HL7 CDA® R2 Implementation Guide:
C-CDA Templates for Clinical Notes R2.1 Companion Guide

Release 2 (US Realm)

Standard for Trial Use

October 2019
October 2021 Errata Version

Appendix B: UDI Organizer template from C-CDA Supplemental Templates for Unique Device Identifier (UDI)

Sponsored by:
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Logical Observation Identifiers Names & Codes (LOINC)	Regenstrief Institute
International Classification of Diseases (ICD) codes	World Health Organization (WHO)
NUCC Health Care Provider Taxonomy code set	American Medical Association. Please see www.nucc.org. AMA licensing contact: 312-464-5022 (AMA IP services)

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1 ENTRY

1.1 UDI Organizer

```
[organizer: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.311:2019-06-21
(open)]
```

Table 1: UDI Organizer Contexts

Contained By:	Contains:
	Distinct Identification Code Observation (optional) Serial Number Observation (optional) Expiration Date Observation (optional) Brand Name Observation (optional) Model Number Observation (optional) Device Identifier Observation (required) Catalog Number Observation (optional) Company Name Observation (optional) Lot or Batch Number Observation (optional) Manufacturing Date Observation (optional) MRI Safety Observation (optional) Latex Safety Observation (optional) Implantable Device Status Observation (optional)

This template is nested in an entryRelationship/Procedure Activity Procedure to record all the UDI-related templates to exchange the parsed UDI data elements and associated data.

- **Device Identifier**
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.304: 2019-06-21 NCIt: C101722 SHALL be included in UDI Organizer

- **Lot or Batch Number**
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.315: 2019-06-21 NCIt:C101672 SHOULD be included in UDI Organizer if present in UDI

- **Serial Number**
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.319: 2019-06-21 NCIt: C101671 SHOULD be included in UDI Organizer if present in UDI

- **Manufacturing Date**
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.316: 2019-06-21 NCIt:C101669 SHOULD be included in UDI Organizer if present in UDI

- **Expiration Date**
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.309: 2019-06-21 NCIt: C101670 SHOULD be included in UDI Organizer if present in UDI

- **Distinct Identification Code**
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.308: 2019-06-21 NCIt: C113843 SHOULD be included in UDI Organizer if present in UDI

- **Brand Name**
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.301: 2019-06-21 NCIt: C71898 MAY be included in the UDI Organizer if available

- **Model Number**
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.317: 2019-06-21 NCIt: C99285 MAY be included in the UDI Organizer if available

- **Catalog Number**
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.302: 2019-06-21 NCIt: C99286 MAY be included in the UDI Organizer if available

- **Company Name**
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.303: 2019-06-21   NCIt: C54131 MAY be included in the UDI Organizer if available

- **MRI Safety**
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.318: 2019-06-21 NCIt: C106044 MAY be included in the UDI Organizer if available

- **Latex Safety**
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.314: 2019-06-21 NCIt: C160938 MAY be included in the UDI Organizer if available

- **Implantable Device Status**
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.305 2019-06-21 NCIt: C160939 MAY be included in the UDI Organizer if available

Table 2: UDI Organizer Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
organizer (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.311:2019-06-21)					
@classCode	1..1	SHALL		4437-3482	CLUSTER
@moodCode	1..1	SHALL		4437-3483	EVN
templateId	1..1	SHALL		4437-3480	
@root	1..1	SHALL		4437-3484	2.16.840.1.113883.10.20.22.4.311
@extension	1..1	SHALL		4437-3485	2019-06-21
id	1..1	SHALL		4437-3541	
@root	1..1	SHALL		4437-3542	
code	0..1	MAY		4437-3481	
@code	0..1	MAY		4437-3486	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 74711-3
@codeSystem	1..1	SHALL		4437-3487	2.16.840.1.113883.6.1
statusCode	1..1	SHALL		4437-3490	
@code	1..1	SHALL		4437-3543	urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed
component	1..1	SHALL		4437-3488	
observation	1..1	SHALL		4437-3489	Device Identifier Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2019-06-21)
component	0..1	SHOULD		4437-3513	
observation	1..1	SHALL		4437-3514	Lot or Batch Number Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.315:2019-06-21)
component	0..1	SHOULD		4437-3515	
observation	1..1	SHALL		4437-3516	Serial Number Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.319:2019-06-21)
component	0..1	SHOULD		4437-3517	

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XPath	Card.	Verb	Data Type	CONF#	Value
observation	1..1	SHALL		[4437-3518](#)	Manufacturing Date Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.316:2019-06-21)
component	0..1	SHOULD		[4437-3525](#)	
observation	1..1	SHALL		[4437-3526](#)	Expiration Date Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.309:2019-06-21)
component	0..1	SHOULD		[4437-3523](#)	
observation	1..1	SHALL		[4437-3524](#)	Distinct Identification Code Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.308:2019-06-21)
component	0..1	MAY		[4437-3521](#)	
observation	1..1	SHALL		[4437-3522](#)	Brand Name Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.301:2019-06-21)
component	0..1	MAY		[4437-3519](#)	
observation	1..1	SHALL		[4437-3520](#)	Model Number Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.317:2019-06-21)
component	0..1	MAY		[4437-3535](#)	
observation	1..1	SHALL		[4437-3536](#)	Company Name Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21)
component	0..1	MAY		[4437-3527](#)	
observation	1..1	SHALL		[4437-3528](#)	Catalog Number Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21)
component	0..1	MAY		[4437-3529](#)	
observation	1..1	SHALL		[4437-3530](#)	Latex Safety Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-21)
component	0..1	MAY		[4437-3533](#)	

XPath	Card.	Verb	Data Type	CONF#	Value
observation	1..1	SHALL		4437-3534	MRI Safety Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.318:2019-06-21
component	0..1	MAY		4437-3531	
observation	1..1	SHALL		4437-3532	Implantable Device Status Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21

1.1.1 Properties

1.1.1.1 @classCode

The UDI Organizer contains the parsed components of the UDI included in the Product Instance.

1. **SHALL** contain exactly one [1..1] **@classCode**="CLUSTER" (CONF:4437-3482).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CONF:4437-3483).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3480) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.311" (CONF:4437-3484).

Revision from "2018-05-01".

   b. **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3485).

The UDI Organizer identifier shall match the Product Instance identifier value. The identifier will tie the specific UDI information to an individual product instance.

4. **SHALL** contain exactly one [1..1] **id** (CONF:4437-3541).
   a. This id **SHALL** contain exactly one [1..1] **@root** (CONF:4437-3542).
5. **MAY** contain zero or one [0..1] **code** (CONF:4437-3481).
   a. The code, if present, **MAY** contain zero or one [0..1] **@code**="74711-3" Unique Device Identifier (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:4437-3486).
   b. The code, if present, **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CONF:4437-3487).

This is the status of the UDI Organizer. The value if fixed to "completed".

6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:4437-3490).
   a. This statusCode **SHALL** contain exactly one [1..1] **@code**="completed" Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4437-3543).

Device Identifier - the mandatory part of the UDI

7. **SHALL** contain exactly one [1..1] **component** (CONF:4437-3488) such that it

   a. **SHALL** contain exactly one [1..1] **Device Identifier Observation** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2019-06-21) (CONF:4437-3489).

Lot or Batch Number - needed if present as a production identifier

8. **SHOULD** contain zero or one [0..1] **component** (CONF:4437-3513) such that it

   a. **SHALL** contain exactly one [1..1] **Lot or Batch Number Observation** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.315:2019-06-21) (CONF:4437-3514).

Serial Number - needed if present as a production identifier

9. **SHOULD** contain zero or one [0..1] **component** (CONF:4437-3515) such that it

   a. **SHALL** contain exactly one [1..1] **Serial Number Observation** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.319:2019-06-21) (CONF:4437-3516).

Manufacturing Date - needed if present as a production identifier

10. **SHOULD** contain zero or one [0..1] **component** (CONF:4437-3517) such that it

   a. **SHALL** contain exactly one [1..1] **Manufacturing Date Observation** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.316:2019-06-21) (CONF:4437-3518).

Expiration Date - needed if present as a production identifier

11. **SHOULD** contain zero or one [0..1] **component** (CONF:4437-3525) such that it

   a. **SHALL** contain exactly one [1..1] **Expiration Date Observation** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.309:2019-06-21) (CONF:4437-3526).

Distinct Identification Code - needed if present as a production identifier for HCT/P regulated as medical devices.

12. **SHOULD** contain zero or one [0..1] **component** (CONF:4437-3523) such that it

   a. **SHALL** contain exactly one [1..1] **Distinct Identification Code Observation** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.308:2019-06-21) (CONF:4437-3524).

Brand Name - when it was extracted from accessGUDID at the time the information was entered in the patient's record.

13. **MAY** contain zero or one [0..1] **component** (CONF:4437-3521) such that it

   a. **SHALL** contain exactly one [1..1] **Brand Name Observation** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.301:2019-06-21) (CONF:4437-3522).

Model Number - when it was extracted from accessGUDID at the time the information was entered in the patient's record.

14. **MAY** contain zero or one [0..1] **component** (CONF:4437-3519) such that it

      a. **SHALL** contain exactly one [1..1] **Model Number Observation** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.317:2019-06-21) (CONF:4437-3520).

Company Name - the name of the company that manufactured the device when it was extracted from accessGUDID at the time the information was entered in the patient's record.

15. **MAY** contain zero or one [0..1] **component** (CONF:4437-3535) such that it

      a. **SHALL** contain exactly one [1..1] **Company Name Observation** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21) (CONF:4437-3536).

Catalog Number - specified by manufacturer or when it was extracted from accessGUDID at the time the information was entered in the patient's record.

16. **MAY** contain zero or one [0..1] **component** (CONF:4437-3527) such that it

      a. **SHALL** contain exactly one [1..1] **Catalog Number Observation** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21) (CONF:4437-3528).

Latex Safety Status when it was extracted from accessGUDID at the time the information was entered in the patient's record.

17. **MAY** contain zero or one [0..1] **component** (CONF:4437-3529) such that it

      a. **SHALL** contain exactly one [1..1] **Latex Safety Observation** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-21) (CONF:4437-3530).

MRI Safety Status when it was extracted from accessGUDID at the time the information was entered in the patient's record.

18. **MAY** contain zero or one [0..1] **component** (CONF:4437-3533) such that it

      a. **SHALL** contain exactly one [1..1] **MRI Safety Observation** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.318:2019-06-21) (CONF:4437-3534).

Implantable Device Status - the status of the device in the body of the patient, it augments the information in **@status.**

19. **MAY** contain zero or one [0..1] **component** (CONF:4437-3531) such that it

      a. **SHALL** contain exactly one [1..1] **Implantable Device Status Observation** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21) (CONF:4437-3532).

Figure 1: Unique Device Identifier (UDI) Organizer

```
<!-- UDI Organizer -->
<organizer classCode="CLUSTER" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.22.4.311"
        extension="2019-06-21"/>
    <id assigningAuthorityName="FDA"
extension="(01)99994328998989(11)160330(10)ABC124(17)200712(21)2302991ABC210181"
root="GS1"/>
    <code code="74711-3" codeSystem="2.16.840.1.113883.6.1"
        displayName="Unique Device Identifier"/>
    <statusCode code="completed"/>
    <!-- UDI components -->
    <component>
        <observation classCode="OBS" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.22.4.304"
                extension="2019-06-21"/>
            <code code="C101722" displayName="Primary DI Number"
                codeSystem="2.16.840.1.113883.3.26.1.1"
                codeSystemName="NCI Thesaurus"/>
            <!-- GS1 Device Identifier -->
            <value xsi:type="II" root="1.3.160"
                extension="99994328998989" displayable="true"
                assigningAuthorityName="GS1"/>
        </observation>
    </component>
    <component>
        <observation classCode="OBS" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.22.4.315"
                extension="2019-06-21"/>
            <code code="C101672" displayName="Lot or Batch Number"
                codeSystem="2.16.840.1.113883.3.26.1.1"
                codeSystemName="NCI Thesaurus"/>
            <value xsi:type="ED">
                <reference value="#LotOrBatchNumber_1"/>
            </value>
        </observation>
    </component>
    <component>
        <observation classCode="OBS" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.22.4.319"
                extension="2019-06-21"/>
            <code code="C101671" displayName="Serial Number"
                codeSystem="2.16.840.1.113883.3.26.1.1"
                codeSystemName="NCI Thesaurus"/>
            <value xsi:type="ED">
                <reference value="#SerialNumber_1"/>
            </value>
        </observation>
    </component>
    <component>
        <observation classCode="OBS" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.22.4.316"
                extension="2019-06-21"/>
            <code code="C101669" displayName="Manufacturing Date"
                codeSystem="2.16.840.1.113883.3.26.1.1"
                codeSystemName="NCI Thesaurus"/>
```

```xml
                    <value xsi:type="TS" value="20181015"/>
            </observation>
        </component>
        <component>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.22.4.309"
                    extension="2019-06-21"/>
                <code code="C101670" displayName="Expiration Date"
                    codeSystem="2.16.840.1.113883.3.26.1.1"
                    codeSystemName="NCI Thesaurus"/>
                <value xsi:type="TS" value="20221015"/>
            </observation>
        </component>
        <component>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.22.4.308"
                    extension="2019-06-21"/>
                <code code="C113843"
                    displayName="Distinct Identification Code"
                    codeSystem="2.16.840.1.113883.3.26.1.1"
                    codeSystemName="NCI Thesaurus"/>
                <value xsi:type="ED">
                    <reference value="#DistinctIdentificationCode_1"/>
                </value>
            </observation>
        </component>
        <component>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.22.4.301"
                    extension="2019-06-21"/>
                <code code="C71898" displayName="Brand Name"
                    codeSystem="2.16.840.1.113883.3.26.1.1"
                    codeSystemName="NCI Thesaurus"/>
                <value xsi:type="ED">
                    <reference value="#BrandName_1"/>
                </value>
            </observation>
        </component>
        <component>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.22.4.317"
                    extension="2019-06-21"/>
                <code code="C99285" displayName="Model Number"
                    codeSystem="2.16.840.1.113883.3.26.1.1"
                    codeSystemName="NCI Thesaurus"/>
                <value xsi:type="ED">
                    <reference value="#ModelNumber_1"/>
                </value>
            </observation>
        </component>
        <component>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.22.4.302"
                    extension="2019-06-21"/>
                <code code="C99286" displayName="Catalog Number"
                    codeSystem="2.16.840.1.113883.3.26.1.1"
                    codeSystemName="NCI Thesaurus"/>
```

```
                <value xsi:type="ED">
                    <reference value="#CatalogNumber_1"/>
                </value>
            </observation>
        </component>
        <component>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.22.4.303"
                    extension="2019-06-21"/>
                <code code="C54131" displayName="Company Name"
                    codeSystem="2.16.840.1.113883.3.26.1.1"
                    codeSystemName="NCI Thesaurus"/>
                <value xsi:type="ED">
                    <reference value="#CompanyName_1"/>
                </value>
            </observation>
        </component>
        <component>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.22.4.318"
                    extension="2019-06-21"/>
                <code code="C106044" displayName="MRI Safety Status"
                    codeSystem="2.16.840.1.113883.3.26.1.1"
                    codeSystemName="NCI Thesaurus"/>
                <value xsi:type="CD" code="C113844"
                    codeSystem="2.16.840.1.113883.3.26.1.1" displayName="Labeling does not
contain MRI Safety Information"
                    codeSystemName="NCI Thesaurus"
sdtc:valueSet="2.16.840.1.113762.1.4.1021.46">
                    <originalText>
                        <reference value="#MRISafety_1"/>
                    </originalText>
                </value>
            </observation>
        </component>
        <component>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.22.4.314"
                    extension="2019-06-21"/>
                <code code="C160938" displayName="Latex Safety Status"
                    codeSystem="2.16.840.1.113883.3.26.1.1"
                    codeSystemName="NCI Thesaurus"/>
                <value xsi:type="CD" code="C106038"
                    codeSystem="2.16.840.1.113883.3.26.1.1" displayName="Not Made with Natural
Rubber Latex"
                    codeSystemName="NCI Thesaurus"
sdtc:valueSet="2.16.840.1.113762.1.4.1021.47">
                    <originalText>
                        <reference value="#LatexSafety_1"/>
                    </originalText>
                </value>
            </observation>
        </component>
        <component>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.22.4.305"
                    extension="2019-06-21"/>
```

```
            <code code="C160939" displayName="Implantable Device Status"
                codeSystem="2.16.840.1.113883.3.26.1.1"
                codeSystemName="NCI Thesaurus"/>
            <value xsi:type="CD" code="C160942"
                codeSystem="2.16.840.1.113883.3.26.1.1" displayName="Reduced Function"
                codeSystemName="NCI Thesaurus"
sdtc:valueSet="2.16.840.1.113762.1.4.1021.48">
                <originalText>
                    <reference value="#ImplantableDeviceStatus_1"/>
                </originalText>
            </value>
        </observation>
    </component>
</organizer>
```

2   SUBENTRY

2.1   *Brand Name Observation*

```
[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.301:2019-06-
21 (open)]
```

Table 3: Brand Name Observation Contexts

Contained By:	Contains:
UDI Organizer (optional)	

This template is intended to be used in addition to the **Product Instance** template urn:oid:2.16.840.1.113883.10.20.22.4.37 to exchange the **Brand Name**. The UDI-DI of the medical device may be used to retrieve the **Brand Name** in accessGUDID, which should be considered the source of truth.

Table 4: Brand Name Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.301:2019-06-21)					
templateId	1..1	SHALL		4437-3403	
@root	1..1	SHALL		4437-3405	2.16.840.1.113883.10.20.22.4.301
@extension	1..1	SHALL		4437-3406	2019-06-21
code	1..1	SHALL		4437-3404	
@code	1..1	SHALL		4437-3407	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C71898
@codeSystem	1..1	SHALL		4437-3408	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3409	NCI Thesaurus
@displayName	0..1	MAY		4437-3410	Brand Name
value	1..1	SHALL	ED	4437-3411	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3403).
   a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.301" (CONF:4437-3405).
      Note: template oid

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   b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3406).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3404).
   Note: Code for "Device Brand Name"

Code used to specify the **Brand Name**.

   a. This code **SHALL** contain exactly one [1..1] **@code**="C71898" Brand Name (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3407).
   b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3408).
   c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3409).
   d. This code **MAY** contain zero or one [0..1] **@displayName**="Brand Name" (CONF:4437-3410).

The Brand Name can point to its corresponding narrative using the approach defined in CDA Release 2, section 4.3.5.1.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="ED" (CONF:4437-3411).

Figure 2: Brand Name Example

```
<observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.22.4.301" extension="2019-06-21"/>
    <code code="C71898" displayName="Brand Name"
          codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
    <value xsi:type="ED">
        <reference value="#BrandName_1"/>
    </value>
</observation>
```

2.2   Catalog Number Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21 (open)]

Table 5: Catalog Number Observation Contexts

Contained By:	Contains:
UDI Organizer (optional)	

This template is intended to be used in addition to the **Product Instance** template urn:oid:2.16.840.1.113883.10.20.22.4.37 to exchange the **Catalog Number**. The UDI-DI of the medical device may be used to retrieve the Catalog Number in accessGUDID, which should be considered the source of truth.

Table 6: Catalog Number Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21)					
templateId	1..1	SHALL		4437-3432	
@root	1..1	SHALL		4437-3434	2.16.840.1.113883.10.20.22.4.302
@extension	1..1	SHALL		4437-3435	2019-06-21
code	1..1	SHALL		4437-3433	
@code	1..1	SHALL		4437-3436	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C99286
@codeSystem	1..1	SHALL		4437-3437	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3438	NCI Thesaurus
@displayName	0..1	MAY		4437-3439	Catalog Number
value	1..1	SHALL	ED	4437-3440	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3432).
   a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.302" (CONF:4437-3434).
   Note: template oid

Revision from "2018-05-01".

   b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3435).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3433).
   Note: Code for "Device Catalog Number"

Code used to specify the **Catalog Number**.

   a. This code **SHALL** contain exactly one [1..1] **@code**="C99286" Catalog Number (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3436).
   b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3437).
   c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3438).
   d. This code **MAY** contain zero or one [0..1] **@displayName**="Catalog Number" (CONF:4437-3439).

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The Catalog Number can point to its corresponding narrative using the approach defined in CDA Release 2, section 4.3.5.1.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="ED" (CONF:4437-3440).

Figure 3: Catalog Number Sample

```
<observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.22.4.302" extension="2019-06-21"/>
    <code code="C99286" displayName="Catalog Number"
        codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
    <value xsi:type="ED">
       <reference value="#CatalogNumber_1"/>
    </value>
  </observation>
```

2.3 Company Name Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21 (open)]

Table 7: Company Name Observation Contexts

Contained By:	Contains:
UDI Organizer (optional)	

This template is intended to be used in addition to the **Product Instance** template urn:oid:2.16.840.1.113883.10.20.22.4.37 to exchange the **Company Name**. The UDI-DI of the medical device may be used to retrieve the **Company Name** in accessGUDID, which should be considered the source of truth.

Table 8: Company Name Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21)					
templateId	1..1	SHALL		4437-3441	
@root	1..1	SHALL		4437-3443	2.16.840.1.113883.10.20.22.4.303
@extension	1..1	SHALL		4437-3444	2019-06-21
code	1..1	SHALL		4437-3442	
@code	1..1	SHALL		4437-3445	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C54131
@codeSystem	1..1	SHALL		4437-3446	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3447	NCI Thesaurus
@displayName	0..1	MAY		4437-3448	Company Name
value	1..1	SHALL	ED	4437-3449	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3441).
   a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.303" (CONF:4437-3443).
      Note: template oid

   Revision from "2018-05-01".

   b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3444).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3442).
   Note: Code for "Company Name"

   Code used to specify the **Company Name**.

   a. This code **SHALL** contain exactly one [1..1] **@code**="C54131" Company Name (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3445).
   b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3446).
   c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3447).
   d. This code **MAY** contain zero or one [0..1] **@displayName**="Company Name" (CONF:4437-3448).

The Company Name can point to its corresponding narrative using the approach defined in CDA Release 2, section 4.3.5.1.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="ED" (CONF:4437-3449).

Figure 4: Company Name

```
<observation classCode="OBS" moodCode="EVN">
   <templateId root="2.16.840.1.113883.10.20.22.4.303" extension="2019-06-21"/>
   <code code="C54131" displayName="Company Name"
      codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
   <value xsi:type="ED">
      <reference value="#CompanyName_1"/>
   </value>
</observation>
```

2.4   Device Identifier Observation

```
[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2019-06-21 (open)]
```

Table 9: Device Identifier Observation Contexts

Contained By:	Contains:
UDI Organizer (required)	

This template is intended to be used in addition to the **Product Instance** template urn:oid:2.16.840.1.113883.10.20.22.4.37 to exchange the **Device Identifier** (also known as the "Primary DI Number") for a medical device marketed in the US. The device identifier is parsed from the UDI value.

The Device Identifier number can be used as a key to look-up device identification information in the publicly available version of the US FDA Global UDI Database (GUDID) - the AccessGUDID: **https://accessgudid.nlm.nih.gov/resources/home**

Table 10: Device Identifier Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2019-06-21)					
templateId	1..1	SHALL		4437-3421	
@root	1..1	SHALL		4437-3424	2.16.840.1.113883.10.20.22.4.304
@extension	1..1	SHALL		4437-3425	2019-06-21
code	1..1	SHALL		4437-3422	
@code	1..1	SHALL		4437-3426	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101722
@codeSystem	1..1	SHALL		4437-3427	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3428	NCI Thesaurus
@displayName	0..1	MAY		4437-3429	Primary DI Number
value	1..1	SHALL	II	4437-3423	
@root	1..1	SHALL		4437-3430	
@extension	1..1	SHALL		4437-3431	
@displayable	1..1	SHALL		4437-3540	true

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3421).
   a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.304" (CONF:4437-3424).
   Note: template oid

Revision from "2018-05-01"

   b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3425).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3422).
   Note: Primary DI Number Code from NCIt

Code used to specify the device identifier, one of the parsed UDI components known as the Primary DI Number (UDI-DI).

   a. This code **SHALL** contain exactly one [1..1] **@code**="C101722" Primary DI Number (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3426).

b. This code **SHALL** contain exactly one [1..1]
   @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3427).

c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus"
   (CONF:4437-3428).

d. This code **MAY** contain zero or one [0..1] **@displayName**="Primary DI Number"
   (CONF:4437-3429).

The value of the Device Identifier assigned using one of the FDA-accredited, UDI issuing agency: GS1, HIBCC, or ICBBA.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="II" (CONF:4437-3423).
   Note: This value is assigned by the Manufacturer by using an FDA-accredited UDI-issuing agency

The "root" specifies the assigning authority, i.e, the UDI issuing agency. The allowable OIDs include:

1.3.160 (GS1)

2.16.840.1.113883.6.18 (ICCBBA - ISBT-128)

2.16.840.1.113883.6.40 (HIBCC)

a. This value **SHALL** contain exactly one [1..1] **@root** (CONF:4437-3430).

The value of the Device Identifier.

b. This value **SHALL** contain exactly one [1..1] **@extension** (CONF:4437-3431).

The Device Identifier can be used to look up device information entered by manufacturers in the FDA GUDID

c. This value **SHALL** contain exactly one [1..1] **@displayable**="true" (CONF:4437-3540).

Figure 5: Device Identifier

```
<observation classCode="OBS" moodCode="EVN">
   <templateId root="2.16.840.1.113883.10.20.22.4.304" extension="2019-06-21"/>
   <code code="C101722" displayName="Primary DI Number"
       codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
       <!-- GS1 Device Identifier -->
   <value xsi:type="II" root="1.3.160" extension="00999998998989" displayable="true"
             assigningAuthorityName="GS1"/>
</observation>
```

2.5 *Distinct Identification Code Observation*

```
[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.308:2019-06-
21 (open)]
```

Table 11: Distinct Identification Code Observation Contexts

Contained By:	Contains:
[UDI Organizer](#) (optional)	

This template is intended to be used in addition to the **Product Instance** template urn:oid:2.16.840.1.113883.10.20.22.4.37 to exchange the **Distinct Identification Code** for an HCT/P product regulated as a device as cited in 21 CFR 1271.290(c). The distinct identification code is parsed from the UDI value, if present.

The distinct identification code may be equivalent to the serial number, lot or batch number, or the donation identification number. The appropriate value should be provided as the distinct identification code.

Table 12: Distinct Identification Code Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.308:2019-06-21)					
templateId	1..1	SHALL		[4437-3348](#)	
@root	1..1	SHALL		[4437-3350](#)	2.16.840.1.113883.10.20.22.4.308
@extension	1..1	SHALL		[4437-3351](#)	2019-06-21
code	1..1	SHALL		[4437-3349](#)	
@code	1..1	SHALL		[4437-3355](#)	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C113843
@codeSystem	1..1	SHALL		[4437-3352](#)	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		[4437-3353](#)	NCI Thesaurus
@displayName	0..1	MAY		[4437-3354](#)	Distinct Identification Code
value	1..1	SHALL	ED	[4437-3340](#)	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3348).
    a. This templateId **SHALL** contain exactly one [1..1] **@root**="`2.16.840.1.113883.10.20.22.4.308`" (CONF:4437-3350).
       Note: template oid

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> b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3351).

2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3349).
   Note: Distinct Identification Code from NCIt

Code used to specify the Distinct Identification Code, one of the parsed UDI components.

> a. This code **SHALL** contain exactly one [1..1] **@code**="C113843" Distinct Identification Code (CodeSystem: `NCI Thesaurus (NCIt)` `urn:oid:2.16.840.1.113883.3.26.1.1` **STATIC**) (CONF:4437-3355).
>
> b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3352).
>
> c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3353).
>
> d. This code **MAY** contain zero or one [0..1] **@displayName**="Distinct Identification Code" (CONF:4437-3354).

The Distinct Identification Code can point to its corresponding narrative using the approach defined in CDA Release 2, section 4.3.5.1.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="ED" (CONF:4437-3340).

Figure 6: Distinct Identification Code

```
<observation classCode="OBS" moodCode="EVN">
   <templateId root="2.16.840.1.113883.10.20.22.4.308" extension="2019-06-21"/>
   <code code="C113843" displayName="Distinct Identification Code"
         codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
   <value xsi:type="ED">
      <reference value="#DistinctIdentificationCode_1"/>
   </value>
</observation>
```

2.6 *Expiration Date Observation*

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.309:2019-06-21 (open)]

Table 13: Expiration Date Observation Contexts

Contained By:	Contains:
UDI Organizer (optional)	

This template is intended to be used in addition to the **Product Instance** template urn:oid:2.16.840.1.113883.10.20.22.4.37 to exchange the **Expiration Date** of the device. The expiration date is parsed from the UDI value, if present.

Table 14: Expiration Date Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.309:2019-06-21)					
templateId	1..1	SHALL		4437-3393	
@root	1..1	SHALL		4437-3396	2.16.840.1.113883.10.20.22.4.309
@extension	1..1	SHALL		4437-3397	2019-06-21
code	1..1	SHALL		4437-3394	
@code	1..1	SHALL		4437-3398	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101670
@codeSystem	1..1	SHALL		4437-3399	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3400	NCI Thesaurus
@displayName	0..1	MAY		4437-3401	Expiration Date
value	1..1	SHALL	TS	4437-3395	
@value	1..1	SHALL		4437-3402	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3393).
   a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.309" (CONF:4437-3396).
   Note: template oid

Revision from "2018-05-01".

   b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3397).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3394).
   Note: Code for "Expiration Date"

Code used to specify the "Expiration Date", one of the parsed UDI components.

   a. This code **SHALL** contain exactly one [1..1] **@code**="C101670" Expiration Date (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3398).
   Note: Expiration Date code
   b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3399).
   c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3400).

d. This code **MAY** contain zero or one [0..1] **@displayName**="Expiration Date" (CONF:4437-3401).

The value of the Expiration Date as a time stamp.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="TS" (CONF:4437-3395). Note: Expiration Date as a time stamp

Expiration Date as a time stamp.

a. This value **SHALL** contain exactly one [1..1] **@value** (CONF:4437-3402).

Figure 7: Expiration Date

```
<observation classCode="OBS" moodCode="EVN">
  <templateId  root="2.16.840.1.113883.10.20.22.4.309" extension="2019-06-21"/>
  <code code="C101670" displayName="Expiration Date"
      codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
  <value xsi:type="TS" value="20221015"/>
</observation>
```

2.7 *Implantable Device Status Observation*

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21 (open)]

Table 15: Implantable Device Status Observation Contexts

Contained By:	Contains:
UDI Organizer (optional)	

This template is intended to be used in addition to the **Product Instance** template urn:oid:2.16.840.1.113883.10.20.22.4.37 to augment the parsed data from the a Unique Device Identifier (UDI). This template is used to exchange the status of the patient's implantable medical device. This status is only relevant to medical devices implanted in the patient's body.

Table 16: Implantable Device Status Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21)					
templateId	1..1	SHALL		4437-3502	
@root	1..1	SHALL		4437-3505	2.16.840.1.113883.10.20.22.4.305
@extension	1..1	SHALL		4437-3506	2019-06-21
code	1..1	SHALL		4437-3503	
@code	1..1	SHALL		4437-3507	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C160939
@codeSystem	1..1	SHALL		4437-3508	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3509	NCI Thesaurus
@displayName	0..1	MAY		4437-3510	Implantable Device Status
value	1..1	SHALL	CD	4437-3504	urn:oid:2.16.840.1.113762.1.4.1021.48 (Implantable Device Status)
@code	1..1	SHALL		4437-3511	
@codeSystem	1..1	SHALL		4437-3512	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3502).
   a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.305" (CONF:4437-3505).
   Note: template oid

Revision from "2018-05-01".

   b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3506).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3503).
   Note: Code for "Implantable Device Status"

Code used to specify the **Implantable Device Status**.

   a. This code **SHALL** contain exactly one [1..1] **@code**="C160939" Implantable Device Status (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3507).
   b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3508).

      c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3509).

Implantable Device Status

      d. This code **MAY** contain zero or one [0..1] **@displayName**="Implantable Device Status" (CONF:4437-3510).

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHALL** be selected from ValueSet Implantable Device Status urn:oid:2.16.840.1.113762.1.4.1021.48 **STATIC** 2019-06-21 (CONF:4437-3504).

      a. This value **SHALL** contain exactly one [1..1] **@code** (CONF:4437-3511).

      b. This value **SHALL** contain exactly one [1..1] **@codeSystem** (CONF:4437-3512).

Figure 8: Implantable Device Status

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.305" extension="2019-06-21"/>
  <code  code="C160939" displayName="Implantable Device Status"
   codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
  <value xsi:type="CD" code="C160942"   codeSystem="2.16.840.1.113883.3.26.1.1"
  displayName="Reduced Function" codeSystemName="NCI  Thesaurus"
  sdtc:valueSet="2.16.840.1.113762.1.4.1021.48">
  <originalText>
    <reference value="#ImplantableDeviceStatus_1"/>
  </originalText>
 </value>
</observation>
```

2.8 Latex Safety Observation

```
[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-
21 (open)]
```

Table 17: Latex Safety Observation Contexts

Contained By:	Contains:
UDI Organizer (optional)	

This template is intended to be used in addition to the **Product Instance** template urn:oid:2.16.840.1.113883.10.20.22.4.37 to exchange the **Latex Safety Status** of the patient's medical device. The UDI-DI of the medical device may be used to retrieve the Latex Safety status in accessGUDID, which should be considered the source of truth.

Table 18: Latex Safety Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-21)					
templateId	1..1	SHALL		4437-3491	
@root	1..1	SHALL		4437-3494	2.16.840.1.113883.10.20.22.4.314
@extension	1..1	SHALL		4437-3495	2019-06-21
code	1..1	SHALL		4437-3492	
@code	1..1	SHALL		4437-3496	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C160938
@codeSystem	1..1	SHALL		4437-3497	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3498	NCI Thesaurus
@displayName	0..1	MAY		4437-3499	Latex Safety Status
value	1..1	SHALL	CD	4437-3493	urn:oid:2.16.840.1.113762.1.4.1021.47 (Device Latex Safety)
@code	1..1	SHALL		4437-3500	
@codeSystem	1..1	SHALL		4437-3501	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3491).
   a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.314" (CONF:4437-3494).
   Note: template oid

Revision from "2018-05-01".

   b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3495).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3492).
   Note: Code for "Latex Status"

Code used to specify the **Latex Safety Status**

   a. This code **SHALL** contain exactly one [1..1] **@code**="C160938" Latex Safety Status (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3496).
   b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3497).

    c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3498).

    d. This code **MAY** contain zero or one [0..1] **@displayName**="Latex Safety Status" (CONF:4437-3499).

The value of the Latex Safety status.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHALL** be selected from ValueSet Device Latex Safety urn:oid:2.16.840.1.113762.1.4.1021.47 **STATIC** 2019-06-21 (CONF:4437-3493).

    a. This value **SHALL** contain exactly one [1..1] **@code** (CONF:4437-3500).

    b. This value **SHALL** contain exactly one [1..1] **@codeSystem** (CONF:4437-3501).

Figure 9: Latex Safety Status

```
<observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.314"
            extension="2019-06-21"/>
        <code code="C160938" displayName="Latex Safety Status"
            codeSystem="2.16.840.1.113883.3.26.1.1"
            codeSystemName="NCI Thesaurus"/>
        <value xsi:type="CD" code="C106038"
            codeSystem="2.16.840.1.113883.3.26.1.1" displayName="Not Made with Natural
Rubber Latex"
            codeSystemName="NCI Thesaurus"
sdtc:valueSet="2.16.840.1.113762.1.4.1021.47">
            <originalText>
                <reference value="#LatexSafety_1"/>
            </originalText>
        </value>
    </observation>
```

2.9 *Lot or Batch Number Observation*

```
[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.315:2019-06-
21 (open)]
```

Table 19: Lot or Batch Number Observation Contexts

Contained By:	Contains:
UDI Organizer (optional)	

This template is intended to be used in addition to the **Product Instance** template urn:oid:2.16.840.1.113883.10.20.22.4.37 to exchange the **Lot or Batch Number** of the device. The Lot or Batch Number is parsed from the UDI value, if present.

Table 20: Lot or Batch Number Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.315:2019-06-21)					
templateId	1..1	SHALL		4437-3450	
@root	1..1	SHALL		4437-3452	2.16.840.1.113883.10.20.22.4.315
@extension	1..1	SHALL		4437-3453	2019-06-21
code	1..1	SHALL		4437-3451	
@code	1..1	SHALL		4437-3454	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101672
@codeSystem	1..1	SHALL		4437-3455	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3456	NCI Thesaurus
@displayName	0..1	MAY		4437-3457	Lot or Batch Number
value	1..1	SHALL	ED	4437-3458	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3450).
   a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.315" (CONF:4437-3452). Note: template oid

Revision from "2018-05-01".

   b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3453).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3451). Note: Code for "Lot or Batch Number"

Code used to specify the **Lot or Batch Number**.

   a. This code **SHALL** contain exactly one [1..1] **@code**="C101672" Lot or Batch Number (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3454).
   b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3455).
   c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3456).
   d. This code **MAY** contain zero or one [0..1] **@displayName**="Lot or Batch Number" (CONF:4437-3457).

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The Lot or Batch Number can point to its corresponding narrative using the approach defined in CDA Release 2, section 4.3.5.1.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="ED" (CONF:4437-3458).

Figure 10: Lot or Batch Number

```
<observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.22.4.315" extension="2019-06-21"/>
    <code  code="C101672" displayName="Lot or Batch Number"
            codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
    <value xsi:type="ED">
        <reference value="#LotOrBatchNumber_1"/>
    </value>
</observation>
```

2.10 Manufacturing Date Observation

```
[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.316:2019-06-
21 (open)]
```

Table 21: Manufacturing Date Observation Contexts

Contained By:	Contains:
UDI Organizer (optional)	

This template is intended to be used in addition to the **Product Instance** template urn:oid:2.16.840.1.113883.10.20.22.4.37 to exchange the **Manufacturing Date** of the device. The manufacturing date is parsed from the UDI value, if present.

Table 22: Manufacturing Date Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.316:2019-06-21)					
templateId	1..1	SHALL		4437-3459	
@root	1..1	SHALL		4437-3462	2.16.840.1.113883.10.20.22.4.316
@extension	1..1	SHALL		4437-3463	2019-06-21
code	1..1	SHALL		4437-3460	
@code	1..1	SHALL		4437-3464	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101669
@codeSystem	1..1	SHALL		4437-3465	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3466	NCI Thesaurus
@displayName	0..1	MAY		4437-3467	Manufacturing Date
value	1..1	SHALL	TS	4437-3461	
@value	1..1	SHALL		4437-3468	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3459).
   a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.316" (CONF:4437-3462).
   Note: template oid

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   b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3463).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3460).
   Note: Code for "Manufacturing Date"

Code used to specify the **Manufacturing Date**.

   a. This code **SHALL** contain exactly one [1..1] **@code**="C101669" Manufacturing Date (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3464).
   Note: Manufacturing Date code
   b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3465).
   c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3466).

d. This code **MAY** contain zero or one [0..1] **@displayName**="Manufacturing Date" (CONF:4437-3467).

The value of the Manufacturing Date as a time stamp.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="TS" (CONF:4437-3461).
Note: Manufacturing Date as a time stamp

Manufacturing Date as a time stamp.

a. This value **SHALL** contain exactly one [1..1] **@value** (CONF:4437-3468).

Figure 11: Manufacturing Date

```
<observation classCode="OBS" moodCode="EVN">
<templateId root="2.16.840.1.113883.10.20.22.4.316" extension="2019-06-21"/>
<code  code="C101669" displayName="Manufacturing Date"
   codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
<value xsi:type="TS" value="20181015"/>
</observation>
```

2.11 Model Number Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.317:2019-06-21 (open)]

Table 23: Model Number Observation Contexts

Contained By:	Contains:
UDI Organizer (optional)	

This template is intended to be used in addition to the **Product Instance** template urn:oid:2.16.840.1.113883.10.20.22.4.37 to exchange the **Model Number** associated with the device. The UDI-DI of the medical device may be used to retrieve the **Model Number** in accessGUDID, which should be considered the source of truth.

Table 24: Model Number Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.317:2019-06-21)					
templateId	1..1	SHALL		4437-3412	
@root	1..1	SHALL		4437-3414	2.16.840.1.113883.10.20.22.4.317
@extension	1..1	SHALL		4437-3415	2019-06-21
code	1..1	SHALL		4437-3413	
@code	1..1	SHALL		4437-3416	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C99285
@codeSystem	1..1	SHALL		4437-3417	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3418	NCI Thesaurus
@displayName	0..1	MAY		4437-3419	Model Number
value	1..1	SHALL	ED	4437-3420	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3412).
    a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.317" (CONF:4437-3414). Note: template oid

Revision from "2018-05-01".

    b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3415).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3413). Note: Code for "Device Model Number"

Code used to specify the **Model Number**.

    a. This code **SHALL** contain exactly one [1..1] **@code**="C99285" Model Number (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3416).
    b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3417).
    c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3418).
    d. This code **MAY** contain zero or one [0..1] **@displayName**="Model Number" (CONF:4437-3419).

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The Model Number can point to its corresponding narrative using the approach defined in CDA Release 2, section 4.3.5.1.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="ED" (CONF:4437-3420).

Figure 12: Model Number

```
<observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.22.4.317" extension="2019-06-21"/>
    <code code="C99285"displayName="Model Number"
        codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
    <value xsi:type="ED">
        <reference value="#ModelNumber_1"/>
    </value>
</observation>
```

2.12 MRI Safety Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.318:2019-06-21 (open)]

Table 25: MRI Safety Observation Contexts

Contained By:	Contains:
UDI Organizer (optional)	

This template is intended to be used in addition to the **Product Instance** template urn:oid:2.16.840.1.113883.10.20.22.4.37 to exchange the MRI Safety Status of the patient's medical device. The UDI-DI of the medical device may be used to retrieve the **MRI Safety Status** in accessGUDID, which should be considered the source of truth.

Table 26: MRI Safety Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.318:2019-06-21)					
templateId	1..1	SHALL		4437-3469	
@root	1..1	SHALL		4437-3471	2.16.840.1.113883.10.20.22.4.318
@extension	1..1	SHALL		4437-3472	2019-06-21
code	1..1	SHALL		4437-3470	
@code	1..1	SHALL		4437-3473	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C106044
@codeSystem	1..1	SHALL		4437-3474	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3475	NCI Thesaurus
@displayName	0..1	MAY		4437-3476	MRI Safety
value	1..1	SHALL	CD	4437-3477	urn:oid:2.16.840.1.113762.1.4.1021.46 (Device Magnetic resonance (MR) Safety)
@code	1..1	SHALL		4437-3478	
@codeSystem	1..1	SHALL		4437-3479	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3469).
   a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.318" (CONF:4437-3471).
      Note: template oid

   Revision from "2018-05-01".

   b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3472).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3470).
   Note: Code for "MRI Safety Status"

   Code used to specify the **MRI Safety Status**.

   a. This code **SHALL** contain exactly one [1..1] **@code**="C106044" MRI Safety (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3473).
   b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3474).

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c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3475).

d. This code **MAY** contain zero or one [0..1] **@displayName**="MRI Safety" (CONF:4437-3476).

The value of the MRI Safety status.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHALL** be selected from ValueSet `Device Magnetic resonance (MR) Safety urn:oid:2.16.840.1.113762.1.4.1021.46` **STATIC** 2019-06-21 (CONF:4437-3477).

   a. This value **SHALL** contain exactly one [1..1] **@code** (CONF:4437-3478).

   b. This value **SHALL** contain exactly one [1..1] **@codeSystem** (CONF:4437-3479).

Figure 13: MRI Safety Status

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.318" extension="2019-06-21"/>
  <code code="C106044" displayName="MRI Safety Status"
      codeSystem="2.16.840.1.113883.3.26.1.1"codeSystemName="NCI Thesaurus"/>
  <value xsi:type="CD" code="C113844" codeSystem="2.16.840.1.113883.3.26.1.1"
       displayName="Labeling does not contain MRI Safety Information"
       codeSystemName="NCI Thesaurus" sdtc:valueSet="2.16.840.1.113762.1.4.1021.46">
  <originalText>
      <reference value="#MRISafety_1"/>
  </originalText>
  </value>
</observation>
```

2.13 Serial Number Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.319:2019-06-21 (open)]

Table 27: Serial Number Observation Contexts

Contained By:	Contains:
UDI Organizer (optional)	

This template is intended to be used in addition to the **Product Instance** template urn:oid:2.16.840.1.113883.10.20.22.4.37 to exchange the **Serial Number** of the device. The serial number is parsed from the UDI value, if present.

Table 28: Serial Number Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.319:2019-06-21)					
templateId	1..1	SHALL		4437-3373	
@root	1..1	SHALL		4437-3377	2.16.840.1.113883.10.20.22.4.319
@extension	1..1	SHALL		4437-3368	2019-06-21
code	1..1	SHALL		4437-3374	
@code	1..1	SHALL		4437-3378	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101671
@codeSystem	1..1	SHALL		4437-3369	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3370	NCI Thesaurus
@displayName	0..1	MAY		4437-3379	Serial Number
value	1..1	SHALL	ED	4437-3372	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3373).
   a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.319" (CONF:4437-3377).
      Note: template oid

Revision from "2018-05-01".

   b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3368).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3374).
   Note: Code for "Serial Number"

Code used to specify the **Serial Number**.

   a. This code **SHALL** contain exactly one [1..1] **@code**="C101671" Serial Number (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3378).
   b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3369).
   c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3370).
   d. This code **MAY** contain zero or one [0..1] **@displayName**="Serial Number" (CONF:4437-3379).

The Serial Number can point to its corresponding narrative using the approach defined in CDA Release 2, section 4.3.5.1.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="ED" (CONF:4437-3372).

Figure 14: Serial Number

```
 <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.22.4.319" extension="2019-06-21"/>
    <code code="C101671" displayName="Serial Number"
        codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
    <value xsi:type="ED">
      <reference value="#SerialNumber_1"/>
    </value>
</observation>
```

3 TEMPLATE IDS IN THIS GUIDE

Table 29: Template List

Template Title	Template Type	templateId
UDI Organizer	entry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.311:2019-06-21
Brand Name Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.301:2019-06-21
Catalog Number Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21
Company Name Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21
Device Identifier Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2019-06-21
Distinct Identification Code Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.308:2019-06-21
Expiration Date Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.309:2019-06-21
Implantable Device Status Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21
Latex Safety Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-21
Lot or Batch Number Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.315:2019-06-21
Manufacturing Date Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.316:2019-06-21
Model Number Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.317:2019-06-21
MRI Safety Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.318:2019-06-21
Serial Number Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.319:2019-06-21

Table 30: Template Containments

Template Title	Template Type	templateId
UDI Organizer	entry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.311:2019-06-21
Distinct Identification Code Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.308:2019-06-21
Serial Number Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.319:2019-06-21
Expiration Date Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.309:2019-06-21
Brand Name Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.301:2019-06-21
Model Number Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.317:2019-06-21
Device Identifier Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2019-06-21
Catalog Number Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21
Company Name Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21
Lot or Batch Number Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.315:2019-06-21
Manufacturing Date Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.316:2019-06-21
MRI Safety Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.318:2019-06-21
Latex Safety Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-21
Implantable Device Status Observation	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21

4   CODE SYSTEMS IN THIS GUIDE

Table 31: Code Systems

Name	OID
HL7ActStatus	urn:oid:2.16.840.1.113883.5.14
LOINC	urn:oid:2.16.840.1.113883.6.1
NCI Thesaurus (NCIt)	urn:oid:2.16.840.1.113883.3.26.1.1