

## 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="#">Device Identifier Observation</a> (required) <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>	
@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>	<a href="#">Device Identifier Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2019-06-21)</a>
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>	

## Appendix B: UDI Organizer template from C-CDA Supplemental Templates for UDI

XPath	Card.	Verb	Data Type	CONF#	Value
observation	1..1	SHALL		<a href="#">4437-3518</a>	<a href="#">Manufacturing Date Observation (identifier: urn:hl7ii:2.16.840.1.113883.1.0.20.22.4.316:2019-06-21)</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:2.16.840.1.113883.1.0.20.22.4.309:2019-06-21)</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:2.16.840.1.113883.1.0.20.22.4.308:2019-06-21)</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:2.16.840.1.113883.1.0.20.22.4.301:2019-06-21)</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: urn:hl7ii:2.16.840.1.113883.1.0.20.22.4.317:2019-06-21)</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:2.16.840.1.113883.1.0.20.22.4.303:2019-06-21)</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:2.16.840.1.113883.1.0.20.22.4.302:2019-06-21)</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:2.16.840.1.113883.1.0.20.22.4.314:2019-06-21)</a>
component	0..1	MAY		<a href="#">4437-3533</a>	

XPath	Card.	Verb	Data Type	CONF#	Value
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
- 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
- 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
- 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
- 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
- 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
- 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
- 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"/>

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        <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>
```