



**HL7 CDA® R2 Implementation Guide:**  
**C-CDA Templates for Clinical Notes STU Companion Guide**  
**Release 3 (US Realm)**  
**Standard for Trial Use**  
**May 2022**

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

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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 <a href="http://www.nucc.org">www.nucc.org</a> . 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:
	<a href="#">Distinct Identification Code Observation</a> (optional) <a href="#">Serial Number Observation</a> (optional) <a href="#">Expiration Date Observation</a> (optional) <a href="#">Brand Name Observation</a> (optional) <a href="#">Model Number Observation</a> (optional) <a href="#">Catalog Number Observation</a> (optional) <a href="#">Company Name Observation</a> (optional) <a href="#">Lot or Batch Number Observation</a> (optional) <a href="#">Manufacturing Date Observation</a> (optional) <a href="#">MRI Safety Observation</a> (optional) <a href="#">Latex Safety Observation</a> (optional) <a href="#">Implantable Device Status Observation</a> (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		<a href="#">4437-3482</a>	CLUSTER
@moodCode	1..1	SHALL		<a href="#">4437-3483</a>	EVN
templateId	1..1	SHALL		<a href="#">4437-3480</a>	
@root	1..1	SHALL		<a href="#">4437-3484</a>	2.16.840.1.113883.10.20.22.4.311
@extension	1..1	SHALL		<a href="#">4437-3485</a>	2019-06-21
id	1..1	SHALL		<a href="#">4437-3541</a>	
@root	1..1	SHALL		<a href="#">4437-3542</a>	
code	0..1	MAY		<a href="#">4437-3481</a>	
@code	0..1	MAY		<a href="#">4437-3486</a>	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 74711-3
@codeSystem	1..1	SHALL		<a href="#">4437-3487</a>	2.16.840.1.113883.6.1
statusCode	1..1	SHALL		<a href="#">4437-3490</a>	

XPath	Card.	Verb	Data Type	CONF#	Value
@code	1..1	SHALL		<a href="#">4437-3543</a>	urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed
component	1..1	SHALL		<a href="#">4437-3488</a>	
observation	1..1	SHALL		<a href="#">4437-3489</a>	Device Identifier Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2019-06-21
component	0..1	SHOULD		<a href="#">4437-3513</a>	
observation	1..1	SHALL		<a href="#">4437-3514</a>	<a href="#">Lot or Batch Number Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.315:2019-06-21</a>
component	0..1	SHOULD		<a href="#">4437-3515</a>	
observation	1..1	SHALL		<a href="#">4437-3516</a>	<a href="#">Serial Number Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.319:2019-06-21</a>
component	0..1	SHOULD		<a href="#">4437-3517</a>	
observation	1..1	SHALL		<a href="#">4437-3518</a>	<a href="#">Manufacturing Date Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.316:2019-06-21</a>
component	0..1	SHOULD		<a href="#">4437-3525</a>	
observation	1..1	SHALL		<a href="#">4437-3526</a>	<a href="#">Expiration Date Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.309:2019-06-21</a>
component	0..1	SHOULD		<a href="#">4437-3523</a>	
observation	1..1	SHALL		<a href="#">4437-3524</a>	<a href="#">Distinct Identification Code Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.308:2019-06-21</a>
component	0..1	MAY		<a href="#">4437-3521</a>	
observation	1..1	SHALL		<a href="#">4437-3522</a>	<a href="#">Brand Name Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.301:2019-06-21</a>
component	0..1	MAY		<a href="#">4437-3519</a>	
observation	1..1	SHALL		<a href="#">4437-3520</a>	<a href="#">Model Number Observation (identifier:</a>



XPath	Card.	Verb	Data Type	CONF#	Value
					<a href="#">urn:hl7ii:2.16.840.1.113883.10.20.22.4.317:2019-06-21</a>
component	0..1	MAY		<a href="#">4437-3535</a>	
observation	1..1	SHALL		<a href="#">4437-3536</a>	<a href="#">Company Name Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21)</a>
component	0..1	MAY		<a href="#">4437-3527</a>	
observation	1..1	SHALL		<a href="#">4437-3528</a>	<a href="#">Catalog Number Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21)</a>
component	0..1	MAY		<a href="#">4437-3529</a>	
observation	1..1	SHALL		<a href="#">4437-3530</a>	<a href="#">Latex Safety Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-21)</a>
component	0..1	MAY		<a href="#">4437-3533</a>	
observation	1..1	SHALL		<a href="#">4437-3534</a>	<a href="#">MRI Safety Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.318:2019-06-21)</a>
component	0..1	MAY		<a href="#">4437-3531</a>	
observation	1..1	SHALL		<a href="#">4437-3532</a>	<a href="#">Implantable Device Status Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21)</a>

## 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 is 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"/>
    </observation>
  </component>
</organizer>
```

```

        <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:
<a href="#">UDI Organizer</a> (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		<a href="#">4437-3403</a>	
@root	1..1	SHALL		<a href="#">4437-3405</a>	2.16.840.1.113883.10.20.22.4.301
@extension	1..1	SHALL		<a href="#">4437-3406</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3404</a>	
@code	1..1	SHALL		<a href="#">4437-3407</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C71898
@codeSystem	1..1	SHALL		<a href="#">4437-3408</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3409</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3410</a>	Brand Name
value	1..1	SHALL	ED	<a href="#">4437-3411</a>	

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

Revision from "2018-05-01".

- 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:
<a href="#">UDI Organizer</a> (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		<a href="#">4437-3432</a>	
@root	1..1	SHALL		<a href="#">4437-3434</a>	2.16.840.1.113883.10.20.22.4.302
@extension	1..1	SHALL		<a href="#">4437-3435</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3433</a>	
@code	1..1	SHALL		<a href="#">4437-3436</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C99286
@codeSystem	1..1	SHALL		<a href="#">4437-3437</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3438</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3439</a>	Catalog Number
value	1..1	SHALL	ED	<a href="#">4437-3440</a>	

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).

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:
<a href="#">UDI Organizer</a> (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		<a href="#">4437-3441</a>	
@root	1..1	SHALL		<a href="#">4437-3443</a>	2.16.840.1.113883.10.20.22.4.303
@extension	1..1	SHALL		<a href="#">4437-3444</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3442</a>	
@code	1..1	SHALL		<a href="#">4437-3445</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C54131
@codeSystem	1..1	SHALL		<a href="#">4437-3446</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3447</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3448</a>	Company Name
value	1..1	SHALL	ED	<a href="#">4437-3449</a>	

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 (V2)

```
[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2022-06-01 (open)]
```

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 9: Device Identifier Observation (V2) Constraints Overview**

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2022-06-01)					
templateId	1..1	SHALL		<a href="#">4524-3421</a>	
@root	1..1	SHALL		<a href="#">4524-3424</a>	2.16.840.1.113883.10.20.22.4.304
@extension	1..1	SHALL		<a href="#">4524-3425</a>	2022-06-01
code	1..1	SHALL		<a href="#">4524-3422</a>	
@code	1..1	SHALL		<a href="#">4524-3426</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101722
@codeSystem	1..1	SHALL		<a href="#">4524-3427</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4524-3428</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4524-3429</a>	Primary DI Number
value	1..1	SHALL	II	<a href="#">4524-3423</a>	
@root	1..1	SHALL		<a href="#">4524-3430</a>	
@extension	0..1	SHOULD		<a href="#">4524-3431</a>	
@displayable	1..1	SHALL		<a href="#">4524-3540</a>	true

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4524-3421).
  - a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.304" (CONF:4524-3424).
  - b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2022-06-01" (CONF:4524-3425).

2. **SHALL** contain exactly one [1..1] **code** (CONF:4524-3422).

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:4524-3426).
- b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4524-3427).

- c. This code **MAY** contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4524-3428).
- d. This code **MAY** contain zero or one [0..1] @displayName="Primary DI Number" (CONF:4524-3429).

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:4524-3423).  
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:4524-3430).

The value of the Device Identifier.

- b. This value **SHOULD** contain zero or one [0..1] @extension (CONF:4524-3431).

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:4524-3540).

**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 10: Distinct Identification Code Observation Contexts**

Contained By:	Contains:
<a href="#">UDI Organizer</a> (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 11: 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		<a href="#">4437-3348</a>	
@root	1..1	SHALL		<a href="#">4437-3350</a>	2.16.840.1.113883.10.20.22.4.308
@extension	1..1	SHALL		<a href="#">4437-3351</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3349</a>	
@code	1..1	SHALL		<a href="#">4437-3355</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C113843
@codeSystem	1..1	SHALL		<a href="#">4437-3352</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3353</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3354</a>	Distinct Identification Code
value	1..1	SHALL	ED	<a href="#">4437-3340</a>	

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

Revision from "2018-05-01"

- 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 12: Expiration Date Observation Contexts**

Contained By:	Contains:
<a href="#">UDI Organizer</a> (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 13: 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		<a href="#">4437-3393</a>	
@root	1..1	SHALL		<a href="#">4437-3396</a>	2.16.840.1.113883.10.20.22.4.309
@extension	1..1	SHALL		<a href="#">4437-3397</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3394</a>	
@code	1..1	SHALL		<a href="#">4437-3398</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101670
@codeSystem	1..1	SHALL		<a href="#">4437-3399</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3400</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3401</a>	Expiration Date
value	1..1	SHALL	TS	<a href="#">4437-3395</a>	
@value	1..1	SHALL		<a href="#">4437-3402</a>	

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 14: Implantable Device Status Observation Contexts**

Contained By:	Contains:
<a href="#">UDI Organizer</a> (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 15: 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		<a href="#">4437-3502</a>	
@root	1..1	SHALL		<a href="#">4437-3505</a>	2.16.840.1.113883.10.20.22.4.305
@extension	1..1	SHALL		<a href="#">4437-3506</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3503</a>	
@code	1..1	SHALL		<a href="#">4437-3507</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C160939
@codeSystem	1..1	SHALL		<a href="#">4437-3508</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3509</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3510</a>	Implantable Device Status
value	1..1	SHALL	CD	<a href="#">4437-3504</a>	urn:oid:2.16.840.1.113762.1.4.1021.48 (Implantable Device Status)
@code	1..1	SHALL		<a href="#">4437-3511</a>	
@codeSystem	1..1	SHALL		<a href="#">4437-3512</a>	

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).

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- 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"
    sdct: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 16: Latex Safety Observation Contexts**

Contained By:	Contains:
<a href="#">UDI Organizer</a> (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 17: 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		<a href="#">4437-3491</a>	
@root	1..1	SHALL		<a href="#">4437-3494</a>	2.16.840.1.113883.10.20.22.4.314
@extension	1..1	SHALL		<a href="#">4437-3495</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3492</a>	
@code	1..1	SHALL		<a href="#">4437-3496</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C160938
@codeSystem	1..1	SHALL		<a href="#">4437-3497</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3498</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3499</a>	Latex Safety Status
value	1..1	SHALL	CD	<a href="#">4437-3493</a>	urn:oid:2.16.840.1.113762.1.4.1021.47 (Device Latex Safety)
@code	1..1	SHALL		<a href="#">4437-3500</a>	
@codeSystem	1..1	SHALL		<a href="#">4437-3501</a>	

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 18: Lot or Batch Number Observation Contexts**

Contained By:	Contains:
<a href="#">UDI Organizer</a> (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 19: 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		<a href="#">4437-3450</a>	
@root	1..1	SHALL		<a href="#">4437-3452</a>	2.16.840.1.113883.10.20.22.4.315
@extension	1..1	SHALL		<a href="#">4437-3453</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3451</a>	
@code	1..1	SHALL		<a href="#">4437-3454</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101672
@codeSystem	1..1	SHALL		<a href="#">4437-3455</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3456</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3457</a>	Lot or Batch Number
value	1..1	SHALL	ED	<a href="#">4437-3458</a>	

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).

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 20: Manufacturing Date Observation Contexts**

Contained By:	Contains:
<a href="#">UDI Organizer</a> (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 21: 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		<a href="#">4437-3459</a>	
@root	1..1	SHALL		<a href="#">4437-3462</a>	2.16.840.1.113883.10.20.22.4.316
@extension	1..1	SHALL		<a href="#">4437-3463</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3460</a>	
@code	1..1	SHALL		<a href="#">4437-3464</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101669
@codeSystem	1..1	SHALL		<a href="#">4437-3465</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3466</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3467</a>	Manufacturing Date
value	1..1	SHALL	TS	<a href="#">4437-3461</a>	
@value	1..1	SHALL		<a href="#">4437-3468</a>	

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

Revision from "2018-05-01".

- 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 22: Model Number Observation Contexts**

Contained By:	Contains:
<a href="#">UDI Organizer</a> (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 23: 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		<a href="#">4437-3412</a>	
@root	1..1	SHALL		<a href="#">4437-3414</a>	2.16.840.1.113883.10.20.22.4.317
@extension	1..1	SHALL		<a href="#">4437-3415</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3413</a>	
@code	1..1	SHALL		<a href="#">4437-3416</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C99285
@codeSystem	1..1	SHALL		<a href="#">4437-3417</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3418</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3419</a>	Model Number
value	1..1	SHALL	ED	<a href="#">4437-3420</a>	

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).

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 24: MRI Safety Observation Contexts**

Contained By:	Contains:
<a href="#">UDI Organizer</a> (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 25: 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		<a href="#">4437-3469</a>	
@root	1..1	SHALL		<a href="#">4437-3471</a>	2.16.840.1.113883.10.20.22.4.318
@extension	1..1	SHALL		<a href="#">4437-3472</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3470</a>	
@code	1..1	SHALL		<a href="#">4437-3473</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C106044
@codeSystem	1..1	SHALL		<a href="#">4437-3474</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3475</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3476</a>	MRI Safety
value	1..1	SHALL	CD	<a href="#">4437-3477</a>	urn:oid:2.16.840.1.113762.1.4.1021.46 (Device Magnetic resonance (MR) Safety)
@code	1..1	SHALL		<a href="#">4437-3478</a>	
@codeSystem	1..1	SHALL		<a href="#">4437-3479</a>	

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).

- 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" sdct: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 26: Serial Number Observation Contexts**

Contained By:	Contains:
<a href="#">UDI Organizer</a> (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 27: 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		<a href="#">4437-3373</a>	
@root	1..1	SHALL		<a href="#">4437-3377</a>	2.16.840.1.113883.10.20.22.4.319
@extension	1..1	SHALL		<a href="#">4437-3368</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3374</a>	
@code	1..1	SHALL		<a href="#">4437-3378</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101671
@codeSystem	1..1	SHALL		<a href="#">4437-3369</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3370</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3379</a>	Serial Number
value	1..1	SHALL	ED	<a href="#">4437-3372</a>	

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 28: Template List**

Template Title	Template Type	templateId
<a href="#">UDI Organizer</a>	entry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.311:2019-06-21
<a href="#">Brand Name Observation</a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.301:2019-06-21
<a href="#">Catalog Number Observation</a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21
<a href="#">Company Name Observation</a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21
<a href="#">Device Identifier Observation (V2)</a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2022-06-01
<a href="#">Distinct Identification Code Observation</a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.308:2019-06-21
<a href="#">Expiration Date Observation</a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.309:2019-06-21
<a href="#">Implantable Device Status Observation</a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21
<a href="#">Latex Safety Observation</a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-21
<a href="#">Lot or Batch Number Observation</a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.315:2019-06-21
<a href="#">Manufacturing Date Observation</a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.316:2019-06-21
<a href="#">Model Number Observation</a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.317:2019-06-21
<a href="#">MRI Safety Observation</a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.318:2019-06-21
<a href="#">Serial Number Observation</a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.319:2019-06-21

**Table 29: Template Containments**

<b>Template Title</b>	<b>Template Type</b>	<b>templateId</b>
<a href="#"><u>UDI Organizer</u></a>	entry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.311:2019-06-21
<a href="#"><u>Distinct Identification Code Observation</u></a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.308:2019-06-21
<a href="#"><u>Serial Number Observation</u></a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.319:2019-06-21
<a href="#"><u>Expiration Date Observation</u></a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.309:2019-06-21
<a href="#"><u>Brand Name Observation</u></a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.301:2019-06-21
<a href="#"><u>Model Number Observation</u></a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.317:2019-06-21
<a href="#"><u>Catalog Number Observation</u></a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21
<a href="#"><u>Company Name Observation</u></a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21
<a href="#"><u>Lot or Batch Number Observation</u></a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.315:2019-06-21
<a href="#"><u>Manufacturing Date Observation</u></a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.316:2019-06-21
<a href="#"><u>MRI Safety Observation</u></a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.318:2019-06-21
<a href="#"><u>Latex Safety Observation</u></a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-21
<a href="#"><u>Implantable Device Status Observation</u></a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21
<a href="#"><u>Device Identifier Observation (V2)</u></a>	subentry	urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2022-06-01

## 4 CODE SYSTEMS IN THIS GUIDE

**Table 30: Code Systems**

<b>Name</b>	<b>OID</b>
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