

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) 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	

XPath	Card.	Verb	Data Type	CONF#	Value
@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	
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:

XPath	Card.	Verb	Data Type	CONF#	Value
					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	
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 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>
```



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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"/>

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        <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>
```