ICS 35.240.80 PREDBEŽNÁ SLOVENSKÁ TECHNICKÁ NORMA Marec 2018

STN P	**Zdravotnícka informatika Identifikácia liekov Implementácia návodu na dátové prvky a štruktúry na jednoznačnú identifikáciu a výmenu regulovaných informácií o látkach (ISO/TS 19844: 2016)**	**STN P CEN ISO/TS 19844** 84 8125

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 19844:2016)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 02/18

Táto predbežná STN je určená na overenie. Pripomienky zasielajte ÚNMS SR najneskôr do júla 2019.

Obsahuje: CEN ISO/TS 19844:2017, ISO/TS 19844:2016

Oznámením tejto normy sa ruší
STN P CEN ISO/TS 19844 (84 8125) z apríla 2016

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TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN ISO/TS 19844

August 2017

ICS 35.240.80

Supersedes CEN ISO/TS 19844:2015

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 19844:2016)

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 19844:2016)

Medizinische Informatik - Identifikation von Arzneimitteln - Implementierungsleitfaden für Datenelemente und Strukturen zur eindeutigen Identifikation und zum Austausch von vorgeschriebenen Informationen von Substanzen (ISO/TS 19844:2016)

This Technical Specification (CEN/TS) was approved by CEN on 26 July 2017 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

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

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European foreword

The text of ISO/TS 19844:2016 has been prepared by Technical Committee ISO/TC 215 “Health informatics” of the International Organization for Standardization (ISO) and has been taken over as CEN ISO/TS 19844:2017 by Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

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 CEN ISO/TS 19844:2015.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: 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/TS 19844:2016 has been approved by CEN as CEN ISO/TS 19844:2017 without any modification.

STN P CEN ISO/TS 19844: 2018

TECHNICAL SPECIFICATION

ISO/TS 19844

Second edition
2016-12-15

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 oeuvre 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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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 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*.

This second edition cancels and replaces the first edition (ISO/TS 19844:2015), which has been technically revised.

Introduction

This document provides guidelines for implementing ISO 11238. This document is 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 document, 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 subclause is identified as ‘optional’ but is implemented in a specific region, conformance described within that subclause is applicable. The scope of this document is to identify the scientifically necessary elements for the unique identification of Substances/Specified Substances.

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

1 Scope

This document is used in the implementation of ISO 11238. This document defines substances based on their scientific identity (i.e. what they are) rather than on their use or method of production.

ISO 11238 provides the conceptual framework for defining Substances and Specified Substances and for assigning unique identifiers in the context of the ISO IDMP standards. ISO 11238 describes general concepts for defining and distinguishing substances and a high level model for the structuring of information for substances. This document provides detailed explanations of each type or grouping of substance information, an element-by-element description for implementation of ISO 11238, and examples for a variety of Substances and Specified Substances.

This second edition of the document addresses substances, Groups 1 to 3 of the Specified Substances as defined in ISO 11238 and Annexes A, B, C, D, E, F, G and H. It is anticipated that Specified Substances Group 4, as defined in ISO 11238, will be addressed in a subsequent edition of this document. Some information that would typically fall under Specified Substances Group 4 may be covered in the Annexes of this document. This information, although not defining of either a Substance or a Specified Substance Group 1, may be essential to distinguishing substances. This document addresses the following:

- Data elements necessary for defining Substances and Specified Substances Groups 1 to 3;
- The logical use of data elements as defined in ISO 11238;
- Substances and Specified Substances Groups 1 to 3 business rules for
    - determining necessary data elements,
    - distinguishing and defining materials according to ISO 11238,
    - triggering the assignment of identifiers.

This document does not address the following:

- Business processes for data management;
- Implementation of a specific data information system (e.g. a relational database schema);
- Normative messaging standards for substances;
- The maintenance of controlled vocabularies;
- The specific global identifier system that should be used;
- Nomenclature standards for substances.

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 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*