

**SLOVENSKI STANDARD**  
**oSIST prEN ISO 13120:2017**  
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**Zdravstvena informatika - Sintaksa predstavitve vsebine klasifikacijskih sistemov v medicini - Označevalski jezik za klasifikacijo (ClaML) (ISO/DIS 13120:2017)**

Health informatics - Syntax to represent the content of healthcare classification systems - Classification Markup Language (ClaML) (ISO/DIS 13120:2017)

Medizinische Informatik - Syntax zur Darstellung des Inhalts medizinischer Klassifikationssysteme - Klassifikations-Auszeichnungssprache (ClaML) (ISO/DIS 13120:2017)

Informatique de santé - Syntaxe de représentation du contenu des systèmes de classification des soins de santé - Langage de marquage de la classification (ClaML) (ISO/DIS 13120:2017)

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# DRAFT INTERNATIONAL STANDARD

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### Health informatics — Syntax to represent the content of healthcare classification systems — Classification Markup Language (ClaML)

*Informatique de santé — Syntaxe de représentation du contenu des systèmes de classification des soins de santé — Langage de marquage de la classification (ClaML)*

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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](mailto:copyright@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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 13120 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

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## Introduction

Healthcare classifications are developed and distributed in a variety of informal formats, such as MS Word, with little consistency in approach between developers. Exchanging data from these systems or attempting to parse the informal text into a more formal structure, say for publishing purposes, presents many challenges because unwanted mistakes are easily made, and difficult to detect. For example, the accidental deletion of a tab can transform a sibling rubric into a parent. ASCII files with comma separated value fields is another mechanism widely used for storing and transferring data, but as a solution here is limited by insufficient formal structuring capabilities.

In the interests of safely exchanging and distributing the content and hierarchical structure of healthcare classification systems, this International Standard presents a simple XML specification, ClaML, for exchange and distribution of healthcare classifications systems. XML is the chosen format for this International Standard as: a) XML provides the necessary structuring elements, and b) there are many readily available XML parsers in existence.

This International Standard builds on EN 14463:2008 and ISO EN 13120:2013. In this version of the standard representing ClaML 3.0 there had been performed a lot of structural and content-related changes to solve known problems with ClaML 2.0 according to experiences out of practical use and to serve additional demands of classification developers and end users. Major changes are the replacement of the DTD (Document Type Definition) by an XSD (XML Schema Definition) and the alignment with HTML by inclusion of XHTML 1.1.

This International Standard is intended to serve as the core representation from which all publication forms can be derived. It contains information of a depth sufficient to uniquely identify and describe the structure and relevant element of healthcare classification systems. This International Standard does not intend to prescribe to developers how healthcare classification systems should be structured, nor does it define or explain the meaning of the structuring elements. This International Standard is not meant to be a direct format for printing or viewing the content of a healthcare classification system. Views and prints are to be derived from this representation by post processing.

This International Standard is targeted at:

- a) developers of first generation (1) healthcare classification systems, to assist in the construction, maintenance and publication (both in paper and electronic formats) of a particular system;
- b) developers of information systems to assist in the inclusion of mechanisms for unambiguous loading of healthcare classification systems in their applications;
- c) organizations responsible for updating healthcare classification systems;
- d) institutions receiving updated healthcare classification systems.





# **Health informatics — Syntax to represent the content of healthcare classification systems — Classification Markup Language (ClaML)**

## **Health informatics — Syntax to represent the content of healthcare classification systems — Classification Markup Language (ClaML)**

### **1 Scope**

#### **1.1 Main purposes**

The main purpose of this International Standard is to formally represent the content and hierarchical structure of healthcare classification systems in a markup language for the safe exchange and distribution of data and structure between organizations and dissimilar software products.

The scope of healthcare classifications systems covered in this International Standard encompasses terminologies, and is constrained to traditional paper-based systems (like ICD-10) and systems built according to categorial structures and a cross thesaurus (like ICNP). (2) This International Standard is intended for representation of healthcare classification systems in which classes have textual definitions, hierarchical ordering, named hierarchical levels (such as “chapter”, “section”), inclusion- and exclusion criteria, and codes. It is not intended to cover any formal representation, either for definition or composition, of concepts, or for specification of classification rules. Systems with such formal specifications can at best be partially represented using this International Standard, and are hence out of scope. The reader of this document will recognize that most of the notes and examples in this standard relate to ICD-10. This is due to the fact that that ICD-10 is the most common classification system in the scope of this standard. As a highly complex classification system it is an inexhaustible source for examples of nearly any kind. But all these notes and examples represent also any other similar classification systems, if applicable, which are usually less complex. An overview of currently known classification systems using ClaML is provided in a separate document attached to the standard in the section resources.

#### **1.2 Topics considered outside the scope of this International standard**

This International Standard is not intended to:

- a) provide a normative syntax on how a healthcare classification system is to be constructed;
- b) define link types between elements in a healthcare classification system; this is left to the developers of healthcare classification systems;
- c) provide a representation for direct viewing or printing.

## 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 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

ISO 639-1, *Codes for the representation of names of languages — Part 1: Alpha-2 code*

## 3 Abbreviated terms

ClaML	Classification Markup Language
XML	eXtensible Markup Language 1.0 (3)
DRG	Diagnosis-Related Group
DTD	Document Type Definition
IANA	Internet Assigned Numbers Authority
ICD	International Classification of Diseases
ICF	International Classification of Functioning, disability and health
ICNP	International Classification for Nursing Practice
HTML	HyperText Markup Language (4) (5) (6)
OPS	“Operationen und Prozedurenschlüssel”, the German procedure classification
WHO	World Health Organization
XHTML	Extensible Hypertext Markup Language (4) (5) (7)

## 4 Conformance

The normative part of this International Standard is written in the form of a XML Schema Definition (XSD). Many commercially available XML tools provide facilities to test the conformance of an XML document with a XSD. Users of this International Standard are encouraged to perform such a test before distributing their healthcare classifications in the format of this International Standard.

## 5 Conventions

The font Arial is used to denote XSD or XML content of ClaML.

**Bold** text is used to denote elements and attributes defined in the XSD. For names of elements CamelCase is used (i.e. a single string, without spaces, consisting of multiple words, each starting with a capital); for names of attributes lowercase is used.

NOTE Names of externally defined XHTML 1.1 elements are in lowercase.

## 6 Classification markup language

### 6.1 Basis of the syntax

The basis of the syntax is to represent the content of healthcare classification systems. The syntax defined in this International Standard is called Classification Markup Language. It is defined here in the form of a XSD. The reference to this syntax will be headed to ClaML in the remainder of this document. The Version of ClaML described in this document is Version 3.0.0.

### 6.2 HTML inclusion

In the previous ClaML 2.0.0 version internally defined elements were used for representation of textual content of the classification system. These elements originated from the DocBook standard. Experiences with this version raised the wish to align ClaML to HTML for various reasons (e.g. HTML more common, enable easier transformation between different formats, missing features for accessibility demands). Therefore from this version on these elements have been removed and replaced by inclusion of externally defined equivalent content of HTML. The module based XHTML 1.1 (5) (7) definition appeared to be the most suitable candidate for integration as it allows the inclusion of the model (xhtml11-model-1.xsd) and modules (xhtml11-modules-1.xsd) schema files into the same namespace of ClaML. This enables the use of these elements in a ClaML file without a prefix. Extensions by redefinition of XHTML modules allow keeping ClaML specific functions. This XHTML 1.1 inclusion should as well cover HTML 5 (6) functionality in its basics, which is not available as XML Schema file. However, this partial inclusion does not meet the official criteria for XHTML Host Language Document Type Conformance or XHTML Integration Set Conformance. ClaML may therefore not be called "XHTML Host Language Conforming" or "XHTML Integration Set Conforming" (7).

For further information on the specific use of XHTML 1.1 elements in ClaML please read the notes on the **Label** element in section 6.7.25.1 and the extended XHTML anchor-Element (**a**) in section 6.7.26.

### 6.3 Electronic inserts

The following electronic inserts are located in the ISO Standards Maintenance Portal 13120 folder: <http://standards.iso.org/iso/13120/ed-2/en>

In the versions of ClaML published so far (EN 11463:2008, ISO 13120:2013), the DTD was only a regular part of the text document. In this version 3.0.0 of the standard the XML schema definition as given in section 6.6 shall be also provided also as electronic insert. The ClaML3.0.0.xsd file has been uploaded to the ISO database and is electronically available.

Direct link: <http://standards.iso.org/iso/13120/ed-2/en/ClaML3.0.0.xsd>

Also a DTD and an XSD file of the previous version 2.0.0 have been generated to support users upgrading to the new version. In the versions of ClaML published so far (EN 11463:2008, ISO 13120:2013), the specification was only defined as DTD. So for this revision the old DTD needed to be translated into XSD first as basis for any further changes. Changes are much better comprehensible when comparing the new ClaML 3.0 XSD to this file instead of the old DTD. This XSD file might as well be used as replacement for the old DTD when dealing with ClaML 2.0 based classifications. The files are stored in the ed-1-en.zip file. File names: ClaML2.0.0.dtd and ClaML2.0.0.xsd

Direct link: <http://standards.iso.org/iso/13120/ed-2/en/ed-1-en.zip>

## ISO/DIS 13120:2017(E)

## 6.4 Informative Addendum

The following informative addendums are located in the ISO Standards Maintenance Portal 13120 folder: <http://standards.iso.org/iso/13120/ed-2/en>

According to the substantial changes from the previous ClaML version 2.0.0 to this version 3.0.0 some informative documents have been generated. These documents shall help to better understand the changes and facilitate the transfer of classification systems to the new version.

The “ClaML\_XSD\_2.0.0\_TO\_3.0.0” document illustrates the changes of the specification in detail and shall help users to better understand them and facilitate an update to the new version. All changes based on the ClaML 2.0 XSD are yellow highlighted. Insertions are displayed as red and underlined text. Deletions are displayed as blue and striked-through text. The ClaML\_XSD\_2.0.0\_TO\_3.0.0.pdf file has been uploaded to the ISO database and is electronically available.

Direct link: [http://standards.iso.org/iso/13120/ed-2/en/ClaML\\_XSD\\_2.0.0\\_TO\\_3.0.0.pdf](http://standards.iso.org/iso/13120/ed-2/en/ClaML_XSD_2.0.0_TO_3.0.0.pdf)

The “Inventory of classification systems using ClaML” document gives an overview of currently known classifications using ClaML. These might serve as example classifications when considering representing a new classification in ClaML and gives a better understanding of the scope of the standard. The file is stored in the ed-1-en.zip file. File name: Inventory\_of\_classification\_systems\_using\_ClaML\_2016-02-15.pdf

Direct link: <http://standards.iso.org/iso/13120/ed-2/en/ed-1-en.zip>

The “ClaML 2.0.0 structure” document displays the ClaML 2.0.0 structure in a diagram. The file is stored in the ed-1-en.zip file. File name: ClaML2.0.0\_structure.pdf

Direct link: <http://standards.iso.org/iso/13120/ed-2/en/ed-1-en.zip>

The “ClaML 3.0.0 structure” document displays the ClaML 3.0.0 structure in a diagram. The ClaML 3.0.0 structure.pdf file has been uploaded to the ISO database and is electronically available.

Direct link: [http://standards.iso.org/iso/13120/ed-2/en/ClaML3.0.0\\_structure.pdf](http://standards.iso.org/iso/13120/ed-2/en/ClaML3.0.0_structure.pdf)

## 6.5 ClaML implementation profile

ClaML offers a wide range of possibilities for the representation of classification content. The defined XML structure partially allows tree structures of endless depth. This generates serious problems for end users when importing ClaML files. As classification systems nowadays contain a huge amount of data, so does the resulting ClaML file. Therefore it is difficult for end users to oversee what needs to be addressed in their import routines so that no important information of the file is overlooked.

Hence classification system developers are highly encouraged to provide an implementation profile with their ClaML files. Such an implementation profile should at a minimum address the following questions:

- Which elements and attributes are used in the current ClaML file
- Maximum expectable depth of the tree structure regarding potentially endless branches
- Notes on further necessary post-processing for generation of output formats
- Subclassifications structure (e.g. maximum level, use of multiple modifiers)

## 6.6 XML Schema Definition

```

<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<!--ClaML ver 3.0.0 -->

<xs:schema xmlns:xs="http://www.w3.org/2001/XMLSchema"
  xmlns:xml="http://www.w3.org/XML/1998/namespace" elementFormDefault="qualified"
  attributeFormDefault="unqualified">
  <xs:import namespace="http://www.w3.org/XML/1998/namespace"
    schemaLocation="http://www.w3.org/2001/xml.xsd"/>

  <xs:include schemaLocation="http://www.w3.org/Markup/SCHEMA/xhtml11-model-1.xsd"/>
  <xs:redefine schemaLocation="http://www.w3.org/Markup/SCHEMA/xhtml11-modules-1.xsd">
    <xs:attributeGroup name="xhtml.a.attlist">
      <xs:attributeGroup ref="xhtml.a.attlist"/>
      <xs:attribute name="modifier" type="xs:string" use="optional"/>
      <xs:attribute name="code" type="xs:string" use="optional"/>
      <xs:attribute name="variants" type="xs:NMTOKEN" use="optional"/>
    </xs:attributeGroup>
    <xs:group name="xhtml.a.content">
      <xs:choice>
        <xs:group ref="xhtml.a.content"/>
        <xs:element ref="Usage"/>
      </xs:choice>
    </xs:group>
  </xs:redefine>

  <xs:group name="rubric.simple">
    <xs:choice>
      <xs:group ref="xhtml.Anchor.class"/>
      <xs:group ref="xhtml.InlPres.class"/>
      <xs:group ref="xhtml.InlPhras.class"/>
    </xs:choice>
  </xs:group>

  <xs:group name="rubric.complex">
    <xs:choice>
      <xs:group ref="rubric.simple"/>
      <xs:group ref="xhtml.BlkStruct.class"/>
      <xs:element ref="Include"/>
      <xs:element ref="IncludeDescendants"/>
      <xs:element ref="Fragment"/>
      <xs:group ref="xhtml.List.class"/>
      <xs:group ref="xhtml.Table.class"/>
    </xs:choice>
  </xs:group>

  <xs:element name="ClaML">
    <xs:complexType mixed="false">
      <xs:sequence>
        <xs:element ref="Classification" minOccurs="1" maxOccurs="unbounded"/>
      </xs:sequence>
      <xs:attribute name="version" type="xs:string" use="required"/>
    </xs:complexType>
  </xs:element>

  <xs:element name="Classification">
    <xs:complexType mixed="false">

```

```

<xs:sequence>
  <xs:element ref="Meta" minOccurs="0" maxOccurs="unbounded"/>
  <xs:element ref="Identifier" minOccurs="0" maxOccurs="unbounded"/>
  <xs:element ref="Title" minOccurs="1" maxOccurs="unbounded"/>
  <xs:element ref="Authors" minOccurs="0" maxOccurs="1"/>
  <xs:element ref="Variants" minOccurs="0" maxOccurs="1"/>
  <xs:element ref="ClassKinds" minOccurs="1" maxOccurs="1"/>
  <xs:element ref="UsageKinds" minOccurs="0" maxOccurs="1"/>
  <xs:element ref="RubricKinds" minOccurs="1" maxOccurs="1"/>
  <xs:element ref="Modifier" minOccurs="0" maxOccurs="unbounded"/>
  <xs:element ref="ModifierClass" minOccurs="0" maxOccurs="unbounded"/>
  <xs:element ref="Class" minOccurs="0" maxOccurs="unbounded"/>
</xs:sequence>
<xs:attribute ref="xml:lang" use="required"/>
<xs:attribute ref="xml:space" use="optional" default="default"/>
</xs:complexType>

<xs:key name="Class-code-key">
  <xs:selector xpath="/Class"/>
  <xs:field xpath="@code"/>
</xs:key>

<xs:keyref name="SubClass-code-keyref" refer="Class-code-key">
  <xs:selector xpath="/Class/SubClass"/>
  <xs:field xpath="@code"/>
</xs:keyref>

<xs:keyref name="SuperClass-code-keyref" refer="Class-code-key">
  <xs:selector xpath="/Class/SuperClass"/>
  <xs:field xpath="@code"/>
</xs:keyref>

<xs:keyref name="IncludeDescendants-code-keyref" refer="Class-code-key">
  <xs:selector xpath="//IncludeDescendants"/>
  <xs:field xpath="@code"/>
</xs:keyref>

<xs:key name="Modifier-code-key">
  <xs:selector xpath="/Modifier"/>
  <xs:field xpath="@code"/>
</xs:key>

<xs:keyref name="ModifierClass-modifier-keyref" refer="Modifier-code-key">
  <xs:selector xpath="/ModifierClass"/>
  <xs:field xpath="@modifier"/>
</xs:keyref>

<xs:keyref name="ModifiedBy-code-keyref" refer="Modifier-code-key">
  <xs:selector xpath="//ModifiedBy"/>
  <xs:field xpath="@code"/>
</xs:keyref>

<xs:keyref name="ExcludeModifier-code-keyref" refer="Modifier-code-key">
  <xs:selector xpath="//ExcludeModifier"/>
  <xs:field xpath="@code"/>
</xs:keyref>

<xs:key name="Variant-name-key">
  <xs:selector xpath="/Variants/Variant"/>
  <xs:field xpath="@name"/>

```

```

</xs:key>

<xs:keyref name="variants-keyref" refer="Variant-name-key">
  <xs:selector xpath="/*"/>
  <xs:field xpath="@variants"/>
</xs:keyref>

<xs:key name="ClassKind-name-key">
  <xs:selector xpath="/ClassKinds/ClassKind"/>
  <xs:field xpath="@name"/>
</xs:key>

<xs:keyref name="Class-kind-keyref" refer="ClassKind-name-key">
  <xs:selector xpath="/Class"/>
  <xs:field xpath="@kind"/>
</xs:keyref>

<xs:keyref name="IncludeDescendants-kind-keyref" refer="ClassKind-name-key">
  <xs:selector xpath="//IncludeDescendants"/>
  <xs:field xpath="@kind"/>
</xs:keyref>

<xs:key name="UsageKind-name-key">
  <xs:selector xpath="/UsageKinds/UsageKind"/>
  <xs:field xpath="@name"/>
</xs:key>

<xs:keyref name="Usage-kind-keyref" refer="UsageKind-name-key">
  <xs:selector xpath="//Usage"/>
  <xs:field xpath="@kind"/>
</xs:keyref>

<xs:key name="RubricKind-name-key">
  <xs:selector xpath="/RubricKinds/RubricKind"/>
  <xs:field xpath="@name"/>
</xs:key>

<xs:keyref name="Rubric-kind-keyref" refer="RubricKind-name-key">
  <xs:selector xpath="*/Rubric"/>
  <xs:field xpath="@kind"/>
</xs:keyref>

<xs:key name="Author-name-key">
  <xs:selector xpath="/Authors/Author"/>
  <xs:field xpath="@name"/>
</xs:key>

<xs:keyref name="History-author-keyref" refer="Author-name-key">
  <xs:selector xpath="//History"/>
  <xs:field xpath="@author"/>
</xs:keyref>

</xs:element>

<xs:element name="Variants">
  <xs:complexType mixed="false">
    <xs:sequence>
      <xs:element ref="Variant" minOccurs="1" maxOccurs="unbounded"/>
    </xs:sequence>
  </xs:complexType>

```