



# SLOVENSKI STANDARD SIST EN ISO 13606-2:2019

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**Zdravstvena informatika - Komunikacija z elektronskimi zapisi na področju zdravstva - 2. del: Specifikacija za zamenjavo arhetipov (ISO 13606-2:2019)**

Health informatics - Electronic health record communication - Part 2: Archetype interchange specification (ISO 13606-2:2019)

Medizinische Informatik - Kommunikation von Patientendaten in elektronischer Form - Teil 2: Spezifikation für den Austausch von Archetypen (ISO 13606-2:2019)

Informatique de santé - Communication du dossier de santé informatisé - Partie 2: Spécification d'échange d'archétype (ISO 13606-2:2019)

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**ICS:**

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology
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EUROPEAN STANDARD

EN ISO 13606-2

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

## Health informatics - Electronic health record communication - Part 2: Archetype interchange specification (ISO 13606-2:2019)

Informatique de santé - Communication du dossier de santé informatisé - Partie 2: Spécification d'échange d'archétype (ISO 13606-2:2019)

Medizinische Informatik - Kommunikation von Patientendaten in elektronischer Form - Teil 2: Spezifikation für den Austausch von Archetypen (ISO 13606-2:2019)

This European Standard was approved by CEN on 2 July 2019.

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**Contents**

Page

European foreword..... 3

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## European foreword

This document (EN ISO 13606-2:2019) 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of an identical text or by endorsement, at the latest by January 2020, and conflicting national standards shall be withdrawn at the latest by January 2020.

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.

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# INTERNATIONAL STANDARD

# ISO 13606-2

Second edition  
2019-06

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## Health informatics — Electronic health record communication —

### Part 2: Archetype interchange specification

*Informatique de santé — Communication du dossier de santé  
informatisé —*

*Partie 2: Spécification d'échange d'archétype*

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# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>vi</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Abbreviations</b> .....	<b>2</b>
<b>5 Conformance</b> .....	<b>2</b>
<b>6 Archetype representation requirements</b> .....	<b>3</b>
6.1 General.....	3
6.2 Archetype definition, description and publication information.....	3
6.3 Archetype node constraints.....	6
6.4 Data value constraints.....	8
<b>7 Archetype object model</b> .....	<b>10</b>
7.1 Preface.....	10
7.1.1 Purpose.....	10
7.1.2 Nomenclature.....	10
7.2 Model overview.....	10
7.2.1 Package structure.....	10
7.2.2 Definition and utility classes.....	11
7.3 The archetype package.....	13
7.3.1 Overview.....	13
7.3.2 Archetype identification.....	15
7.3.3 Top-level meta-data.....	16
7.3.4 Governance meta-data.....	16
7.3.5 Structural definition.....	18
7.3.6 Class descriptions.....	22
7.3.7 Validity rules.....	29
7.4 Constraint model package.....	30
7.4.1 Overview.....	30
7.4.2 Semantics.....	32
7.4.3 Second order constraints.....	38
7.4.4 AOM type substitutions.....	39
7.4.5 Class definitions.....	41
7.5 The rules package.....	56
7.5.1 Overview.....	56
7.5.2 Semantics.....	57
7.5.3 Class descriptions.....	57
7.6 Terminology package.....	62
7.6.1 Overview.....	62
7.6.2 Semantics.....	64
7.6.3 Class descriptions.....	65
7.7 Templates.....	67
<b>Annex A (informative) Archetype Definition Language</b> .....	<b>69</b>
<b>Annex B (informative) Example Representation</b> .....	<b>70</b>
<b>Bibliography</b> .....	<b>71</b>

## ISO 13606-2:2019(E)

### 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 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 [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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

This second edition cancels and replaces the first edition (ISO 13606-2:2008), which has been technically revised. The main changes compared to the previous edition are as follows:

- Introduction of new internal coding scheme, consisting of id-codes, at-codes and ac-codes.
- Replace string archetype identifier with multi-part, namespace identifier.
- Addition of explicit value-sets replacing in-line value sets in the terms and definitions.
- Renaming archetype ontology section to terminology.
- Expression of all external term bindings as URIs following IHTSDO format.
- Introduction of 'tuple' constraints for co-varying attributes within Quantity, Ordinal structures.
- Re-engineering of all primitive constrainer types, i.e. C\_STRING, C\_DATE etc.
- Removal of the Archetype Profile specification.
- Full specialisation support: the addition of an attribute to the C\_ATTRIBUTE class, allowing the inclusion of a path that enables specialised archetype redefinitions deep within a structure.
- Addition of node-level annotations.
- Structural simplification of archetype ontology section.
- The name of the invariant section has been changed to rules, to better reflect its purpose.
- A template is now just an archetype.

A list of all parts in the ISO 13606 series can be found on the ISO website.

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 [www.iso.org/members.html](http://www.iso.org/members.html).

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## ISO 13606-2:2019(E)

### Introduction

This document is part of a five-part standard series, published jointly by CEN and ISO through the Vienna Agreement. In this document dependency upon any of the other parts of this series is explicitly stated where it applies.

Comprehensive, multi-enterprise and longitudinal electronic health records will often in practice be achieved through the joining up of multiple clinical applications, databases (and increasingly devices) that are each tailored to the needs of individual conditions, specialties or enterprises.

This requires that Electronic Health Record (EHR) data from diverse systems be capable of being mapped to and from a single comprehensive representation, which is used to underpin interfaces and messages within a distributed network (federation) of EHR systems and services. This common representation has to be sufficiently generic and rich to represent any conceivable health record data, comprising part or all of an EHR (or a set of EHRs) being communicated.

The approach adopted in the ISO 13606 standards series, underpinned by international research on the EHR, has been to define a rigorous and generic Reference Model that is suitable for all kinds of data and data structures within an EHR, and in which all labelling and context information is an integral part of each construct. An EHR Extract (as defined in ISO 13606-1) will contain all of the names, structure and context required for it to be interpreted faithfully on receipt even if its organisation and the nature of the clinical content have not been “agreed” in advance.

However, the wide-scale sharing of health records, and their meaningful analysis across distributed sites, also requires that a consistent approach is used for the clinical (semantic) data structures that will be communicated via the Reference Model, so that equivalent clinical information is represented consistently. This is necessary in order for clinical applications and analysis tools safely to process EHR data that have come from heterogeneous sources.

#### 0.1 Archetypes

The challenge for EHR interoperability is therefore to devise a generalised approach to representing every conceivable kind of health record data structure in a consistent way. This needs to cater for records arising from any profession, speciality or service, whilst recognising that the clinical data sets, value sets, templates etc. required by different health care domains will be diverse, complex and will change frequently as clinical practice and medical knowledge advance. This requirement is part of the widely acknowledged health informatics challenge of semantic interoperability.

The approach adopted by this standard series distinguishes a Reference Model, used to represent the generic properties of health record information, and Archetypes (conforming to an Archetype Model), which are meta-data used to define patterns for the specific characteristics of the clinical data that represent the requirements of each particular profession, speciality or service.

**The Reference Model** is specified as an Open Distributed Processing (ODP) Information Viewpoint model, representing the global characteristics of health record components, how they are aggregated, and the context information required to meet ethical, legal and provenance requirements. In the 13606 standards series, the Reference Model is defined in Part 1. This model defines the set of classes that form the generic building blocks of the EHR. It reflects the stable characteristics of an electronic health record, and would be embedded in a distributed (federated) EHR environment as specific messages or interfaces (as specified in Part 5 of this standard series).

**Archetypes** are effectively pre-coordinated combinations of named RECORD\_COMPONENT hierarchies that are agreed within a community in order to ensure semantic interoperability, data consistency and data quality.

For an EHR\_EXTRACT, as defined in ISO 13606-1, an archetype specifies (and effectively constrains) a particular hierarchy of RECORD\_COMPONENT sub-classes, defining or constraining their names and other relevant attribute values, optionality and multiplicity at any point in the hierarchy, the datatypes and value ranges that ELEMENT data values can take, and might include other dependency constraints. Archetype instances themselves conform to a formal model, known as an Archetype Model

(which is a constraint model, also specified as an ODP Information Viewpoint Model). Although the Archetype Model is stable, individual archetype instances can be revised or succeeded by others as clinical practice evolves. Version control ensures that new revisions do not invalidate data created with previous revisions.

Archetypes can be used within EHR systems to govern the EHR data committed to a repository. However, for the purposes of this interoperability standard series, no assumption is made about the use of archetypes within the EHR Provider system whenever this standard series is used for EHR communication. It is assumed that the original EHR data, if not already archetyped, can be mapped to a set of archetypes, if desired, when generating the EHR\_EXTRACT.

The reference model defined in ISO 13606-1 has a property that can be used to specify the archetype to which any RECORD\_COMPONENT within an EHR\_EXTRACT conforms. The class RECORD\_COMPONENT includes an attribute *archetype\_id* to identify the archetype and node to which that RECORD\_COMPONENT conforms.

Part 3 of this standard series includes a set of Reference Archetypes: which are base archetypes that are likely to be specialised further before they are used. Those archetypes are example instances of this Archetype Model.

The Archetype Model specified in this document was originally developed by the openEHR Foundation, which publishes its archetypes using Archetype Definition Language, conforming to this Archetype Model, referenced within [Annex A](#). The Archetype Model has been the subject of collaborative updating to incorporate the requirements and modelling inputs from the Clinical Information Modeling Initiative (CIMI). CIMI is in the process of submitting a modelling language (Archetype Modeling Language, AML) to the Object Management Group. AML also aligns to this Archetype Model.

## 0.2 Archetype datatypes

It should be noted that ISO 13606-1 and ISO 13606-2 use datatypes for different purposes.

Part 1 defines datatypes to represent the properties of the Reference Model, as a profile of ISO 21090, in 5.3. It separately defines in [Clause 7](#) the data types that can be the values of Element, also a subset of ISO 21090. All these datatypes are finally expressed in terms of the so-called “primitive” datatypes (Integer, Real, String, Boolean, Date/Time/Datetime).

Part 2 uses the same set of primitive datatypes to represent the properties of the Archetype Object Model. Additionally, Part 2 defines a set of classes that allow defining constraints over primitive datatypes of Part 1. These constraining classes are shown in [Figure 9](#) of Part 2, as descendants of the C\_PRIMITIVE\_OBJECT class.

A single Part 1 complex datatype (e.g. PHYSICAL\_QUANTITY) can be constrained by a combination of the constraining classes of the Archetype Object Model, defining constraints on both the complex and primitive datatypes it contains. Thus, Part 1 complex datatypes are treated as classes when defining constraints with Part 2, while Part 1 primitive data types are constrained by the C\_PRIMITIVE\_OBJECT hierarchy.

An example of a PHYSICAL\_QUANTITY archetype can be seen in the example below. In this example, the value on a PHYSICAL\_QUANTITY shall be between 0.0 and 1000.0 and their units shall be UCUM ‘mm[Hg]’ code.

```
PHYSICAL_QUANTITY matches {
  value matches {[0.0..<1000.0]}
  units matches {
    CODED_SIMPLE matches {
      value matches {"mm[Hg]"}
```