

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 11: Distinct Identification Code Observation Contexts

Contained By:	Contains:
UDI Organizer (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 12: 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		4437-3348	
@root	1..1	SHALL		4437-3350	2.16.840.1.113883.10.20.22.4.308
@extension	1..1	SHALL		4437-3351	2019-06-21
code	1..1	SHALL		4437-3349	
@code	1..1	SHALL		4437-3355	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C113843
@codeSystem	1..1	SHALL		4437-3352	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3353	NCI Thesaurus
@displayName	0..1	MAY		4437-3354	Distinct Identification Code
value	1..1	SHALL	ED	4437-3340	

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 value of the Distinct Identification Code as a text string.

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 13: Expiration Date Observation Contexts

Contained By:	Contains:
UDI Organizer (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.