

- c. This code **MAY** contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4524-3428).
- d. This code **MAY** contain zero or one [0..1] @displayName="Primary DI Number" (CONF:4524-3429).

The value of the Device Identifier assigned using one of the FDA-accredited, UDI issuing agency: GS1, HIBCC, or ICBBA.

3. **SHALL** contain exactly one [1..1] value with @xsi:type="II" (CONF:4524-3423).  
Note: This value is assigned by the Manufacturer by using an FDA-accredited UDI-issuing agency

The "root" specifies the assigning authority, i.e, the UDI issuing agency. The allowable OIDs include:

1.3.160 (GS1)

2.16.840.1.113883.6.18 (ICCBBA - ISBT-128)

2.16.840.1.113883.6.40 (HIBCC)

- a. This value **SHALL** contain exactly one [1..1] @root (CONF:4524-3430).

The value of the Device Identifier.

- b. This value **SHOULD** contain zero or one [0..1] @extension (CONF:4524-3431).

The Device Identifier can be used to look up device information entered by manufacturers in the FDA GUDID

- c. This value **SHALL** contain exactly one [1..1] @displayable="true" (CONF:4524-3540).

**Figure 5: Device Identifier**

```
<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="00999998998989" displayable="true"
    assigningAuthorityName="GS1"/>
</observation>
```

## 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 10: Distinct Identification Code Observation Contexts**

Contained By:	Contains:
<a href="#">UDI Organizer</a> (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 11: 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		<a href="#">4437-3348</a>	
@root	1..1	SHALL		<a href="#">4437-3350</a>	2.16.840.1.113883.10.20.22.4.308
@extension	1..1	SHALL		<a href="#">4437-3351</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3349</a>	
@code	1..1	SHALL		<a href="#">4437-3355</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C113843
@codeSystem	1..1	SHALL		<a href="#">4437-3352</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3353</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3354</a>	Distinct Identification Code
value	1..1	SHALL	ED	<a href="#">4437-3340</a>	

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

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- 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 Distinct Identification Code can point to its corresponding narrative using the approach defined in CDA Release 2, section 4.3.5.1.

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 12: Expiration Date Observation Contexts**

Contained By:	Contains:
<a href="#">UDI Organizer</a> (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.