

<b>STN</b>	<b>Zdravotnícka informatika. Identifikácia liekov. Návod na implementáciu dátových prvkov a štruktúry na jednoznačnú identifikáciu a výmenu regulovaných informácií o farmaceutických dávkových formách, jednotkách prezentácie, spôsobe podania a balenia zavedených v ISO 11239 (ISO/TS 20440: 2016).</b>	<b>STN P CEN ISO/TS 20440</b>  84 8127
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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 20440:2016)

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. 11/16

Táto predbežná STN je určená na overenie. Pripomienky zasielajte ÚNMS SR najneskôr do 01. 06. 2018.

Obsahuje: CEN ISO/TS 20440:2016, ISO/TS 20440:2016

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Úrad pre normalizáciu, metrológiu a skúšobníctvo SR, 2016  
Podľa zákona č. 264/1999 Z. z. v znení neskorších predpisov sa môžu slovenské technické normy rozmnožovať a rozširovať iba so súhlasom Úradu pre normalizáciu, metrológiu a skúšobníctvo SR.

ICS 35.240.80

English Version

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 20440:2016)

Informatique de santé - Identification des produits  
médicaux - Guide de mise en oeuvre des éléments de  
données et structures pour l'identification unique et  
l'échange d'informations réglementées sur les formes  
des doses pharmaceutiques, les unités de présentation,  
les voies d'administration et les emballages de l'ISO  
11239 (ISO/TS 20440:2016)

Medizinische Informatik - Identifikation von  
Arzneimitteln - Implementierungsleitfaden für ISO  
11239 Datenelemente und Strukturen zur eindeutigen  
Identifikation und zum Austausch von  
vorgeschriebenen Informationen über  
pharmazeutische Darreichungsformen,  
pharmazeutische Konventionseinheiten,  
Anwendungsarten und Verpackungen (ISO/TS  
20440:2016)

This Technical Specification (CEN/TS) was approved by CEN on 29 May 2016 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.

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

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

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## European foreword

This document (CEN ISO/TS 20440:2016) 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 20440:2016 has been approved by CEN as CEN ISO/TS 20440:2016 without any modification.

First edition  
2016-06-01

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**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**

*Informatique de santé — Identification des produits médicaux —  
Guide de mise en oeuvre des éléments de données et structures pour  
l'identification unique et l'échange d'informations réglementées sur  
les formes des doses pharmaceutiques, les unités de présentation, les  
voies d'administration et les emballages de l'ISO 11239*



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ISO copyright office  
Ch. de Blandonnet 8 • CP 401  
CH-1214 Vernier, Geneva, Switzerland  
Tel. +41 22 749 01 11  
Fax +41 22 749 09 47  
copyright@iso.org  
www.iso.org

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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](http://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 (see [www.iso.org/patents](http://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 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**

The terminologies described in EN/ISO 11239:2012 (hereafter referred to as ISO 11239) and in this Technical Specification are essential for the implementation of the IDMP standards as a whole.

Each region traditionally uses its own sets of terminologies to describe the concepts covered in ISO 11239 within their regions; these terminologies are not harmonised with those of the other regions. Therefore, harmonised controlled terminologies need to be provided to ensure that all regions can refer to a given concept in the same manner. The purpose of this Technical Specification is to describe how these controlled vocabularies are constructed and illustrate their use for ISO 11239 implementation.

# 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

## 1 Scope

This Technical Specification describes 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.

Based on the principles outlined in this Technical Specification, harmonised controlled terminologies will be developed according to an agreed maintenance process, allowing users to consult the terminologies and locate the appropriate terms for the concepts that they wish to describe. Provisions to allow for the mapping of existing regional terminologies to the harmonised controlled terminologies will also be developed in order to facilitate the identification of the appropriate terms. The codes provided for the terms can then be used in the relevant fields in the PhPID, PCID and MPID in order to identify those concepts.

This Technical Specification is intended for use by:

- any organisation that might be responsible for developing and maintaining such controlled vocabularies;
- any regional authorities or software vendors who wish to use the controlled vocabularies in their own systems and need to understand how they are created;
- owners of databases who wish to map their own terms to a central list of controlled vocabularies;
- other users who wish to understand the hierarchy of the controlled vocabularies in order to help identify the most appropriate term to describe a particular concept.

The terminology to be applied in the context of this Technical Specification and set out in ISO 11239 is under development. All codes, terms and definitions used as examples in this Technical Specification are provided for illustration purposes only, and are not intended to represent the final terminology.

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**