

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

## 125992

Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2018  
Podľa zákona č. 264/1999 Z. z. o technických požiadavkách na výrobky a o posudzovaní zhody a o zmene a doplnení niektorých zákonov v znení neskorších predpisov sa slovenská technická norma a časti slovenskej technickej normy môžu rozmnožovať alebo rozširovať len so súhlasom slovenského národného normalizačného orgánu.

TECHNICAL SPECIFICATION

**CEN ISO/TS 19844**

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

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.

CEN members are the national standards bodies of 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 United Kingdom.



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

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

<b>Contents</b>	<b>Page</b>
<b>European foreword.....</b>	<b>3</b>

## 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.

---

---

**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*





**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2016, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

## Contents

<b>1</b>	<b>Scope .....</b>	<b>1</b>
<b>2</b>	<b>Normative references .....</b>	<b>2</b>
<b>3</b>	<b>General background and history .....</b>	<b>2</b>
<b>4</b>	<b>Substance (Mandatory) .....</b>	<b>3</b>
4.1	General .....	3
4.2	Defining substances .....	5
4.2.1	Substance type (Mandatory) .....	7
4.2.2	Substance ID (Mandatory) .....	10
4.3	Substance names (Mandatory) .....	11
4.3.1	Substance name .....	12
4.3.2	Substance name type .....	13
4.3.3	Language .....	14
4.3.4	Official name (Conditional) .....	14
4.4	Reference source (Conditional) .....	17
4.4.1	Public domain .....	17
4.4.2	Reference source type .....	18
4.4.3	Reference source class .....	18
4.4.4	Reference source ID .....	19
4.4.5	Reference source citation .....	19
4.5	Reference source document (Conditional) .....	19
4.5.1	Public domain .....	19
4.5.2	Reference source document .....	20
4.5.3	Reference source document type .....	20
4.5.4	Reference source document ID .....	21
4.5.5	Reference source document classification .....	21
4.5.6	Reference source document URL .....	21
4.6	Substance code (Conditional) .....	21
4.6.1	Code .....	22
4.6.2	Code system .....	22
4.6.3	Code system ID .....	23
4.6.4	Code system status .....	23
4.6.5	Code change date .....	24
4.6.6	Comment .....	24
4.6.7	Reference source .....	24
4.7	Reference information (Conditional) .....	24
4.7.1	Comment .....	25
4.7.2	Substance classification (Conditional) .....	25
4.7.3	Substance relationship (Conditional) .....	28
4.7.4	Target (Conditional) .....	30
4.7.5	Gene (Conditional) .....	33
4.7.6	Gene element (Conditional) .....	35
4.8	Structure .....	36
4.8.1	Structural Representation (Conditional) .....	36
4.8.2	Stereochemistry .....	42
4.8.3	Optical activity .....	43

4.8.4	Molecular Formula .....	44
4.8.5	Molecular Formula by Moiety .....	44
4.8.6	Molecular weight (Mandatory) .....	44
4.8.7	Isotope (Conditional).....	44
4.9	Amount (Conditional).....	46
4.9.1	Average .....	46
4.9.2	Low limit.....	47
4.9.3	High limit.....	47
4.9.4	Unit.....	47
4.9.5	Non-numeric Value.....	48
4.9.6	Reference Source (Conditional).....	48
4.9.7	Reference source document (Conditional).....	48
4.10	Source material (Conditional).....	48
4.10.1	Source material class .....	49
4.10.2	Source material type.....	50
4.10.3	Source material state .....	50
4.10.4	Organism ID.....	50
4.10.5	Organism name .....	51
4.10.6	Parent substance ID .....	51
4.10.7	Parent substance name.....	51
4.10.8	Development stage .....	52
4.10.9	Part Description (CONDITIONAL) .....	52
4.10.10	Fraction (Conditional) .....	54
4.10.11	Organism (Conditional).....	57
4.11	Modification (Conditional) .....	64
4.11.1	Modification type .....	66
4.11.2	Residue modified .....	66
4.11.3	Residue sites .....	66
4.11.4	Structural modification (Conditional).....	67
4.11.5	Agent modification (Conditional) .....	69
4.11.6	Physical Modification (Conditional).....	70
4.12	Property (Conditional).....	72
4.12.1	Property type.....	72
4.12.2	Property name .....	73
4.12.3	Property parameters .....	73
4.12.4	Substance ID.....	73
4.12.5	Substance name .....	74
4.12.6	Amount type (Mandatory) .....	74
4.13	Version (Mandatory) .....	74
4.13.1	Version number .....	74
4.13.2	Effective date .....	75
4.13.3	Change made.....	75
5	Substance definitions .....	75
5.1	Chemical substance .....	75
5.1.1	Comment .....	76
5.1.2	Structure.....	77
5.1.3	Stoichiometric/Non-stoichiometric chemicals .....	77
5.1.4	Stoichiometric chemicals .....	78
5.1.5	Non-stoichiometric chemicals (Conditional) .....	81
5.1.6	Substance Name (Mandatory) .....	83
5.1.7	Substance Code (Conditional).....	83
5.1.8	Version (Mandatory) .....	83



<b>5.1.9</b>	<b>Reference information</b> .....	<b>83</b>
<b>5.1.10</b>	<b>Reference source (Conditional)</b> .....	<b>83</b>
<b>5.1.11</b>	<b>Reference source document (Conditional)</b> .....	<b>83</b>
<b>5.2</b>	<b>Proteins/peptides</b> .....	<b>83</b>
<b>5.2.1</b>	<b>Microheterogeneity</b> .....	<b>84</b>
<b>5.2.2</b>	<b>Sequence type</b> .....	<b>86</b>
<b>5.2.3</b>	<b>Number of subunits</b> .....	<b>86</b>
<b>5.2.4</b>	<b>Disulfide linkage</b> .....	<b>86</b>
<b>5.2.5</b>	<b>Comment</b> .....	<b>87</b>
<b>5.2.6</b>	<b>Protein subunit (Mandatory)</b> .....	<b>87</b>
<b>5.2.7</b>	<b>Molecular weight (Conditional)</b> .....	<b>90</b>
<b>5.2.8</b>	<b>Glycosylation (Conditional)</b> .....	<b>91</b>
<b>5.2.9</b>	<b>Property (Conditional)</b> .....	<b>92</b>
<b>5.2.10</b>	<b>Structure (Mandatory)</b> .....	<b>93</b>
<b>5.2.11</b>	<b>Substance name (Mandatory)</b> .....	<b>93</b>
<b>5.2.12</b>	<b>Modification (Conditional)</b> .....	<b>93</b>
<b>5.2.13</b>	<b>Substance code (Conditional)</b> .....	<b>93</b>
<b>5.2.14</b>	<b>Source material (Conditional)</b> .....	<b>93</b>
<b>5.2.15</b>	<b>Version (Mandatory)</b> .....	<b>93</b>
<b>5.2.16</b>	<b>Reference information (Conditional)</b> .....	<b>93</b>
<b>5.2.17</b>	<b>Reference source (Conditional)</b> .....	<b>93</b>
<b>5.2.18</b>	<b>Reference source document (Conditional)</b> .....	<b>93</b>
<b>5.3</b>	<b>Nucleic acids</b> .....	<b>93</b>
<b>5.3.1</b>	<b>Structure (Conditional)</b> .....	<b>94</b>
<b>5.3.2</b>	<b>Sequence type</b> .....	<b>95</b>
<b>5.3.3</b>	<b>Number of subunits</b> .....	<b>95</b>
<b>5.3.4</b>	<b>Area of hybridisation</b> .....	<b>96</b>
<b>5.3.5</b>	<b>Comment</b> .....	<b>96</b>
<b>5.3.6</b>	<b>Nucleic acid subunit (Mandatory)</b> .....	<b>96</b>
<b>5.3.7</b>	<b>Modification (Conditional)</b> .....	<b>100</b>
<b>5.3.8</b>	<b>Property (Conditional)</b> .....	<b>100</b>
<b>5.3.9</b>	<b>Molecular weight (Conditional)</b> .....	<b>101</b>
<b>5.3.10</b>	<b>Substance Name (Mandatory)</b> .....	<b>101</b>
<b>5.3.11</b>	<b>Substance Code (Conditional)</b> .....	<b>101</b>
<b>5.3.12</b>	<b>Version (Mandatory)</b> .....	<b>101</b>
<b>5.3.13</b>	<b>Reference information (Conditional)</b> .....	<b>101</b>
<b>5.3.14</b>	<b>Reference source (Conditional)</b> .....	<b>101</b>
<b>5.3.15</b>	<b>Reference source document (Conditional)</b> .....	<b>101</b>
<b>5.4</b>	<b>Polymers</b> .....	<b>101</b>
<b>5.4.1</b>	<b>Polymer class</b> .....	<b>103</b>
<b>5.4.2</b>	<b>Polymer geometry</b> .....	<b>103</b>
<b>5.4.3</b>	<b>Copolymer sequence type</b> .....	<b>103</b>
<b>5.4.4</b>	<b>Comment</b> .....	<b>103</b>
<b>5.4.5</b>	<b>Substance name (Mandatory)</b> .....	<b>103</b>
<b>5.4.6</b>	<b>Structure (Mandatory)</b> .....	<b>104</b>
<b>5.4.7</b>	<b>Monomer description (Conditional)</b> .....	<b>104</b>
<b>5.4.8</b>	<b>Structural repeat (Conditional)</b> .....	<b>105</b>
<b>5.4.9</b>	<b>Molecular weight (Mandatory)</b> .....	<b>108</b>
<b>5.4.10</b>	<b>Property (Conditional)</b> .....	<b>108</b>
<b>5.4.11</b>	<b>Substance code (Conditional)</b> .....	<b>108</b>
<b>5.4.12</b>	<b>Version (Mandatory)</b> .....	<b>108</b>
<b>5.4.13</b>	<b>Reference information (Conditional)</b> .....	<b>108</b>

5.4.14	Modification (Conditional) .....	108
5.4.15	Source material (Conditional).....	109
5.4.16	Reference source (Conditional) .....	109
5.4.17	Reference source document (Conditional).....	109
5.5	Structurally diverse substances.....	109
5.5.1	Comment .....	110
5.5.2	Substance name (Mandatory).....	110
5.5.3	Structure (Mandatory) .....	110
5.5.4	Property (Conditional).....	110
5.5.5	Molecular weight.....	111
5.5.6	Glycosylation (Conditional).....	111
5.5.7	Modification (Conditional) .....	111
5.5.8	Source material (Conditional).....	111
5.5.9	Substance code (Conditional) .....	111
5.5.10	Reference information (Conditional) .....	111
5.5.11	Version (Mandatory) .....	111
5.5.12	Reference source (Conditional) .....	111
5.5.13	Reference source document (Conditional).....	111
5.5.14	Herbals and substances used in the preparation of plant-based allergenic extracts .....	111
5.5.15	Vaccines.....	114
5.5.16	Plasma-derived substance for human blood products and polyclonal antibodies.....	114
5.5.17	Allergens.....	114
5.5.18	Advance Therapies and Advanced Vaccines (Genes, Modified Viruses, Cells and Tissues as Substances) .....	115
5.5.19	Minerals.....	115
5.6	Mixture substance.....	116
5.6.1	Mixture type .....	116
5.6.2	Mixture constituent (Mandatory) .....	116
5.6.3	Modification (Conditional) .....	117
5.6.4	Source material (Conditional).....	117
5.6.5	Substance name (Mandatory).....	117
5.6.6	Substance code (Conditional) .....	117
5.6.7	Reference information (Conditional) .....	118
5.6.8	Version (Mandatory) .....	118
6	Specified substance (Optional) .....	118
6.1	Specified Substance Group 1 (repeat as necessary) .....	118
6.1.1	Specified substance Group 1 ID.....	119
6.1.2	Specified substance Group1 Name.....	120
6.1.3	Substance Name (Mandatory) .....	120
6.1.4	Substance Code (Conditional).....	120
6.1.5	Version (Mandatory) .....	120
6.1.6	Reference source (Conditional) .....	120
6.1.7	Reference source document (Conditional).....	120
6.1.8	Property (Conditional).....	120
6.1.9	Fraction (Conditional).....	121
6.1.10	Modification (Conditional) .....	125
6.1.11	Reference Information (Conditional) .....	125
6.1.12	Constituent (Mandatory).....	125
6.1.13	Physical form (Conditional) .....	127
6.1.14	Specified substance particulars .....	128
6.2	Specified substance Group 2 .....	133
6.2.1	Specified Substance Group2 ID .....	135

6.2.2	Specified Substance Group2 Name .....	136
6.2.3	Parent Substance ID.....	136
6.2.4	Reference source (Conditional).....	136
6.2.5	Reference source document (Conditional) .....	136
6.2.6	Manufacturing (Mandatory) .....	136
6.3	Specified Substance Group 2 for Herbal preparations.....	142
6.3.1	Specified Substance Group2 ID.....	142
6.3.2	Specified substance Group2 Name .....	142
6.3.3	Parent Substance ID.....	142
6.3.4	Manufacturing.....	143
6.3.5	Version.....	144
6.4	Specified Substance Group 3 .....	144
6.4.1	Specified Substance Group 3 ID .....	145
6.4.2	Specified Substance Group3 Name .....	145
6.4.3	Parent Substance ID.....	145
6.4.4	Grade (Mandatory).....	145
6.4.5	Version (Mandatory) .....	146
6.4.6	Reference source (Conditional).....	146
6.4.7	Reference source document (Conditional) .....	147
6.4.8	Substance name (Mandatory) .....	147
6.4.9	Substance code (Conditional) .....	147
6.4.10	Version (Mandatory) .....	147
7	Description of the information modelling principles and practices.....	147
Annex A (normative)	Choosing a Substance ID .....	148
Annex B (normative)	Chemical substance .....	150
Annex C (normative)	Protein substance.....	270
Annex D (normative)	Nucleic acid substance .....	329
Annex E (normative)	Structurally Diverse Substance – Herbal Substance/Herbal Specified Substance.....	348
Annex F (normative)	Structurally Diverse Substance, Homeopathic substance .....	466
Annex G (normative)	Structurally Diverse Substance – Plasma-derived substances.....	509
Annex H (normative)	Polymer Substance.....	581

## 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*.

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*

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