for the expression of measurements have been specified in the ISO 31, ISO 1000 and ISO 80000 series of standards, which implement the International System of Units (SI) defined by the General Conference on Weights and Measures. The implications of those standards are summarized in 4.2.

Implementation of this International Standard will provide wider comprehension and interaction between countries and specialists in the field of medicinal product identification and pharmacovigilance.

While the immediate scope is medicinal product identification, this International Standard was designed with a rather general view on units of measurement. Therefore, it is also potentially applicable in other contexts.

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Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of units of measurement

1 Scope

This International Standard:

— specifies rules for the usage and coded representation of units of measurement for the purpose of exchanging information about quantitative medicinal product characteristics that require units of measurement (e.g. strength) in the human medicine domain;

— establishes requirements for units in order to provide traceability to international metrological standards;

— provides rules for the standardized and machine-readable documentation of quantitative composition and strength of medicinal products, specifically in the context of medicinal product identification;

— defines the requirements for the representation of units of measurement in coded form;

— provides structures and rules for mapping between different unit vocabularies and language translations to support the implementation of this International Standard, taking into account that existing systems, dictionaries and repositories use a variety of terms and codes for the representation of units.

The scope of this International Standard is limited to the representation of units of measurement for data interchange between computer applications.

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

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

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