SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 19844:2016

01-april-2016

Zdravstvena informatika - Identifikacija medicinskih izdelkov - Vodilo za uporabo podatkovnih elementov in struktur za enotno identifikacijo in izmenjavo predpisanih informacij o substancah (ISO/TS 19844:2015)

Health informatics - Identification of medicinal products - Implementation guide for data elements and structures for the unique identification and exchange of regulated information on substances (ISO/TS 19844:2015)

Medizinische Informatik - Identifikation von Arzneimitteln - Anwendungsleitfaden für die Struktur und kontrollierten Vokabularien zur Identifikation und Beschreibung von Substanzen und Inhaltsstoffen (ISO/TS 19844:2015)

Informatique de santé - Identification des médicaments - Guide pour la mise en oeuvre des éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les substances (ISO/TS 19844:2015)

Ta slovenski standard je istoveten z: **CEN ISO/TS 19844:2015**

ICS:

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

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TECHNICAL SPECIFICATION

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CEN ISO/TS 19844

December 2015

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English Version

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 19844:2015)

Informatique de santé - Identification des médicaments - Lignes directrices pour la mise en oeuvre des éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les substances (ISO/TS 19844:2015)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

This document (CEN ISO/TS 19844:2015) 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.

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Endorsement notice

The text of ISO/TS 19844:2015 has been approved by CEN as CEN ISO/TS 19844:2015 without any modification.

TECHNICAL SPECIFICATION

ISO/TS 19844

First edition
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Health informatics — Identification of medicinal products — Implementation guidelines for data elements and structures for the unique identification and exchange of regulated information on substances

Informatique de santé — Identification des médicaments — Lignes directrices pour la mise en œuvre des éléments 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 (see www.iso.org/directives).

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For an explanation on 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

The committee responsible for this document is ISO/TC 215, *Health informatics*.

Introduction

This Technical Specification is a guide for implementing ISO 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*. This Technical Specification was developed in response to a worldwide demand for guidance on the implementation of internationally harmonised specifications for medicinal products. It is one of a group of four implementation guides for a total of five ISO standards which together provide the basis for the unique identification of medicinal products. The other standards in this group are:

- 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 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*

The 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.

The business objective of this implementation guide is to provide a means for exchanging regulatory substance information. To meet the primary objectives of the regulation of medicines and pharmacovigilance, it is necessary to exchange medicinal product information in a robust and reliable manner.

For the purposes of this Technical Specification, all conditions (e.g. mandatory, conditional, optional) correspond to the necessary requirements to uniquely and unambiguously identify a substance. Implementation of the ISO IDMP standards may dictate that mandatory elements for identification be tagged as conditional or optional, based on regional requirements. If a section is identified as 'optional' but is implemented in a specific region, conformance described within that section is applicable. The scope of this Technical Specification is to identify the scientifically necessary elements for the unique identification of substances/specified substances.