Health informatics - Syntax to represent the content of healthcare classification systems - Classification Markup Language (ClaML) (ISO 13120:2019)



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Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.		
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## EUROPEAN STANDARD

## NORME EUROPÉENNE

### **EUROPÄISCHE NORM**

May 2019

**EN ISO 13120** 

ICS 35.240.80

Supersedes EN ISO 13120:2013

#### **English Version**

## Health informatics - Syntax to represent the content of healthcare classification systems - Classification Markup Language (ClaML) (ISO 13120:2019)

Informatique de santé - Syntaxe de représentation du contenu des systèmes de classification des soins de santé - Langage de balisage de la classification (ClaML) (ISO 13120:2019)

Medizinische Informatik - Syntax zur Darstellung des Inhalts medizinischer Klassifikationssysteme -Klassifikations-Auszeichnungssprache (ClaML) (ISO 13120:2019)

This European Standard was approved by CEN on 16 November 2018.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

#### **European foreword**

This document (EN ISO 13120:2019) 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.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2019, and conflicting national standards shall be withdrawn at the latest by November 2019.

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 EN ISO 13120:2013.

According to the CEN-CENFLEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: 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 13120:2019 has been approved by CEN as EN ISO 13120:2019 without any modification.

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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 <a href="www.iso.org/directives">www.iso.org/directives</a>).

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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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see <a href="https://www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

This document was prepared by Technical Committee ISO/TC 215, Health informatics.

This second edition cancels and replaces the first edition (ISO 13120:2013), which has been technically revised. The main changes compared to the previous edition are as follows:

- Alignment of the Classification Markup Language (ClaML) to HTML;
- Replacement of the format 'Document Type Definition' (DTD) by an 'XML Schema Definition' (XSD);
- Provision of XSD files and further informative Annexes on the ISO Standards Maintenance Portal;
- Addition of a new Annex C on 'Different ways of modification';
- Complete editorial revision.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at <a href="https://www.iso.org/members.html">www.iso.org/members.html</a>.

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#### Introduction

Healthcare classification systems 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 mistakes are easily made and difficult to detect. For example, the accidental deletion of a tab can transform a sibling rubric into a parent. Text files with comma-separated value fields are another mechanism widely used for storing and transferring data, but as a solution here are limited by insufficient formal structuring capabilities.

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

This document builds on EN 14463:2008 and ISO 13120:2013.

In this version of the syntax representing ClaML 3.0.0 there had been performed a lot of structural and content-related changes to solve known problems with ClaML 2.0.0 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.

ClaML 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 elements of healthcare classification systems. This document 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. ClaML is not meant to be a direct format for viewing or printing the content of a healthcare classification system. Views and prints are to be derived from this representation by post processing.

#### ClaML 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 their particular healthcare classification systems;
- b) developers of information systems to assist in the inclusion of mechanisms for unambiguous loading of healthcare classification systems into their applications;
- c) organizations responsible for updating healthcare classification systems;
- d) institutions receiving updated healthcare classification systems.

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

#### 1 Scope

The main purpose of ClaML 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 classification systems covered by this document 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]. ClaML 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, neither for definition or composition of concepts, nor for specification of classification rules. Systems with such formal specifications can at best be partially represented using ClaML, and are hence out of scope. Most of the notes and examples in this document relate to ICD. This is because ICD is the most common classification system in the scope of this document. 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 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 which is electronically available (see 7.3).

This document 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 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 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 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <a href="https://www.iso.org/obp">https://www.iso.org/obp</a>
- IEC Electropedia: available at <a href="http://www.electropedia.org/">http://www.electropedia.org/</a>