# 1 ENTRY

## 1.1 *UDI Organizer*

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

*Table 1: UDI Organizer Contexts*

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

This template is used to manage 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

HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 STU- US Realm
October 2019

*Table 2: UDI Organizer Constraints Overview*

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

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

HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 STU- US Realm
October 2019

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

### 1.1.1 Properties

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

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

Revision from "2018-05-01".

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

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

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

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

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

**Device Identifier** - the mandatory part of the UDI

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

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

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

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

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

**Serial Number** - needed if present as a production identifier

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

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

**Manufacturing Date** - needed if present as a production identifier

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

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

**Expiration Date** - needed if present as a production identifier

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*Figure 1: Unique Device Identifier (UDI) Organizer*

```
< !-- UDI Organizer -->
<organizer classCode="CLUSTER" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.22.4.312"
        extension="2019-06-21"/>
    <id assigningAuthorityName="FDA" extension="(01)4328998989(11)160330(10)ABC124"
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"/>
```

```
                <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>
```