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:
	<u>Distinct Identification Code Observation</u> (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

Appendix B: UDI Organizer template from C-CDA Supplemental Templates for 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	11	SHALL		<u>4437-</u> <u>3482</u>	CLUSTER	
@moodCode	11	SHALL		<u>4437-</u> <u>3483</u>	EVN	
templateId	11	SHALL		<u>4437-</u> <u>3480</u>		
@root	11	SHALL		<u>4437-</u> <u>3484</u>	2.16.840.1.113883.10.20.22.4 .311	
@extension	11	SHALL		<u>4437-</u> <u>3485</u>	2019-06-21	
id	11	SHALL		<u>4437-</u> <u>3541</u>		
@root	11	SHALL		<u>4437-</u> <u>3542</u>		
code	01	MAY		<u>4437-</u> <u>3481</u>		
@code	01	MAY		<u>4437-</u> <u>3486</u>	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 74711-3	
@codeSystem	11	SHALL		<u>4437-</u> <u>3487</u>	2.16.840.1.113883.6.1	
statusCode	11	SHALL		4437- 3490		
@code	11	SHALL		<u>4437-</u> <u>3543</u>	urn:oid:2.16.840.1.113883.5.1 4 (HL7ActStatus) = completed	
component	11	SHALL		<u>4437-</u> <u>3488</u>		
observation	11	SHALL		<u>4437-</u> <u>3489</u>	Device Identifier Observation (identifier: urn:hl7ii:2.16.840.1.113883.1 0.20.22.4.304:2019-06-21	
component	01	SHOULD		<u>4437-</u> <u>3513</u>		
observation	11	SHALL		4437- 3514	Lot or Batch Number Observation (identifier: urn:hl7ii:2.16.840.1.113883.1 0.20.22.4.315:2019-06-21	
component	01	SHOULD		<u>4437-</u> <u>3515</u>		
observation	11	SHALL		<u>4437-</u> <u>3516</u>	Serial Number Observation (identifier: urn:hl7ii:2.16.840.1.113883.1 0.20.22.4.319: 2019-06-21	
component	01	SHOULD		<u>4437-</u> <u>3517</u>		

${\bf Appendix\,B: UDI\,Organizer\,template\,from\,C-CDA\,Supplemental\,Templates\,for\,UDI}$

XPath	Card.	Verb	Data Type	CONF#	Value
observation	11	SHALL		4437- 3518	Manufacturing Date Observation (identifier: urn:hl7ii:2.16.840.1.113883.1 0.20.22.4.316:2019-06-21
component	01	SHOULD		4437- 3525	
observation	11	SHALL		4437- 3526	Expiration Date Observation (identifier: urn:hl7ii:2.16.840.1.113883.1 0.20.22.4.309: 2019-06-21
component	01	SHOULD		<u>4437-</u> <u>3523</u>	
observation	11	SHALL		4437- 3524	Distinct Identification Code Observation (identifier: urn:hl7ii:2.16.840.1.113883.1 0.20.22.4.308: 2019-06-21
component	01	MAY		<u>4437-</u> <u>3521</u>	
observation	11	SHALL		4437- 3522	Brand Name Observation (identifier: urn:hl7ii:2.16.840.1.113883.1 0.20.22.4.301: 2019-06-21
component	01	MAY		4437- 3519	
observation	11	SHALL		4437- 3520	Model Number Observation (identifier: urn:hl7ii:2.16.840.1.113883.1 0.20.22.4.317:2019-06-21
component	01	MAY		4437- 3535	
observation	11	SHALL		4437- 3536	Company Name Observation (identifier: urn:hl7ii:2.16.840.1.113883.1 0.20.22.4.303:2019-06-21
component	01	MAY		4437- 3527	
observation	11	SHALL		4437- 3528	Catalog Number Observation (identifier: urn:hl7ii:2.16.840.1.113883.1 0.20.22.4.302:2019-06-21
component	01	MAY		<u>4437-</u> <u>3529</u>	
observation	11	SHALL		4437- 3530	Latex Safety Observation (identifier: urn:hl7ii:2.16.840.1.113883.1 0.20.22.4.314: 2019-06-21
component	01	MAY		4437- 3533	

XPath	Card.	Verb	Data Type	CONF#	Value
observation	11	SHALL		4437- 3534	MRI Safety Observation (identifier: urn:hl7ii:2.16.840.1.113883.1 0.20.22.4.318: 2019-06-21
component	01	MAY		<u>4437-</u> <u>3531</u>	
observation	11	SHALL		4437- 3532	Implantable Device Status Observation (identifier: urn:hl7ii:2.16.840.1.113883.1 0.20.22.4.305:2019-06-21

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] <u>Device Identifier Observation</u> (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] <u>Serial Number Observation</u> (identifier: urn:h17ii: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] <u>Manufacturing Date Observation</u> (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] <u>Expiration Date Observation</u> (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] <u>Distinct Identification Code Observation</u> (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] <u>Model Number Observation</u> (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] <u>Company Name Observation</u> (identifier: urn:h17ii: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] <u>Catalog Number Observation</u> (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] <u>Latex Safety Observation</u> (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] <u>MRI Safety Observation</u> (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] <u>Implantable Device Status Observation</u> (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"</pre>
        extension="2019-06-21"/>
    <id assigningAuthorityName="FDA" extension="(01)4328998989(11)160330(10)ABC124"</pre>
root="GS1"/>
    <code code="74711-3" codeSystem="2.16.840.1.113883.6.1"</pre>
        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"</pre>
                 extension="2019-06-21"/>
            <code code="C101722" displayName="Primary DI Number"</pre>
                 codeSystem="2.16.840.1.113883.3.26.1.1"
                 codeSystemName="NCI Thesaurus"/>
            <!-- GS1 Device Identifier -->
            <value xsi:type="II" root="1.3.160"</pre>
                 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"</pre>
                 extension="2019-06-21"/>
            <code code="C101672" displayName="Lot or Batch Number"</pre>
                 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"</pre>
                 extension="2019-06-21"/>
            <code code="C101671" displayName="Serial Number"</pre>
                 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"</pre>
                 extension="2019-06-21"/>
            <code code="C101669" displayName="Manufacturing Date"</pre>
                 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"</pre>
            extension="2019-06-21"/>
        <code code="C101670" displayName="Expiration Date"</pre>
            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"</pre>
            extension="2019-06-21"/>
        <code code="C113843"</pre>
            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"/>
    </observation>
</component>
<component>
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.301"</pre>
            extension="2019-06-21"/>
        <code code="C71898" displayName="Brand Name"</pre>
            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"</pre>
            extension="2019-06-21"/>
        <code code="C99285" displayName="Model Number"</pre>
            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"</pre>
            extension="2019-06-21"/>
        <code code="C99286" displayName="Catalog Number"</pre>
            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"</pre>
                 extension="2019-06-21"/>
            <code code="C54131" displayName="Company Name"</pre>
                 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"</pre>
                 extension="2019-06-21"/>
            <code code="C106044" displayName="MRI Safety Status"</pre>
                 codeSystem="2.16.840.1.113883.3.26.1.1"
                 codeSystemName="NCI Thesaurus"/>
            <value xsi:type="CD" code="C113844"</pre>
                 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"</pre>
                 extension="2019-06-21"/>
            <code code="C160938" displayName="Latex Safety Status"</pre>
                codeSystem="2.16.840.1.113883.3.26.1.1"
                 codeSystemName="NCI Thesaurus"/>
            <value xsi:type="CD" code="C106038"</pre>
                 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"</pre>
                 extension="2019-06-21"/>
```

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