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**Medizinische Informatik –
Allgemein verwendbare Informationskomponenten –
Teil 3: Klinische Informationen;
Englische Fassung EN 14822-3:2005**

Health informatics –
General purpose information components –
Part 3: Clinical;
English version EN 14822-3:2005

Informatique de santé –
Unité d'information dans les messages –
Partie 3: Clinique;
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Nationales Vorwort

Diese Norm enthält unter Berücksichtigung des Präsidialbeschlusses 13/1983 den englischen Originaltext der Europäischen Norm EN 14822-3:2005-10. Die Europäische Norm wurde in der WG I „Information Models“ des CEN/TC 251 „Medizinische Informatik“ erarbeitet, dessen Sekretariat vom NEN (Niederlande) gehalten wird. Der Arbeitsausschuss NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 07 „Medizinische Informatik“ des Normenausschusses Medizin im DIN hat an der Erarbeitung mitgewirkt.

Diese Europäische mehrteilige Norm legt generelle Anforderungen für allgemein verwendbare Informationskomponenten, die in Normen zum Datenaustausch eingesetzt werden, unter gesundheits-spezifischen Aspekten fest. Die Komponenten die durch diese Norm festgelegt werden, sind die am häufigsten gebrauchten, grundlegenden Bausteine für derartige Normen. Diese können allerdings weitere Spezialisierungen und Ergänzungen für bestimmte Anwendungen benötigen, die nicht durch die hier beschriebenen generell anwendbaren Komponenten abgedeckt werden.

In diesem Teil werden die klinischen Daten beschrieben, insbesondere die Daten zu den zu analysierenden Objekten, medizinischen Informationen, Medizinprodukten, Angaben zur Medikation und anderen Maßnahmen sowie Informationen zu Gesundheitsdienstleistungen. Der Begriff „klinisch“ beschreibt hier alle medizinischen Daten und geht über den klinikinternen Verwendungszweck hinaus und gilt insbesondere auch für den ambulanten Bereich. Die Komponenten sollen gerade auch sektorenübergreifend benutzt werden.

English Version

Health informatics – General purpose information components – Part 3: Clinical

Informatique de santé – Unité d'information dans les
messages – Partie 3: Clinique

Medizinische Informatik – Allgemein verwendbare
Informationskomponenten – Teil 3: Klinische Informationen

This European Standard was approved by CEN on 16 August 2005.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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Foreword

This European Standard (EN 14822-3:2005) has been prepared by 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 April 2006, and conflicting national standards shall be withdrawn at the latest by April 2006.

This is part three of a multipart standard under the heading:

Health informatics - General purpose information components:

- Part 1: Overview
- Part 2: Non-clinical
- Part 3: Clinical

This European Standard is definition of a set of clinical general purpose information components.

IMPORTANT — Within this draft document each of the General Purpose Information Components and various sub-components are provided with identifiers, which are unique only internally within this European Standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

Many previous messaging and information structure standards for health have overlapping parts with a number of objects being defined in separate documents, sometimes with small variations making implementation of conformant applications more difficult. It therefore makes sense to define a set of general purpose components that can be used for definition of message structures for different purposes¹. This approach was suggested and approved as a strategy for CEN/TC 251 in the Short Strategic Study on message standards alignment in 1999 examining a set of five European prestandards for messages. This document is aiming to provide such a set of components and has been developed jointly with a new European standard for Service Request and Report messages that is using the components defined herein.

Another important background to the development of this European Standard has been the wish for a harmonisation of information models for health developed in Europe and the USA expressed in the collaboration agreement entered March 2000 between CEN/TC 251 and HL7 (Health Level Seven, Ann Arbor, Michigan). The goal was set for a maximum degree of alignment while maintaining their independence and need to serve the business requirements of the respective markets but also to make the results available to ISO for possible international standardization.

HL7 have adapted a general strategy similar to CEN/TC 251 using information modelling² expressed in UML (Unified Modeling Language) for their new standards and a lot of interaction and information sharing has occurred between CEN experts and HL7 in an open spirit of collaboration.

This European Standard includes a large number of objects which are technically identical to descriptions in draft documents of HL7, although partly described differently due to the fact that CEN is following the ISO rules for drafting and presentation of standards which HL7 is not. CEN wishes to express its gratitude towards HL7 experts for generously sharing their models with the European expert team.

This European Standard contains definition of a set of clinical general purpose information components.

Many aspects of this document require explanation which is provided in EN 14822-1.

¹ See Annex A: Rationale for this document on General Purpose Information Components.

² Modelling is British English spelling whereas Modeling is US English spelling.

1 Scope

This European Standard specifies the definition and structuring of information relating to entities that are commonly encountered in communications with and between clinical information computer systems.

Within the scope of this European Standard is a description of components and their use. In particular, these components relate to the following sub-domains:

- Analysable objects: including samples, body parts, x-rays and other study products, together with their collection and properties.
- Clinical information: including observations, patient conditions, procedures, medication treatment, investigations, counselling plus how these items are organised within a record.
- Medicinal products: including appliances, dosage regimes, etc.
- Routing aspects of medication treatment or other procedures.

Care Service information: including referrals for care services, care encounter information and scheduling.

2 Normative references

Not applicable.

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

3.1

analysable object

something derived from or to be derived from a patient as part of a diagnostic or laboratory investigation
[ENV 12539:1997 - revised]

NOTE 1 Analysed object is a generalisation that includes samples taken from a patient and physical or digital records of information derived from a patient as part of a diagnostic service. An analysed object that is not a sample is referred to as a study product.

NOTE 2 An analysed object need not exist in a tangible form but may represent something observed briefly by a diagnostic service provider.

EXAMPLE 1 An x-ray image, a series of x-ray images, part of an x-ray image. The image may exist in a digitised form or as a film.

EXAMPLE 2 An electrocardiograph (ECG) monitor tracing or a twelve lead ECG.

EXAMPLE 3 An organ removed during surgery or post-mortem, a biopsy, a particular slide containing a section taken from a biopsy.

EXAMPLE 4 A view observed through an endoscope, an observation during an echocardiographic examination.

3.2

analysable object in use

information about an analysable object and the part it plays in an activity

EXAMPLE 1 Blood collected for a biochemical or hematological analysis during exploratory surgery.

EXAMPLE 2 Urine sample taken by the patient to a routine examination.

3.3

body system

demarcated system that is related to a subject of care or component of a subject of care

EXAMPLE 1 Systems: a man, an organ or anatomical structure.

EXAMPLE 2 Components: pathological cells in a biopsy from an organ.

3.4

care encounter

situation on the uninterrupted course of which one or more health care professionals delivers health care services to a subject of care

[ENV 13940:2001 - modified]

3.5

care service

activity performed for a subject of care by a health care provider with the intention of directly or indirectly improving or maintaining the health of that subject of care

[ENV 13940:2001 - modified]

3.6

clinical information

information about a patient, relevant to the health or treatment of that patient, that is recorded by or on behalf of a healthcare professional

[ENV 13606:2000]

NOTE Clinical information about a patient may include information about the patient's environment or about related people where this is relevant.

3.7

clinical information complex

healthcare record component representing an aggregation of other healthcare record components

[ENV 13606:2000]

3.8

clinical observation

clinical information excluding information about treatment and intervention

NOTE The observer may be the patient or related person (information about symptoms, family history, occupation or life style), or a healthcare professional (information about physical signs, measurements, properties observed or diagnoses). While information about the nature of a planned or performed treatment is excluded by the definition, clinical observations may be recorded as the results of a treatment or during the course of a treatment or as its result.

3.9

clinical procedure

clinical intervention or treatment of a subject of care or group of subjects of care excluding counselling, investigation or medication

3.10

General Purpose Information Component

GPIC

commonly useful information component that is a specialisation of classes in an international reference information model which is intended to be used in the specification of an information service for health or of a communication between health information systems

3.11

healthcare

provision of health related services

[ENV 13940:2001 - modified]

NOTE 1 This includes more than performing procedures on subjects of care. It also includes, for example, the management of the information about patients, their health status and their relations within the health care framework.

NOTE2 In the present European pre-standard, the term 'care' may be used as a synonym for 'health care'.

3.12

healthcare agent

healthcare person, healthcare organisation, healthcare device or that performs a role in a healthcare activity

3.13

healthcare device

device or equipment involved in the direct or indirect provision of healthcare services to an individual or to a population

[ENV 13606:2000]

EXAMPLES ECG machine, auto-analyser, syringe pump.

3.14

healthcare organisation

organisation involved in the direct provision of health care services

[ENV 13606-4:2000 - modified] [ENV 1613:1995, modified]

3.15

healthcare party

organisation or person involved in the direct or indirect provision of healthcare services to an individual or to a population

[ENV 13606:2000]

3.16

healthcare professional

person involved in the direct or indirect provision of healthcare services to an individual or to a population

[ENV 13606:2000 –revised]

NOTE A carer or the patient may be a healthcare person.

3.17

medicinal appliance

device or piece of equipment which may be used by human beings or administered to animals for treating or preventing disease, with the view to making medical diagnosis, to restore, correct or modify physiological functions or to alleviate handicap

EXAMPLES Syringes, spacers for inhalation, diagnostic kits for pregnancy, bandages, catheters, diapers for incontinence, orthopaedic shoes, colostomy bags, wheel chairs, pneumatic mattresses.

3.18

medicinal product

any substance or combination of substances, which may be administered to human beings or animals for treating or preventing disease, with the view to making medical diagnosis or to restore, correct or modify physiological functions

NOTE Some medicinal products are prescribed as a combination of a medicinal product and a medicinal appliance. Such combinations are regarded in this document as medicinal products. [Directive 65/65/EEC, modified]

3.19**medicinal product package**

delivery unit of a medicinal product in an outer container
[ENV 12610:1997]

3.20**medication supply**

provision of one or more medicinal products for administration to a subject of care

3.21**medication treatment**

administration of one or more medicinal products to a subject of care at one or more administration events

3.22**object characteristics**

measurement made upon, or a measurement parameter of a specimen or study product

3.23**organisation**

unique framework of authority within which a person or persons act, or are designated to act towards some purpose

NOTE Groupings or subdivisions of an organisation may also be considered as organisations where there is need to identify them for information interchange. [ISO 6523:1998]

3.24**preservation material**

material or substance that is used in order to preserve a specimen or body part

3.25**specimen**

one or more parts taken or to be taken from a system and intended to provide information on that system or on a subsystem, or to provide a basis for decision on either of these

[ENV 12359:1997 - modified]

NOTE The system from which a sample is taken may be a patient or may itself be a specimen. The specimen is assumed to be representative of the system. The term sample is sometimes used with the same meaning.

3.26**study product**

identifiable record of information derived from a patient as part of a diagnostic service. It may take the form of a physical object or may consist of digital information in an electronic information system
[ENV 12539:1997]

NOTE A study product differs from a sample in that a sample is something taken from a patient whereas a study product is a recording of information derived from a patient. A consequence of this distinction is that a study product can be copied. Furthermore, if the study product is represented in a digital form it can be held within or transferred between computer systems.

EXAMPLE 1 An x-ray image, a series of x-ray images, part of an x-ray image.

EXAMPLE 2 The image(s) may exist in a digitised form or as a film.

EXAMPLE 3 An electrocardiograph (ECG) monitor tracing or a twelve lead ECG.

EXAMPLE 4 The tracing may exist on paper or as a digitised signal.

3.27

subject of care

person or other living subject, or group of persons or other living subjects, scheduled to receive or receiving healthcare services

4 Abbreviations

NOTE All those marked by ‡ as defined in the CEN/TS 14796:2003 "Health Informatics - Data Types".

BL ‡	Boolean
CD ‡	Concept Descriptor
CS ‡	Coded Simple value
CV ‡	Coded Value
ED ‡	Encapsulated Data
GP	General Practitioner
GPIC	General Purpose Information Component
II ‡	Instance Identifier
IVL ‡	Interval
IVL<PQ> ‡	Interval of Physical Quantity
IVL<TS> ‡	Interval of Time
INT ‡	Integer
PQ ‡	Physical Quantity
ST ‡	String
TS ‡	Time stamp (point in time)
UML	Unified Modelling Language

5 Rules governing the use of general purpose information components

5.1

When using a GPIC, a system or communication protocol which conforms to this document shall implement all of the features (classes, associations, attributes) that are described within the GPIC core³. In particular, a conformant system that utilises a GPIC shall be able to receive and process information present in all classes and attributes, even where these classes and attributes are specified as being optional.

A conformant system that utilises a GPIC to send information shall not be obliged to populate optional classes or attributes.

5.2

Each of the classes and embedded GPICs that constitute a GPIC description has a class type. These are shown as follows⁴:

³ See Annex B: How to read the models.

⁴ See Annex C: Health Level 7 (HL7) Reference Information Model.

A	Act	Describe actions, plans etc. Examples include observations, tests, referrals, transportation etc.
AR	Act Relationship	Relationships between acts. Often used to group Acts together, for example, a test result with a clinical observation.
P	Participation	Used to links an Act to Entities. May include information about the type of participation of the Entity.
R	Role	Used to provide information about the roles entities play.
RL	Role link	Used to link two Entity/Role pairs together, for example person/employee $\leftrightarrow$ organisation/employer.
E	Entity	Describe physical things. Examples include people, animals, organisations, places, materials, devices etc.

For each GPIC there is a definition of the type(s) of objects to which the GPIC may be attached within any external models or implementations. A conformant system will restrict GPIC use accordingly⁵.

5.3

GPICs may be associated with other GPICs in ways which extend their functionality. These extensions are informative in nature and will not subject to conformance testing.

5.4

A user community, e.g. a national body or a message development agency, may wish to 'localise' a GPIC for use in a particular circumstance. The rules which underpin such localisation are⁶:

- All mandatory attributes and associations shall be present in any design using the GPIC, i.e. it is not permitted to omit these features.
- A user community may in any part of a communication or system design:
 - specify that certain specialisations of a general class are not allowed;
 - specify that certain optional attributes or associations are omitted;
 - restrict (constrain) a data type: For example, the data type ST (string) being defined in place of ED (multimedia data);
 - define constraints on the allowable values of an attribute;

⁵ See Annex D: Common features of the General Purpose Information Components.

⁶ See Annex E: Localisation of the general purpose information components.

- define constraints on the vocabulary sets that may be associated with a coded attribute.
- A user community shall **not**:
 - omit mandatory attributes and associations but may restrict values and vocabulary sets as outlined above;
 - add attributes;
 - add associations except to other GPICs as formal extensions.

5.5

User communities may create new GPICs.

6 General Purpose Information Components – an overview

GPIC Name	Description/Use
AnalysableObject R	Information about something derived from, or to be derived from, a living subject of care, or a physical location, as part of a diagnostic or laboratory investigation. This GPIC shall be used only where the application or communication about this entity is concerned with a: — Specimen, i.e. substances or samples that are analysed in laboratory investigations or; — Study products such as ECG tracings, x-rays, digital representation of an x-ray etc. NOTE Where it can be identified that only one of these options is required, and where the Role interface and/or the associations to the external GPICs are required, the user should utilise this GPIC but specify a restriction to either the Specimen GPIC or StudyProduct GPIC specialisation.
AnalysableObjectInUse P	An AnalysableObject GPIC with a Participation interface allowing it to be associated with an action or activity. EXAMPLES 1) Blood for a biochemical or hematological analysis collected during exploratory surgery. 2) Urine sample taken by the patient to a routine examination.

GPIC Name	Description/Use
Specimen E	Information about one or more parts taken or to be taken from a system and intended to provide information on that system or on a subsystem, or to provide a basis for decision on either of these. This GPIC may be used in the following situations: 1) In its own right when it is used to specify information concerning a non-manufactured substance without the explicit use of the <code>AnalysableObject</code> class 2) As a specialisation of the <code>AnalysableObject</code> class within the <code>AnalysableObject</code> GPIC where the user or application needs to: — leave open the possibility of referring to a specimen or study product; — provide a role interface as in the <code>AnalysableObject</code> GPIC (Note that it is possible to restrict the <code>AnalysableObject</code> GPIC so as to only include the possibility of describing a specimen); — provide links to external GPICs such as <code>ObjectCharacteristic</code>, <code>BodySystem</code> or acquisition details. NOTE If there is a requirement to relate this specimen to other specimen use the <code>RelatedAnalysableObject</code> facility within the <code>AnalysableObject</code> GPIC.
RelatedAnalysableObject RL	Provides a means of linking a specimen or study product to a related specimen or study product.
ManufacturedSpecimen R	Information about a sample of material that is a representative part of a manufactured substance. EXAMPLES A sample of vaccine, blood products.
SpecimenTreatment A	Information about any physical or chemical treatment of a specimen. EXAMPLES Freezing, centrifuging, treatment with a preservation material.
RelatedSpecimenTreatment P	SpecimenTreatment GPIC with a Participation interface. This permits the treatment to be associated with a specimen through <code>RelatedAnalysableObject</code> GPIC.

GPIC Name	Description/Use
AssociatedSpecimenTreatment AR	Information about the treatment of a specimen. Used where information about the treatment of a specimen needs to be associated with another action, i.e. obtaining the sample, and especially where a sequential set of treatment procedures are carried out upon a particular specimen.
StudyProduct E	1) This GPIC allows a record of a clinical investigation result item to refer to a physical or digital record made during an investigation. 2) This GPIC may be used in the following situations: — in its own right when it is used to specify information concerning a non-manufactured substance without the explicit use of the AnalysableObject class; — as a specialisation of the AnalysableObject class within the AnalysableObject GPIC where the user or application needs to: — leave open the possibility of referring to a specimen or study product; — provide a role interface as provided in the AnalysableObject GPIC (Note that it is possible to restrict the AnalysableObject GPIC so as to only include the possibility of describing study product); — provide links to external GPICs such as ObjectCharacteristic, BodySystem or acquisition details. NOTE If there is a requirement to relate this study product to other study products the RelatedAnalysableObject facility should be used within the AnalysableObject GPIC.
ObjectCharacteristics P	Information about a measurement made upon, or a measurement parameter of a specimen or study product.
PreservationMaterial R	Information about a material or substance that is used in order to preserve a specimen or body part.
AcquiredAnalysableObject P	Information about an analysable object which has been, is to be, acquired. Used to relate information about an analysable object to some activity.

GPIC Name	Description/Use
AnalysableObjectAcquisition 	Information about the acquisition of the analysable object. Used to relate information about the acquisition procedures to the associated analysable object.
RelatedObjectAcquisition 	An AnalysableObjectAcquisition GPIC with a Role interface. Used to related the acquisition information directly to the analysable object entity
AcquisitionProcedure 	Information about how an analysable object has or is to be obtained.
ExternalDataReference 	Reference to external information stored in digital form.
ClinicalInformation 	Information about a patient, relevant to the health or treatment of that patient, that is recorded by or on behalf of a healthcare professional. An abstract class which may be specialised as a ClinicalInformationComplex or ClinicalInformationItem GPIC. EXAMPLES An observation, a laboratory result, results of an examination, a set of related laboratory results, clinical information relevant to a referral, current medication, family history.
ClinicalInformationComplex 	Description of the 'context' or 'container' that is used to organise one or more items of clinical information. A collection of clinical information items equates to a 'complex' in ENV 13606 terminology. ClinicalInformationComplex is a specialisation of ClinicalInformation ClinicalInformationComplex is further specialised as one of: — ClinicalInformationContext (default) — CareServiceRequest — CareServiceReport — CareEncounter
ClinicalInformationContext 	Default specialisation ClinicalInformationComplex which describes the 'context' or 'container' that is used to organise one or more items of clinical information.

GPIC Name	Description/Use
ClinicalInformationItem A	Single unit of clinical information that in a certain context is considered indivisible. NOTE The context may mean that this component's content may represent for example either a single clinical statement or a single complex type such as an x-ray report. Its granularity is determined by the context. A clinical information item equates to a 'data item' in ENV 13606 terminology. ClinicalInformationItem is a specialisation of ClinicalInformation.
RelatedClinicalInformation AR	Information about an item or collection of clinical information with some relationship to some healthcare related activity. Used primarily to associate a relevant set of clinical information about a patient with a request or a report.
RelatedClinicalInformationComplex AR	Information about an item or collection of clinical information with some relationship to some other healthcare related activity or collection of activities/documents.
ClinicalObservation A	A specialisation of ClinicalInformationItem which provides a general description of a clinical observation. A clinical observation may be composed of a single observation or a number of sub-observations which are summarised at the top level.
RelatedPatientCondition AR	Information about any condition that is related to one or more items of clinical information.
ClinicalProcedure A	A specialisation of ClinicalInformationItem which provides a general description of a clinical procedure.
PatientPreparationProcedure AR	Information about conditions applied or substances administered, that prepare or challenge a patient before or during the collection of an analysable object or the performing of some other procedure(s). Patient preparation procedure refers to something done to the patient that is intended to affect or may incidentally have affected: — an analysable object obtained from the patient; — the carrying out of one or more other procedures; — one or more clinical observations.
PatientPreparationSubstance AR	Information about a drug or other chemical compound administered or withheld as a part of a patient preparation step.

GPIC Name	Description/Use
Counselling A	A specialisation of ClinicalInformationItem which provides information about counselling or advice that is given to a patient or to a related person or professional.
UnclassifiedClinicalInformation A	A specialisation of ClinicalInformationItem which provides a description of clinical information that has not been categorised as an observation, procedure, investigation (request or report), counselling or medication (treatment or supply).
InvestigationRequest A	A specialisation of ClinicalInformationItem which provides a set of information that may be used to define a laboratory investigation that has been, may be, or is to be ordered, or which has been carried out. EXAMPLES Order for complete blood count, intention to carry out an endoscopy investigation, request for chest x-ray.
RelatedInvestigationRequest AR	An InvestigationRequest GPIC with an Act Relationship interface which permits the investigation request to be associated with other acts/activities.
InvestigationResultItem A	A specialisation of ClinicalInformationItem which provides a set of information including all essential or useful data relevant to the result of a clinical investigation.
RelatedInvestigationResult AR	Information about any laboratory or diagnostic investigation that has relevance to another item or group of clinical information.
ReferenceLimit AR	Description of a normal range expressed as a numeric measurement range or in a coded form. These limits may be applicable to a particular population and may be of a specified type.
ReferencePopulation AR	Links a reference population to a reference limit.
InvestigationSpecification AR	A structured representation of an attribute of a phenomenon, body or substance that may be distinguished qualitatively and subjected to observation or determined quantitatively.
BodySystem P	Information about a demarcated body system or component of a body system, or some multimedia representation of such a system or component. EXAMPLES A man, an organ or anatomical structure, a biopsy sample, an anatomic pathological section, pathological cells in a biopsy from an organ.
RelatedBodySystem R	Information about a body system or sub-component thereof. Generally used to describe a sub-component of a body system.

GPIC Name	Description/Use
MeasurementProcedure AR	Information about a set of operations used in the performance of a measurement on a system or subsystem.
MedicationTreatment A	A specialisation of ClinicalInformationItem which provides a set of information about a medicinal treatment that is requested, intended or has occurred.
MedicationSupply A	A specialisation of ClinicalInformationItem which provides a set of information about the supply of medicinal products that has happened, is intended/recommended to commence or stop, or is planned.
MedicinalProduct R	Information about a medicinal product. This GPIC describes the medicinal product generically. Generally used where a 'code' attribute in some activity is not sufficient to fully describe the product. This permits 'virtual' products to be specified such as 100 mg atenolol, without reference to a particular concrete product with a particular form.
Ingredient R	Information about an ingredient of a medicinal product.
MedicinalProductInUse P	GPIC designed so as to permit a MedicinalProduct GPIC to be associated with an action.
MedicinalProductPack R	Delivery unit of a medicinal product in an outer container and its contents.
MedicinalProductPackInUse P	GPIC designed so as to permit a MedicinalProductPack GPIC to be associated with an action.
MedicationAppliance R	Provides information concerning an appliance that is used in the administration of one or more medicinal products.
MedicationApplianceInUse P	GPIC designed so as to permit a MedicationAppliance GPIC to be associated with an action.
MedicationTreatmentRegimen AR	Information about how the medicinal products were administered or are intended to be administered over the treatment period. EXAMPLES Take 2 tablets 3 times per day with meals for seven days then take 2 tables twice per day with meals for seven days, then
DoseAdministration A	Information concerning a single event or instruction of the administration of a medicinal product or set of medicinal products.
MedicationTreatmentCondition AR	Information about any condition which should trigger the starting or stopping of medication treatment.

GPIC Name	Description/Use
RoutingOption 	Information concerning the route whereby treatment is administered to a patient including: — route of administration of a medicinal product; — route used for access to an anatomical site when carrying out a procedure.
RoutingDevice 	Information concerning a device used to route medication to a treatment site. This GPIC is particularly specialised to the routing of medication. For other device descriptions use the DeviceInUse GPIC described in this document.
CareServiceRequest 	A specialisation of ClinicalInformationComplex containing a set of information that relates to a request for one or more care services. EXAMPLES Referral for physiotherapy course, request for set of investigative procedure.
RelatedServiceRequest 	A set of information concerning a request for one or more care services that may be related to another activity.
CareServiceReport 	A specialisation of ClinicalInformationComplex containing a set of information contained in a report on the planning or delivery of care services.
RelatedServiceReport 	A set of information concerning a report on the delivery or planning of one or more care services that may be related to another activity.
CareEncounter 	A specialisation of ClinicalInformationComplex containing a set of information about a patient care encounter that has happened or is planned, cancelled, postponed etc.
RelatedCareEncounter 	Set of information concerning a care encounter that is related to some other activity.
CareServiceDelivery 	Information about a healthcare service that is planned or been delivered to a subject of care. EXAMPLES Counselling provided to a patient's guardian, planned set of physiotherapy sessions, planned triple bypass surgery.
PreviousRelatedActivity 	This GPIC may be used to provide information which links two instances of the same type of activity.

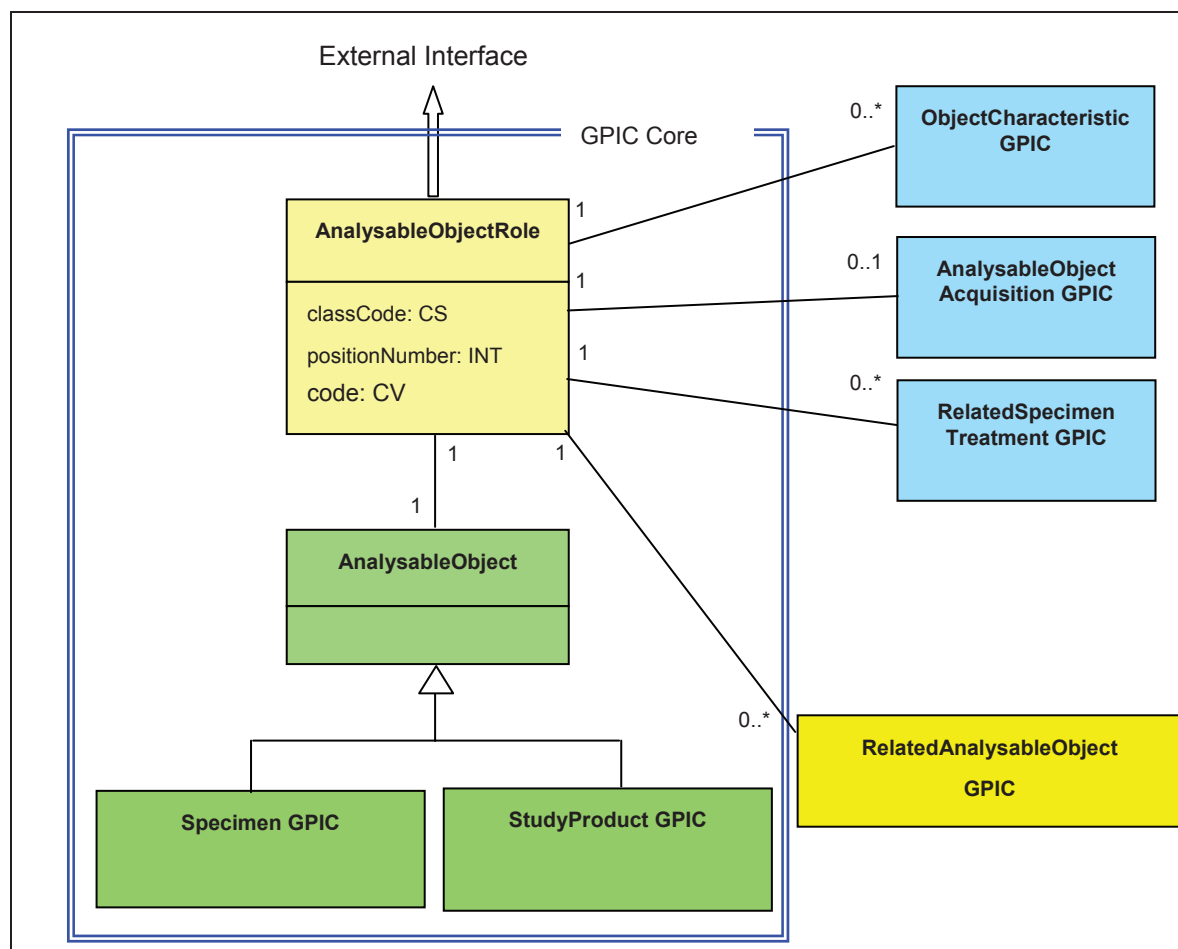
7 General Purpose Information Components

7.1 Analysable Object GPICs

7.1.1 Analysable Object

7.1.1.1 General description

GPIC Name	
AnalysableObject GPIC_ID = 3.001 R	
Description	Information about something derived from, or to be derived from, a living subject of care, or a physical location, as part of a diagnostic or laboratory investigation.
External Connection Types	This GPIC may be integrated into other models with the proviso that the connection point is of the generic type (see EN 14822-1:2005, Clause 5): — Participation (the most common connection type) — Role link
Use	This GPIC shall be used only where the application or communication about this entity is concerned with a: — Specimen, i.e. substance or sample that is analysed in a laboratory investigation or; — Study product such as an ECG tracing, x-ray, digital representation of an x-ray etc. NOTE Where it can be identified that only one of these options is required, and where the Role interface and/or the associations to the external GPICs are required, the user should utilise this GPIC but specify a restriction to either the Specimen GPIC or StudyProduct GPIC specialisation.
Examples	An x-ray image, a series of x-ray images, part of an x-ray image. The image may exist in a digitised form or as a film. An electrocardiograph (ECG) monitor tracing or a twelve lead ECG. An organ removed during surgery or post-mortem, a biopsy, a particular slide containing a section taken from a biopsy. A view observed through an endoscope, an observation during an echocardiographic examination. A sample of cooked meat taken from a food shop.
Comments	1) Analysable object is a general term that includes samples taken from a patient and physical or digital records of information derived from a patient as a part of a diagnostic service. 2) The anatomical site of acquisition of the analysable object is found in the AnalysableObjectAcquisition GPIC.
UML Representation	



7.1.1.2 Analysable Object Core Classes

AnalysableObjectRole R		
Description	Used to link the analysable object information to a larger model and to provide its context when more than one such objects are collected.	
Comments	This class and its associations are inherited by the Specimen GPIC and the StudyProduct GPIC.	
Related Class	Type of Relationship	Cardinality
AnalysableObject	Association	1
Related GPIC (optional extension)	Type of Relationship	Cardinality
ObjectCharacteristic	Association	0 to many
AnalysableObjectAcquisition	Association	0 or 1
RelatedSpecimenTreatment	Association	0 to many
RelatedAnalysableObject	Association	0 to many

Attributes	O	Type	Description
classCode	M	CS	Fixed value = INST (instance of).
positionNumber	O	INT	When a number of analysable objects are being collected and processed it may be convenient to utilise this attribute to denote the chronology or order of the objects.
code	O	CV	Code providing some form of context to the role being played by the analysable object. EXAMPLES <u>Post-operative</u> (blood sample), <u>pre-operative</u> (blood sample). NOTE Only the role of the analysed object should be described here. The actual description of the 'thing' or object utilises an attribute in the description of the analysable object..

AnalysableObject E		
Description	See GPIC description.	
Comments	This is an abstract class without any attributes of its own. The class is specialised as either an instance of Specimen (see Specimen GPIC) or an instance of StudyProduct (see StudyProduct GPIC).	
Related GPICs	Type of Relationship	Cardinality
Specimen	Specialisation	-
StudyProduct	Specialisation	-

Specimen GPIC (3.003) E	
Description	Specialisation of AnalysableObject containing information about one or more parts taken or to be taken from a system and intended to provide information on that system or on a subsystem, or to provide a basis for decision on either of these.
Examples	A blood sample, a urine sample, an organ removed during surgery or post-mortem, a biopsy, a particular slide containing a section taken from a biopsy, a sample of meat taken from a food shop.

StudyProduct GPIC (3.009) E	
Description	Specialisation of AnalysableObject containing a digital or multimedia information derived from a patient as part of a diagnostic service. It may take the form of a physical object or may consist of digital information in an electronic information system.
Examples	An x-ray image, a series of x-ray images, part of an x-ray image (in a digitised form or as a film), an electrocardiograph (ECG) monitor tracing, a twelve lead ECG.

7.1.1.3 Analysable Object GPIC Extension (Informative)

ObjectCharacteristic GPIC (3.010) P	
Description	Information about a characteristic or measurement parameter of the analysable object.
Occurrences	Each instance of the AnalysableObject GPIC may be associated with zero to many instances of ObjectCharacteristic GPIC.
Examples	The volume of a urine sample, the size of a biopsy sent for histology, the volume of aspirate sent for cytology, length of ECG Tracing.

AnalysableObjectAcquisition GPIC (3.013) P	
Description	Information about the acquisition of the analysable object.
Occurrences	Each instance of the AnalysableObject GPIC may be associated with zero or one instance of AnalysableObjectAcquisition GPIC.
Comments	This GPIC may be used to provide details of the source of the analysable object.

RelatedSpecimenTreatment GPIC (3.007) P	
Description	Information about any physical or chemical treatment of a specimen.
Occurrences	Each instance of the AnalysableObject GPIC may be associated with zero to many instances of RelatedSpecimenTreatment GPIC.
Examples	Freezing, centrifuging, treatment with a preservation material.

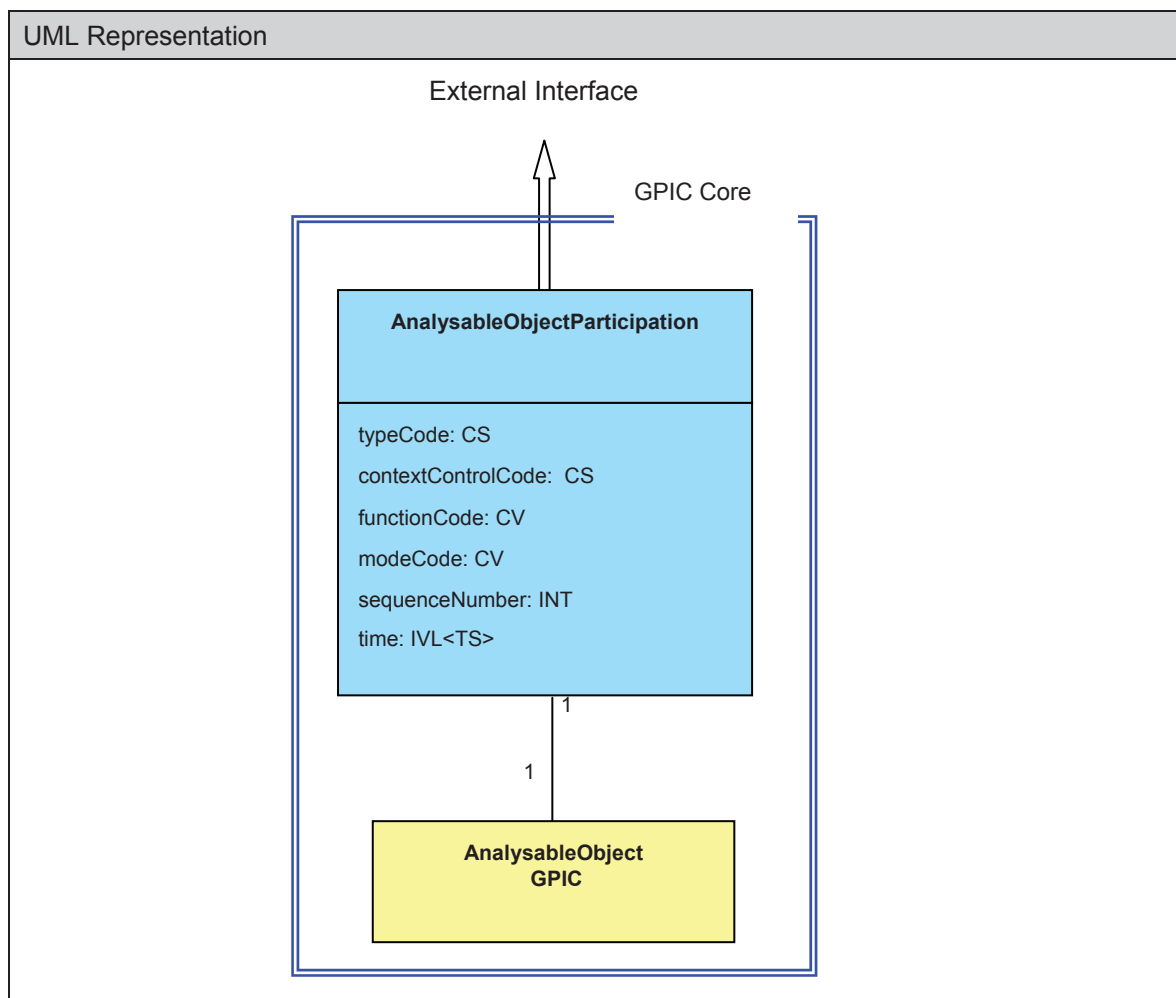
RelatedAnalysableObject GPIC (3.004) RL	
Description	Information about another analysable object and its relationship to the one described in this instance.

Occurrences	Each instance of the AnalysableObject GPIC may be associated with zero to many instance of RelatedAnalysableObject GPIC.
Use	Use to relate groups of analysable objects.

7.1.2 Analysable Object In Use

7.1.2.1 General description

GPIC Name		P
AnalysableObjectInUse		
GPIC_ID = 3.002		
Description	An AnalysableObject GPIC with a participation interface allowing it to be associated with an action or activity.	
External Connection Types	This GPIC may be integrated into other models with the proviso that the connection point is of the generic type (see EN 14822-1:2005, Clause 5): — Act	
Examples	1) Blood for a biochemical or haematological analysis collected during exploratory surgery. 2) Urine sample taken by the patient to a routine examination.	
Comments	This GPIC is used to link an analysable object to a particular activity (e.g. a request or service or the undertaking of a procedure). However, the activity itself may be associated with more than one of these analysable objects and the Participation aspect (i.e. AnalysableObjectParticipation) may be used to provide any information or comments about the exact nature of the part played or to be played by these individual objects.	



7.1.2.2 Analysable Object In Use Core Features

AnalysableObjectParticipation P			
Description	Used to link the AnalysableObjectInUse GPIC to an Act.		
Related GPIC		Type of Relationship	Cardinality
AnalysableObject		Association	1
Attribute	O	Type	Description
typeCode	M	CS	Fixed value = SPC (specimen).
contextControlCode	O	CS	Code indicating whether the information about this AnalysableObjectInUse can be inherited by other Acts in addition to the one which the GPIC is directly attached to. A code shall be chosen from the set presented in 9.6.

functionCode	O	CV	Code representing the function or purpose played by the analysable object. EXAMPLE Locating of extent of tumour.
modeCode	O	CV	The analysable object may be actually present or be located remotely, for example a video image of a sample may be viewed remotely. This attribute provides a means of specifying the aspect of the nature of the participation of the analysable object in the related activity.
sequenceNumber	O	INT	Where a number of analysable objects are utilised in an activity, a sequence can be used as a means of specifying the order of their participation. For example, to sequence a set of blood samples taken during a procedure.
time	O	IVL<TS>	A time or time interval may be associated with the participation of the analysable object in the activity.
noteText	O	ED	Provides a means of attaching additional information about the particular part played or to be played by the analysable object in the associated activity. EXAMPLES Analysable object provides the definitive evidence for the arrival at a definitive diagnosis.

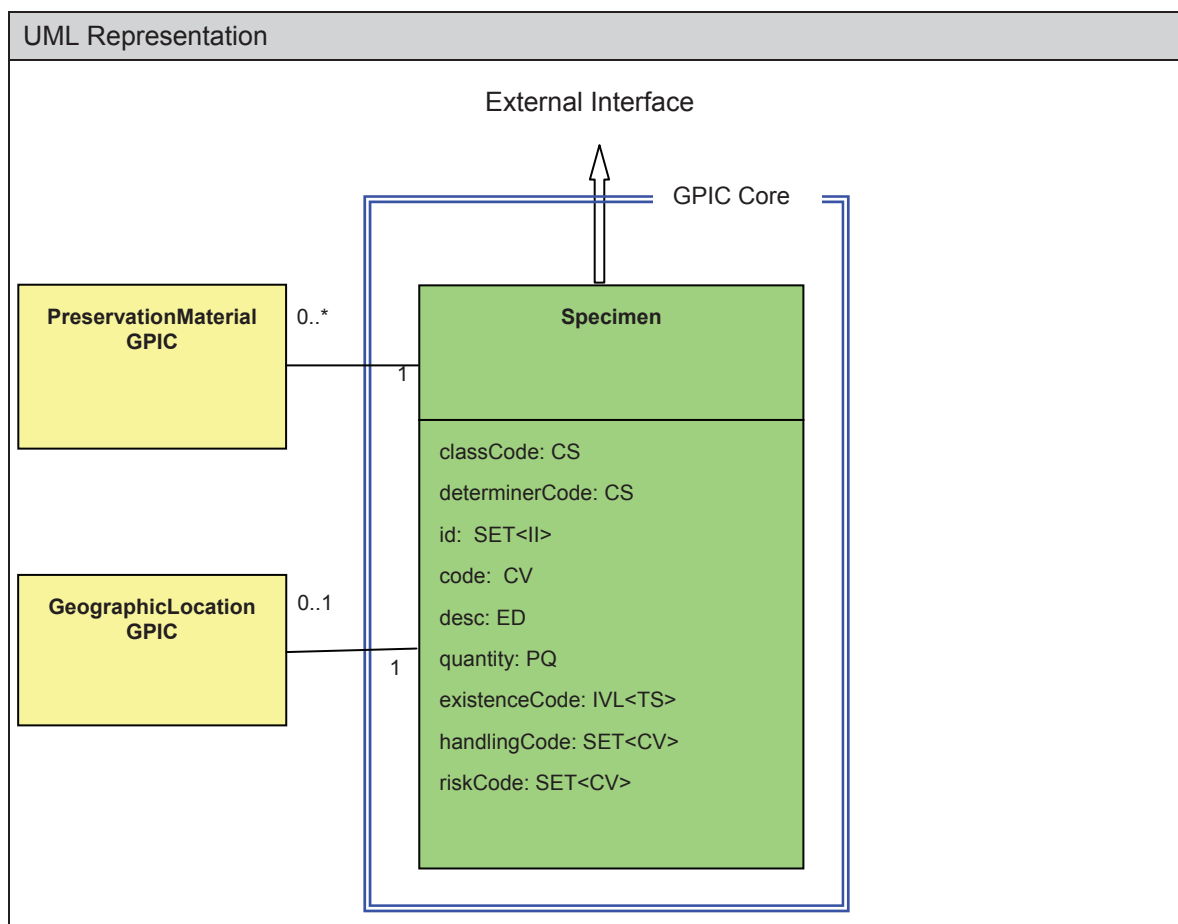
AnalysableObject GPIC (3.001) R		
Description	Information about the associated analysable object.	
Related Class	Type of Relationship	Cardinality
AnalysableObjectParticipation	Association	1

7.1.3 Specimen

7.1.3.1 General description

GPIC Name E	
Specimen	GPIC_ID = 3.003
Description	A specialisation of AnalysableObject which provides information about one or more parts taken or to be taken from a system and intended to provide information on that system or on a subsystem, or to provide a basis for decision on either of these.
External Connection Types	This GPIC may be integrated into other models with the proviso that the connection point is of the generic type (see EN 14822-1:2005, Clause 5): — Role

Use	This GPIC may be used in the following situations: 1) In its own right when it is used to specify information concerning a non-manufactured substance without the explicit use of the AnalysableObject class. 2) As a specialisation of the AnalysableObject class within the AnalysableObject GPIC where the user or application needs to: — leave open the possibility of referring to a specimen or study product; — provide a role interface as in the AnalysableObject GPIC (Note that it is possible to restrict the AnalysableObject GPIC so as to only include the possibility of describing a specimen); — provide links to external GPICs such as ObjectCharacteristic, BodySystem or acquisition details.
Note	If there is a requirement to relate this specimen to other specimens use the RelatedAnalysableObject facility within the AnalysableObject GPIC.
Examples	A blood sample, a urine sample, an organ removed during surgery or post-mortem, a biopsy, a particular slide containing a section taken from a biopsy, a sample of meat taken from a food shop.
Additional Associations	By utilising the facilities described in the AnalysableObject GPIC, the specimen can also be associated with: — Object characteristics: e.g. length, volume, mass etc. — Body system: i.e. anatomic site or system. — Acquisition information: i.e. how the specimen was taken. — Related specimen or study products.



7.1.3.2 Specimen GPIC Core Description

Specimen E			
Description	Information about something derived from, or to be derived from, a subject of care or a location as part of a laboratory investigation.		
Examples	Blood sample, cervical smear, biopsy sample, sample of meat from a butcher's shop.		
Comments	This class, used by itself describes substances or samples that are not manufactured (e.g. vaccine). For manufactured substances the ManufacturedSpecimen GPIC should be used.		
Related GPICs (optional extensions)		Type of Relationship	Cardinality
PreservationMaterial		Association	0 to many
GeographicLocation (specified in Part 2)		Association	0 or 1
Attributes	O	Type	Description
classCode	M	CS	Fixed value = ENT (entity).

determinerCode	M	CS	Specifies whether the GPIC is describing an actual instance of an object or is providing a generic description of such an object. VALUES INST: - used if the GPIC is describing an actual instance of a specimen; KIND: - used if the GPIC is describing a type or kind of specimen (as when requesting that such a specimen or sample be obtained).
id	O / M	SET<II>	One or more unique identifiers for the specimen. When the attribute determinerCode = INST there shall always be at least one identifier. When the attribute determinerCode = KIND there shall NOT be any accompanying identifiers.
code	O	CV	A code depicting the nature of the specimen. NOTE The nature of the specimen should be identified either by this 'code' attribute (recommended) or the 'desc' attribute, or both. Where both are used, the 'code' attribute shall take primacy in the identification and the 'desc' attribute be considered as providing confirmation or additional information.
desc	O	ED	Used to provide a description of the specimen and/or additional information concerning it.
quantity	O	PQ	The quantity of the specimen limited to the number of objects or the number of containers used to contain the specimen. EXAMPLE Number of blood sample containers. NOTE Other quantities such as volume, mass, height etc. are conveyed using the ObjectCharacteristic GPIC.
existenceCode	O	IVL<TS>	Date and time or period when the specimen was created or collected.
handlingCode	O	SET<CV>	Coded representation of instructions on how the specimen is to be stored and/or handled.
riskCode	O	SET<CV>	A code indicating the existence of a risk or hazard associated with the specimen or the source of the specimen. EXAMPLE HIV status unknown.

7.1.3.3 Specimen GPIC Extensions (Informative)

PreservationMaterial GPIC (3.011) R	
Description	Information about any reagents or other materials used to store and /or preserve the specimen.
Occurrences	Each instance of the Specimen GPIC may be associated with zero to many instances of PreservationMaterial GPIC.
Examples	— A bacteriostatic agent. — A reducing substance (to hinder oxidation). — An anticoagulant.
Comments	When using this extension it should be noted that there is a single Role class shared by two Entity classes. The logic is that the specimen is preserved in a preservation material and the preservation material preserves the specimen. Since we do not need to be explicit, a single Role class instance will suffice for the preserver and preserved, i.e. the Role class within the PreservationMaterial GPIC is shared by two Entities; Specimen and PreservationMaterial. The Role --> typeCode attribute shall be set to PRSV (preservation material) and the semantics to be understood as: <i>'the Specimen Entity is preserved in or with the preservation material'</i>.

GeographicLocation GPIC (specified in prEN 14822-2) R	
Description	Information about a geographical location associated with the specimen.
Occurrences	Each instance of the Specimen GPIC may be associated with zero or one instance of GeographicLocation GPIC.
Examples	Meat cold store, toddler's swimming pool.
Comments	The intention is not to denote where a subject of care is located, but rather a geographic location that is pertinent to the source of the analysable object. This GPIC 'scopes' the instance of Sample GPIC, i.e. the Role class within the GeographicLocation GPIC is shared by two Entities; Specimen described above and the location in the GeographicLocation GPIC. The Role --> typeCode attribute shall be set to PLC (place) and the semantics to be understood as: <i>'the Specimen Entity originated at the geographic location'</i>.

7.1.4 Related Analysable Object

7.1.4.1 General description

GPIC Name		GPIC_ID = 3.004	RL
RelatedAnalysableObject			
Description	Provides a means of linking a specimen or study product to a related specimen or study product.		
External Connection Types	This GPIC may be integrated into other models with the proviso that the connection point is of the generic type (see EN 14822-1:2005, Clause 5): — Role		
UML Representation			
External Interface <pre>classDiagram class GPIC_Core { class RelatedObjectLink { typeCode: CS } class AnalysableObject_GPIC { } RelatedObjectLink "1" -- "1" AnalysableObject_GPIC } GPIC_Core --> ExternalInterface</pre>			

7.1.4.2 Related Analysable Object Core Features

RelatedObjectLink			RL
Description	Specifies the nature of the relationship between the AnalysableObject contained within this GPIC and some other Entity/Role combination.		
Example	Could be used to relate two analysable objects.		
Related GPIC	Type of Relationship	Cardinality	
AnalysableObject	Association	1	

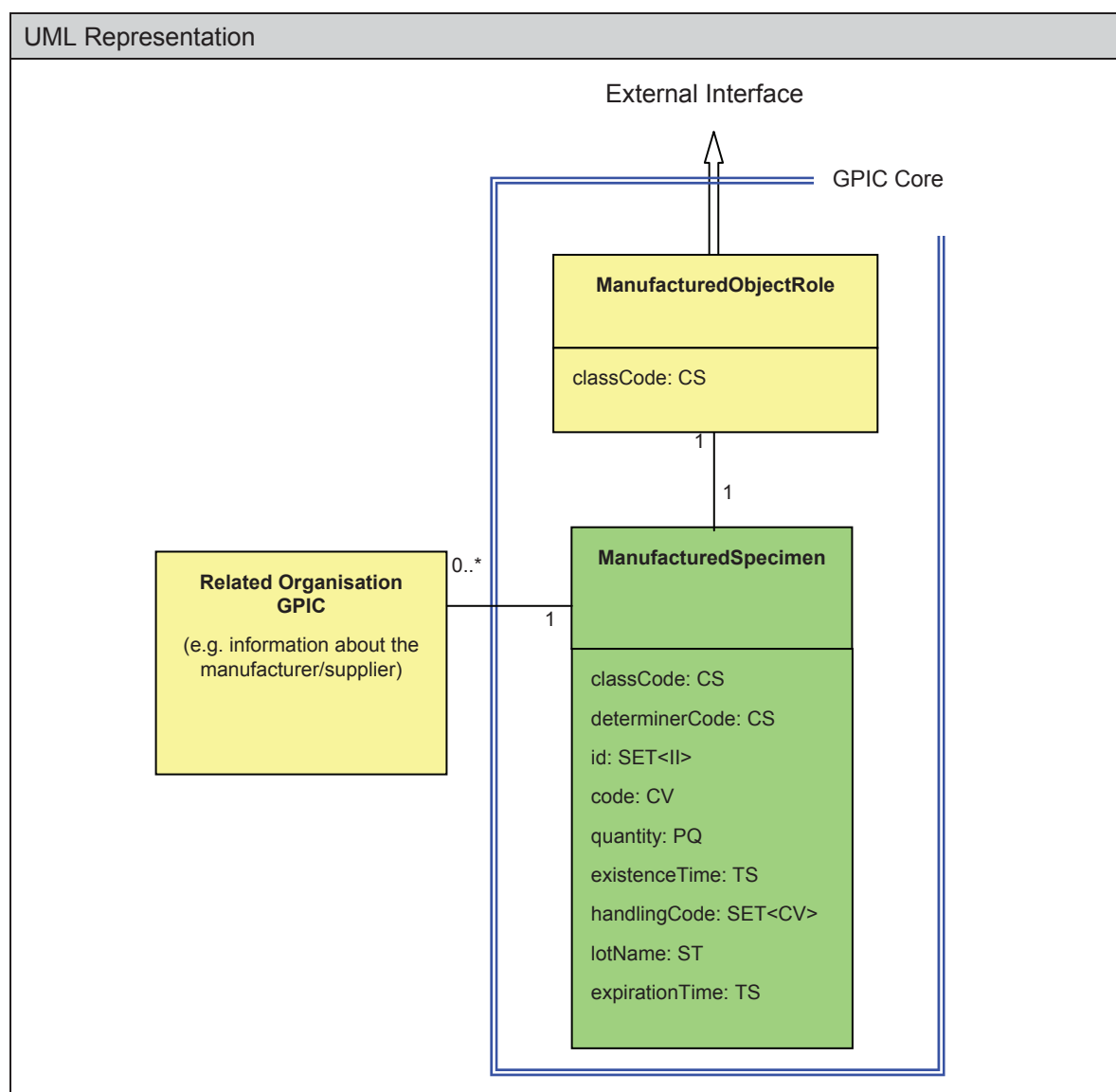
Attribute	O	Type	Description
typeCode	M	CS	Code representing the relationship between Analysable Objects. VALUES — PART (denotes that the second named entity has a 'part of' relationship to the first named entity); — REPL (denotes that the second named entity is replacing the first named entity); — SUCC (denotes that the second named entity is succeeds the first named entity).

AnalysableObject GPIC (3.001) R		
Description	Information about the related analysable object.	
Related Class	Type of Relationship	Cardinality
RelatedObjectLink	Association	1

7.1.5 Manufactured Specimen

7.1.5.1 General description

GPIC Name R	
ManufacturedSpecimen	GPIC_ID = 3.005
Description	Information about a sample of material that is a representative part of a manufactured substance.
External Connection Types	This GPIC may be integrated into other models with the proviso that the connection point is of the generic type (see EN 14822-1:2005, Clause 5): — Participation — Role link
Examples	A sample of vaccine, a sample of blood product.



7.1.5.2 Manufactured Specimen GPIC Core Description

ManufacturedObjectRole R			
Description	Used to provide a Role interface to the GPIC.		
Related Class	Type of Relationship		Cardinality
ManufacturedSpecimen	Association		1
Attributes	O	Type	Description
classCode	M	CS	Fixed value = MANU (Manufactured product).

ManufacturedSpecimen E			
Description	Information about the manufactured specimen.		
Related Class		Type of Relationship	Cardinality
ManufacturedObjectRole		Association	1
Related GPIC (optional extension)		Type of Relationship	Cardinality
RelatedOrganisation (specified in Part 2)		Association	0 to many
Attributes	O	Type	Description
classCode	M	CS	Fixed value = MMAT (manufactured material).
determinerCode	M	CS	Specifies whether the GPIC is describing an actual instance of an object or is providing a generic description of such an object. VALUES INST: - used if the GPIC is describing an actual instance of a manufactured specimen; KIND: - used if the GPIC is describing a type or kind of manufactured specimen.
id	O / M	SET<II>	One or more unique identifiers for the manufactured specimen. When the attribute determinerCode = INST there shall always be at least one identifier. When the attribute determinerCode = KIND there shall NOT be any accompanying identifiers.
code	O	CV	A code depicting the nature of the manufactured specimen.
quantity	O	PQ	The quantity of the manufactured specimen
existenceTime	O	TS	Date and time of the completion of the manufacturing process.
handlingCode	O	SET<CV>	Coded representation of instructions on how the manufactured specimen is to be stored and/or handled.
lotName	O	ST	Used to identify a particular batch of manufactured material. NOTE A lot number is not meant to be a unique identifier, but is meaningful only when the product kind and manufacturer are also identified.
expirationTime	O	TS	The date and time the manufacturer stops ensuring the safety, quality, and/or proper functioning of the material.

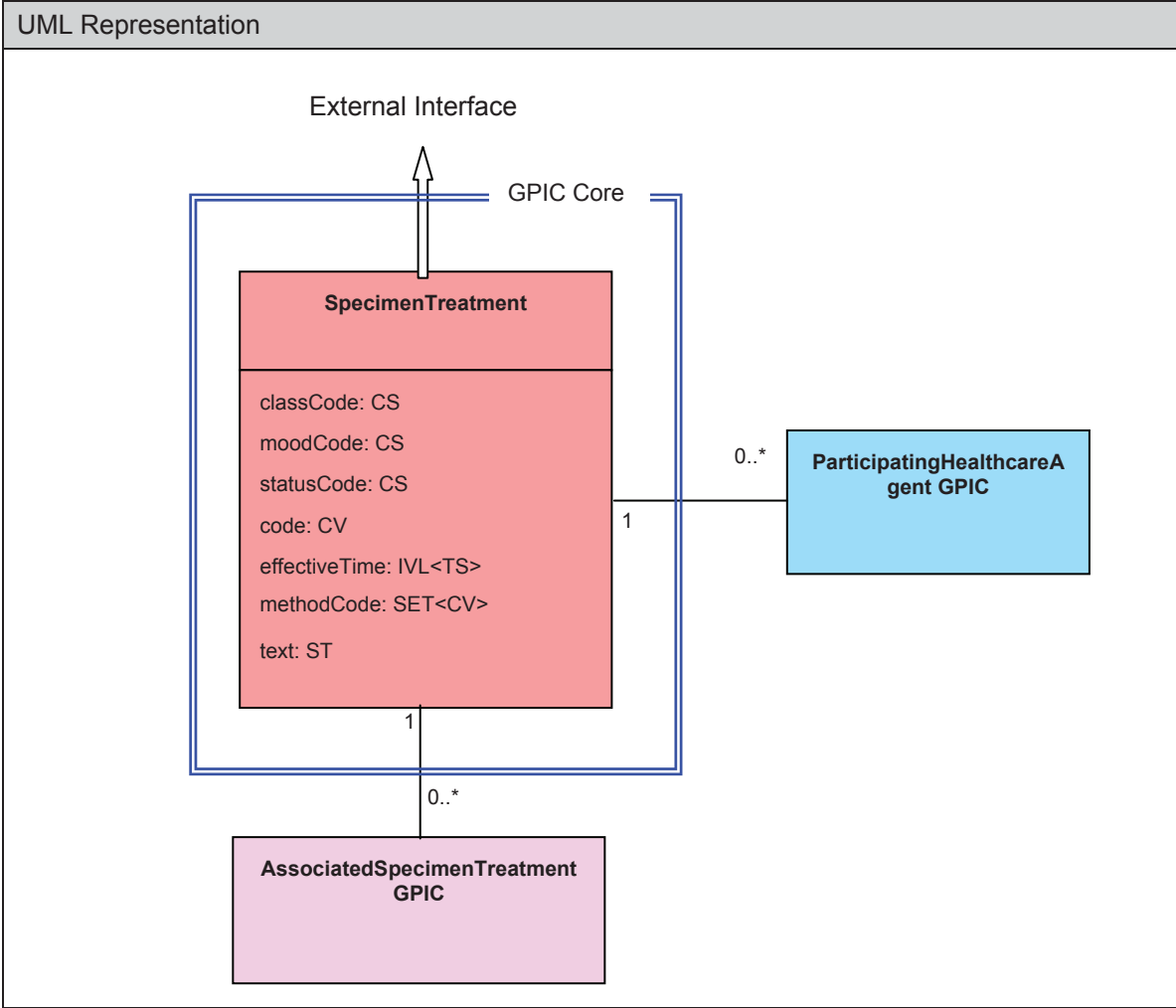
7.1.5.3 Manufactured Specimen GPIC Extension (Informative)

RelatedOrganisation GPIC (specified in EN 14822-2)		R
Description	Information about the manufacturer or supplier of the object or material/specimen.	
Occurrences	Each instance of the ManufacturedSpecimen GPIC may be associated with zero to many instances of RelatedOrganisation GPIC.	
Comments	This GPIC provides a 'scoped role' interface, i.e. the Role class in the RelatedOrganisation GPIC is shared with two Entity classes, the Organisation in that GPIC and the ManufacturedSpecimen in this GPIC. The Role classCode in the RelatedOrganisation shall be set as 'MANU'. The semantics of the linkage is to be taken as: ' <i>ManufacturedSpecimen manufactured by Related Organisation</i> '.	

7.1.6 Specimen Treatment

7.1.6.1 General description

GPIC Name		A
SpecimenTreatment		GPIC_ID = 3.006
Description	Information about any physical or chemical treatment of a specimen.	
External Connection Types	This GPIC may be integrated into other models with the proviso that the connection point is of the generic type (see EN 14822-1:2005, Clause 5): — Act Relationship — Participation	
Examples	Freezing, centrifuging, treatment with a preservation material.	



7.1.6.2 Specimen Treatment GPIC Core Description

SpecimenTreatment				A
Description	Information about a treatment or related set of treatment applied to a specimen.			
Related GPIC (optional extensions)		Type of Relationship	Cardinality	
AssociatedSpecimenTreatment		Association	0 to many	
ParticipatingHealthcareAgent (specified in Part 2)		Association	0 to many	
Attributes	O	Type	Description	
classCode	M	CS	Fixed value = PROC (procedure).	
moodCode	M	CS	A code specifying whether the specimen treatment is an activity that has happened, can happen, is happening, is intended to happen, or is requested/demanded to happen. The code shall be selected from the set specified in 9.2.	

statusCode	O	CS	Code used to specify the status of the specimen treatment. The status is intimately linked to the moodCode above. For example, if the mood is INT (intended activity), the status may be active, cancelled, suspended, etc. A code shall be chosen from the set presented in 9.3.
code	O	CV	A code depicting the nature of the treatment upon the specimen
effectiveTime	O	IVL<TS>	Time interval or period of time during which the treatment process was/is to be carried out.
methodCode	O	SET<CV>	A set of codes describing the method(s) employed during the treatment process.
text	O	ST	Free text description of the treatment or additional notes used to enhance the coded descriptions.

7.1.6.3 Specimen Treatment GPIC Extension (Informative)

AssociatedSpecimenTreatment GPIC (3.008) AR	
Description	Information about any discrete treatments upon a specimen that are relevant and especially those which are linked together sequentially.
Occurrences	Each instance of the SpecimenTreatment GPIC may be associated with zero to many instances of AssociatedSpecimenTreatment GPIC.

ParticipatingHealthcareAgent GPIC (specified in EN 14822-2) R	
Description	Information about any persons, organisations or devices that are relevant to the treatment of the specimen.
Occurrences	Each instance of the SpecimenTreatment GPIC may be associated with zero to many instances of ParticipatingHealthcareAgent GPIC.

7.1.7 Related Specimen Treatment

7.1.7.1 General description

GPIC Name		P
RelatedSpecimenTreatment		GPIC_ID = 3.007
Description	SpecimenTreatment GPIC with a Participation interface.	
External Connection Types	This GPIC may be integrated into other models with the proviso that the connection point is of the generic type (see EN 14822-1:2005, Clause 5): — Role	
Uses	This GPIC permits the specimen treatment to be associated with an actual specimen which will tend to have a Role interface.	
UML Representation		
External Interface <pre>classDiagram class SpecimenTreatmentParticipation { typeCode: CS contextControlCode: CS } class SpecimenTreatmentGPIC["SpecimenTreatment GPIC"] SpecimenTreatmentParticipation "1" -- "1" SpecimenTreatmentGPIC SpecimenTreatmentParticipation --> ExternalInterface</pre>		

7.1.7.2 Related Specimen Treatment GPIC Core Description

SpecimenTreatmentParticipation P			
Description	Used to provide the Participation link.		
Related GPIC		Type of Relationship	Cardinality
SpecimenTreatment		Association	1
Attribute	O	Type	Description
typeCode	M	CS	Fixed value = SPC (specimen).
contextControlCode	O	CS	Code indicating whether this GPIC instance can be inherited by other Acts in addition to the one which the GPIC is directly attached to. A code shall be chosen from the set provided in 9.6.

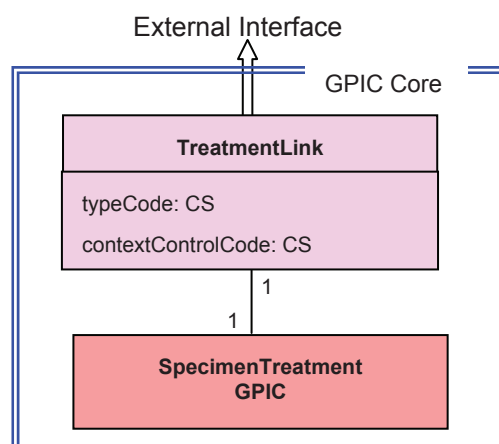
SpecimenTreatment GPIC (3.006) A		
Description	Information about a treatment or related set of treatment applied to a specimen.	
Related Classes (Core)		Type of Relationship
SpecimenTreatmentParticipation		Association
		Cardinality
		1

7.1.8 Associated Specimen Treatment

7.1.8.1 General description

GPIC Name AR	
AssociatedSpecimenTreatment GPIC_ID = 3.008	
Description	SpecimenTreatment GPIC with an Act Relationship interface which provides information about the treatment of a specimen that is related to some other activity, e.g. obtaining the specimen.
External Connection Types	This GPIC may be integrated into other models with the proviso that the connection point is of the generic type (see EN 14822-1:2005, Clause 5): — Act
Use	Used where information about the treatment of a specimen needs to be associated with another action, i.e. obtaining the sample, and especially where a sequential set of treatment procedures are carried out upon a particular specimen.

UML Representation



7.1.8.2 Associated Specimen Treatment GPIC Core Description

TreatmentLink AR			
Description	Used to link the SpecimenTreatment to another act and especially to another specimen treatment procedure.		
Related GPIC		Type of Relationship	Cardinality
SpecimenTreatment		Association	1
Attribute	O	Type	Description
typeCode	M	CS	Fixed value = PERT (pertains to)
contextControlCode	O	CS	Where a number of specimen are similarly treated it is possible to flag that this GPIC instance is inheritable by Acts other than the one associated directly with this GPIC instance. The code value shall be one specified in 9.5.
sequenceNumber	O	INT	May be used to denote the order in a complex sequence of treatment steps.

SpecimenTreatment GPIC (3.006) A		
Description	Information about a treatment or related set of treatment applied to a specimen.	
Related Classes (Core)		Cardinality
TreatmentLink		1

7.1.9 Study Product

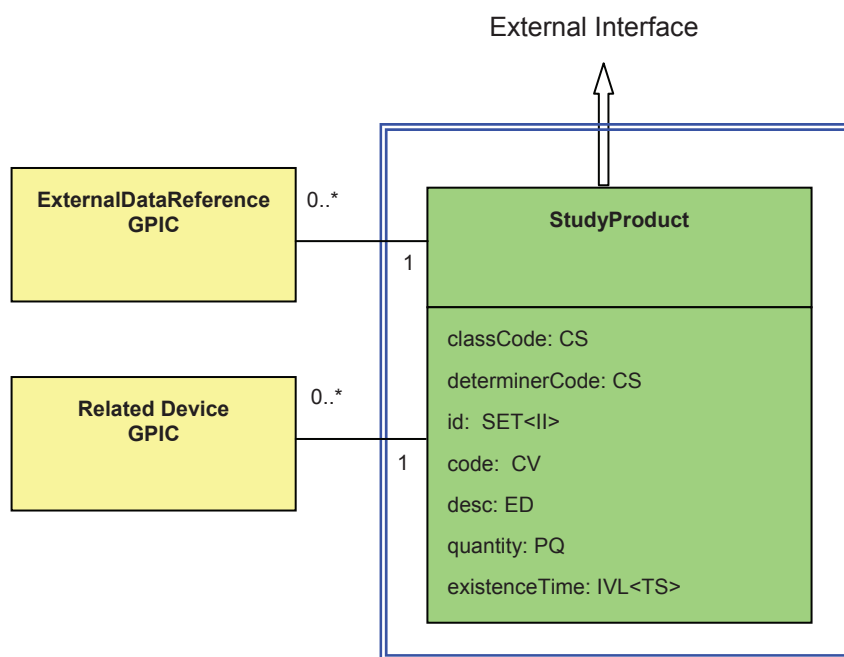
7.1.9.1 General description

GPIC Name		E
StudyProduct		
GPIC_ID = 3.009		
Description	An identifiable record of information derived from a patient as part of a diagnostic service. It may take the form of a physical object or may consist of digital information in an electronic information system.	
External Connection Types	This GPIC may be integrated into other models with the proviso that the connection point is of the generic type (see EN 14822-1:2005, Clause 5): — Role (see especially AnalysableObject GPIC)	
Comments	A study product differs from a specimen in that a specimen is something taken from a patient whereas a study product is a recording of information derived from a patient. A consequence of this distinction is that a study product can be copied. Furthermore, if the study product is represented in a digital form it can be held within or transferred between computer systems.	
Use	1) This GPIC allows a record of a clinical investigation result item to refer to a physical or digital record made during an investigation. 2) This GPIC may be used in the following situations: — In its own right when it is used to specify information concerning a non-manufactured substance without the explicit use of the AnalysableObject class. — As a specialisation of the AnalysableObject class within the AnalysableObject GPIC where the user or application needs to: — leave open the possibility of referring to a specimen or study product; — provide a role interface as provided in the AnalysableObject GPIC (Note that it is possible to restrict the AnalysableObject GPIC so as to only include the possibility of describing study product); — provide links to external GPICs such as ObjectCharacteristic, BodySystem or acquisition details.	
Note	If there is a requirement to relate this study product to other study products, use the RelatedAnalysableObject facility within the AnalysableObject GPIC.	
Examples	An x-ray image, a series of x-ray images, part of an x-ray image (in a digitised form or as a film), an electrocardiograph (ECG) monitor tracing, a twelve lead ECG.	
Additional Associations	By utilising the facilities described in the AnalysableObject GPIC, the Study Product can also be associated with: — Object characteristics. — Body system: i.e. anatomic site or system associated with the study	

product.

- Acquisition information: i.e. how the study product was acquired.
- Related study products.

UML Representation



7.1.9.2 Study Product GPIC Core Description

StudyProduct E			
Description	Information about something derived from or to be derived from a patient as part of a clinical investigation.		
Examples	An x-ray image, a series of x-ray images, part of an x-ray image (in a digitised form or as a film), an electrocardiograph (ECG) monitor tracing, a twelve lead ECG.		
Related Class		Type of Relationship	Cardinality
AnalysableObjectRole		Association	1
Related GPICs (optional extensions)		Type of Relationship	Cardinality
ExternalDataReference		Association	0 to many
RelatedDevice (specified in EN 14822-2)		Association	0 to many
Attributes	O	Type	Description
classCode	M	CS	Fixed value = ENT (entity).

determinerCode	M	CS	Used to specify whether the GPIC is describing an actual instance of an object or is providing a generic description of such an object. VALUES INST: - used if the GPIC is describing an actual instance of study product; KIND: - used if the GPIC is describing a type or kind of study product.
id	O / M	SET<II>	One or more unique identifiers for the study product. When the attribute determinerCode = INST there shall always be at least one identifier. When the attribute determinerCode = KIND there shall NOT be any accompanying identifiers.
code	M	CV	A code depicting the nature of the study product.
desc	O	ED	Used to provide a description of the study product and/or additional information concerning it.
quantity	O	PQ	The quantity of the study product limited to the number of such objects. EXAMPLE Number of x-ray films.
existenceTime	O	IVL<TS>	Date and time or period during which the study product was created.

7.1.9.3 Study Product GPIC Extensions (Informative)

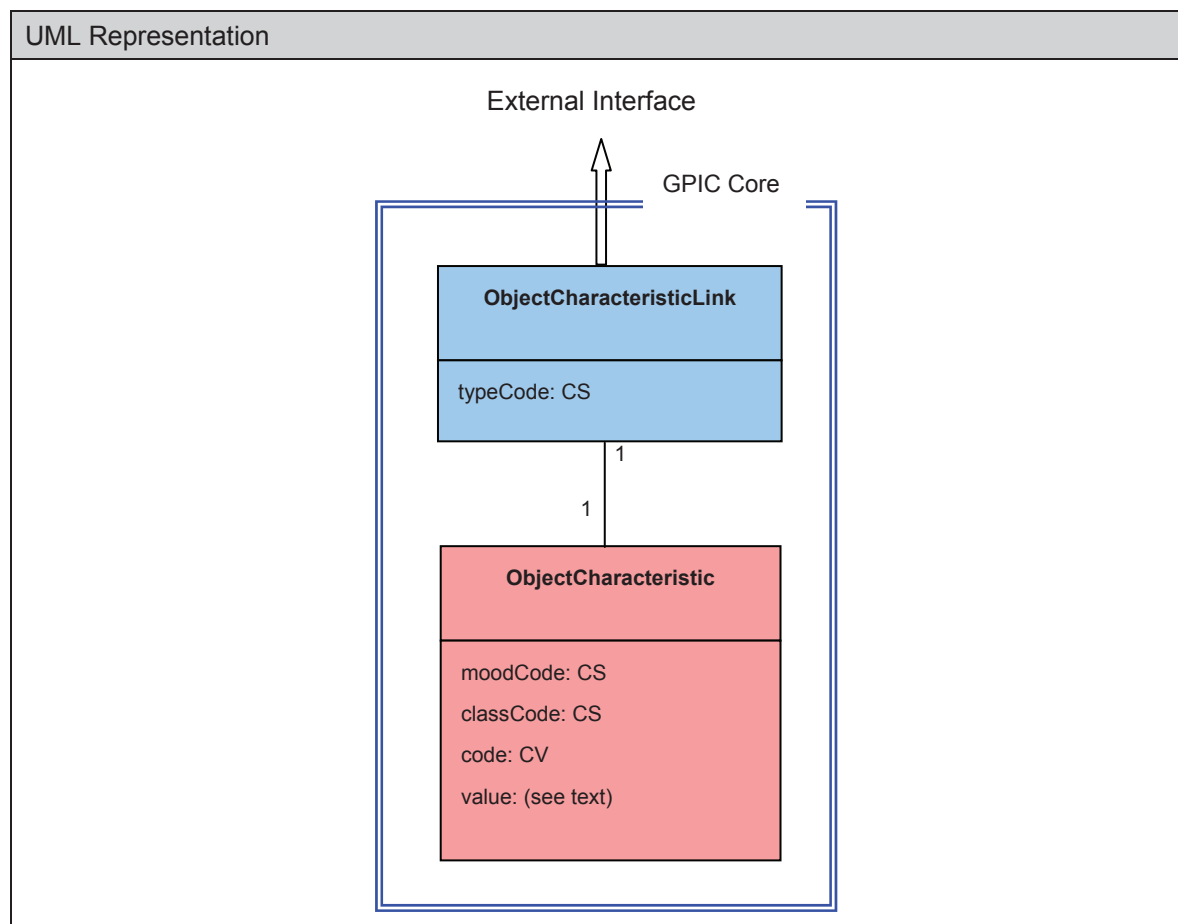
ExternalDataReference GPIC (3.016) R	
Description	Reference to external information that supports or constitutes a study product and which is stored in digital form.
Occurrences	Each instance of the StudyProduct GPIC may be associated with zero to many instances of ExternalDataReference GPIC.
Comments	A digital representation of an image such as an x-ray or an electrocardiograph may be stored on, or transferred between, computer systems in a manner that makes it accessible to communicating parties. A communication may contain no information about the format of the digital information. The use of the reference pointers requires that the communicating parties have a shared understanding of the information types referred to. This GPIC provides a 'scoped role' interface, i.e. The Role class in the ExternalDataReference GPIC is shared with two Entity classes. The Role.classCode in the ExternalDataReference shall be set as CONT (content). The semantics of the linkage is to be taken as: '<i>Study Product represented by data content at External Data Reference</i>'.

RelatedDevice GPIC (specified in EN 14822-2) R	
Description	Information about a device or other equipment used in the process of acquiring the StudyProduct.
Occurrences	Each instance of the StudyProduct GPIC may be associated with zero to many instances of RelatedDevice GPIC.
Examples	Equipment used to produce: — an x-ray image; — an electrocardiograph (ECG) monitor tracing; — a twelve lead ECG.
Comments	This GPIC provides a 'scoped role' interface, i.e. The Role class in the RelatedDevice GPIC is shared with two Entity classes. The Role.classCode in the ExternalDataReference shall be set as DEV (Device). The semantics of the linkage is to be taken as: <i>'Study Product captured using Related Device'</i> .

7.1.10 Object Characteristic

7.1.10.1 General description

GPIC Name P	
ObjectCharacteristic GPIC_ID = 3.010	
Description	Information about a measurement made upon, or a measurement parameter of a specimen or study product.
External Connection Types	This GPIC may be integrated into other models with the proviso that the connection point is of the generic type (see EN 14822-1:2005, Clause 5): — Role
Examples	The volume of a urine sample, the size of a biopsy sent for histology, the volume of aspirate sent for cytology.



7.1.10.2 ObjectCharacteristic GPIC Core Classes

ObjectCharacteristicLink P				
Description	Used to link the characteristic to object that it is associated with.			
Related Class		Type of Relationship		Cardinality
ObjectCharacteristic		Association		1
Attributes	O	Type	Description	
typeCode	M	CS	Fixed value = SUB (subject).	

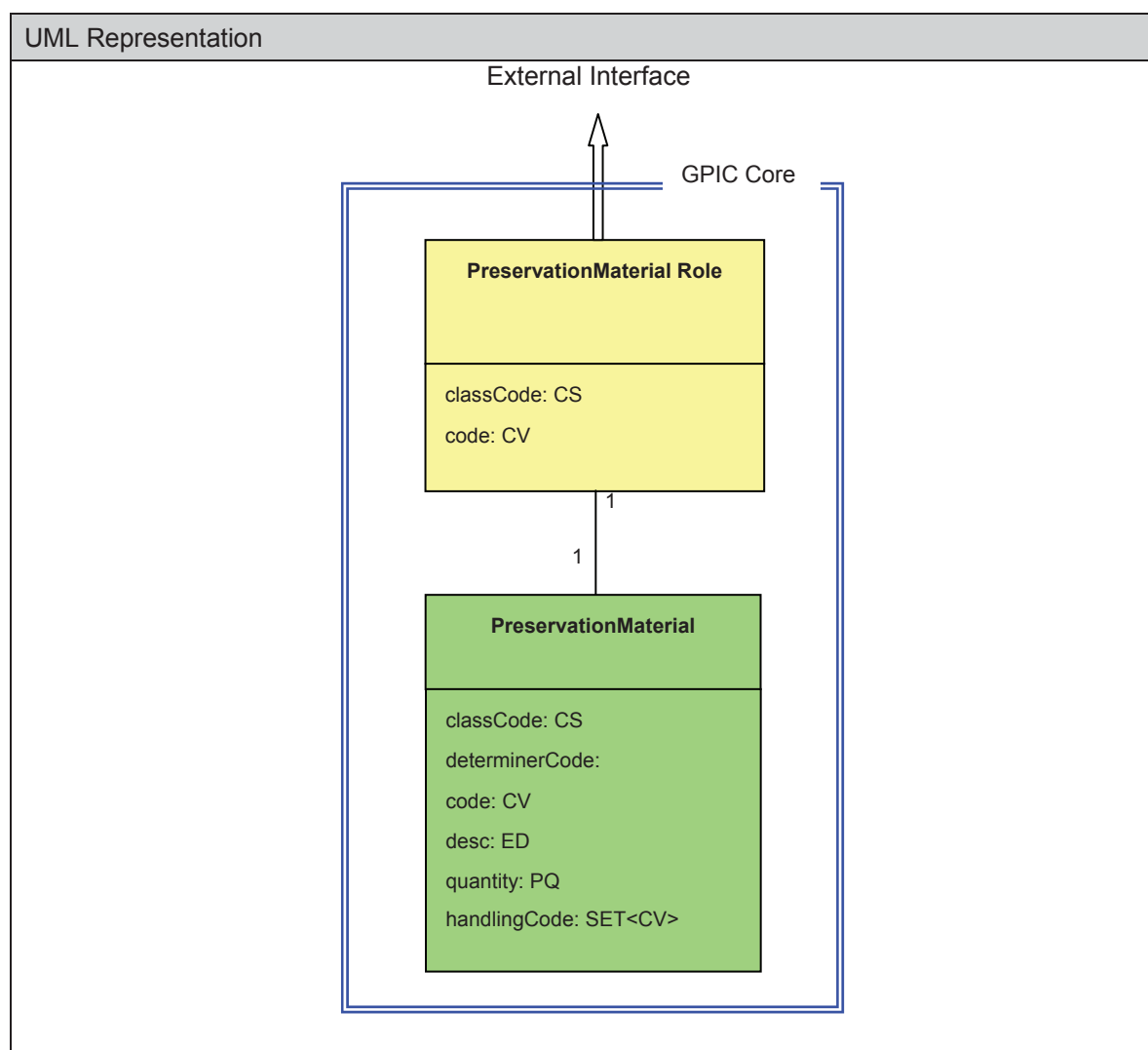
ObjectCharacteristic A				
Description	Identifies a type of characteristic and the value(s) that apply.			
Examples	The size of a biopsy sent for histology, the volume of aspirate sent for cytology, the length of an ECG tracing.			
Related Class		Type of Relationship		Cardinality
ObjectCharacteristicLink		Association		1

Attributes	O	Type	Description
moodCode	M	CS	Fixed value = EVN (event).
classCode	M	CS	Fixed value = OBS (observation).
code	M	CV	Used to describe the aspect of the object that is being described. EXAMPLES Length, height, dilution, volume, circumference, mass, colour.
value	M	Various (subset of ALL)	The values associated with the characteristic parameter shall be one of the following types: — PQ — IVL<PQ> — CV — ST

7.1.11 Preservation Material

7.1.11.1 General description

GPIC Name		R
PreservationMaterial		
GPIC_ID = 3.011		
Description	Information about a material or substance that is used in order to preserve a specimen or body part.	
External Connection Types	This GPIC may be integrated into other models with the proviso that the connection point is of the generic type (see EN 14822-1:2005, Clause 5): — Participation (the most common connection type) — Role link	



7.1.11.2 Preservation Material GPIC Core Classes

PreservationMaterialRole R			
Description	Used to link the preservation material details to details of the specimen or activities related to the specimen or body part.		
Related Class		Type of Relationship	Cardinality
PreservationMaterial		Association	1
Attribute	O	Type	Description
classCode	M	CS	Fixed value = INST (instantiates).

code	O	CV	A code representing the role that is played by the preservation material. EXAMPLES — Bacteriostatic agent; — reducing substance; — anticoagulant.
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PreservationMaterial				E
Description	Used to supply details of any substance used to preserve an analysable object or body part.			
Related Classes		Type of Relationship		Cardinality
PreservationMaterialRole		Association		1
Attribute	O	Type	Description	
classCode	M	CS	Fixed value = MMAT (manufactured material).	
determinerCode	M	CS	Fixed value = KIND (a kind of material).	
code	O	CV	Code used to identify the substance used in the preservation of the specimen. Each instance of PreservationMaterial shall identify the type of the preservation material by use of this attribute (preferred) OR the 'desc' attribute OR both. Where both are used, the 'desc' attribute shall be used to provide additional information about the preservation material.	
desc	O	ED	Used to describe or to provide additional information about the preservation material.	
quantity	O	PQ	The quantity of preservation material used.	
handlingCode	O	SET<CV>	A code to describe how the material needs to be handled or has been handled to avoid damage to the preserved object(s). Examples include: Keep at room temperature; Keep frozen below 0 C; Keep in a dry environment; Keep upright, do not turn upside down.	