

Revision from "2018-05-01".

- b. This templateId **SHALL** contain exactly one [1..1] @extension="2019-06-21" (CONF:4437-3406).
2. **SHALL** contain exactly one [1..1] code (CONF:4437-3404).
Note: Code for "Device Brand Name"

Code used to specify the **Brand Name**.

- a. This code **SHALL** contain exactly one [1..1] @code="C71898" Brand Name (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3407).
- b. This code **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3408).
- c. This code **MAY** contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3409).
- d. This code **MAY** contain zero or one [0..1] @displayName="Brand Name" (CONF:4437-3410).

The value of the Brand Name as a text string.

3. **SHALL** contain exactly one [1..1] value with @xsi:type="ED" (CONF:4437-3411).
Note: Brand Name as a text value

Figure 2: Brand Name Example

```
<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>
```

2.2 Catalog Number Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21 (open)]

Table 5: Catalog Number 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 **Catalog Number**. The UDI-DI of the medical device may be used to retrieve the Catalog Number in accessGUDID, which should be considered the source of truth.

Table 6: Catalog Number Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21)					
templateId	1..1	SHALL		4437-3432	
@root	1..1	SHALL		4437-3434	2.16.840.1.113883.10.20.22.4.302
@extension	1..1	SHALL		4437-3435	2019-06-21
code	1..1	SHALL		4437-3433	
@code	1..1	SHALL		4437-3436	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C99286
@codeSystem	1..1	SHALL		4437-3437	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3438	NCI Thesaurus
@displayName	0..1	MAY		4437-3439	Catalog Number
value	1..1	SHALL	ED	4437-3440	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3432).

- This **templateId** **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.302" (CONF:4437-3434).
Note: template oid

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- This **templateId** **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3435).

2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3433).

Note: Code for "Device Catalog Number"

Code used to specify the **Catalog Number**.

- This code **SHALL** contain exactly one [1..1] **@code**="C99286" Catalog Number (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3436).
- This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3437).
- This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3438).
- This code **MAY** contain zero or one [0..1] **@displayName**="Catalog Number" (CONF:4437-3439).

The value of the Catalog Number is represented as a text string.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="ED" (CONF:4437-3440).
Note: Catalog Number as a text value

Figure 3: Catalog Number Sample

```
<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>
```

2.3 Company Name Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21 (open)]

Table 7: Company Name 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 **Company Name**. The UDI-DI of the medical device may be used to retrieve the **Company Name** in accessGUDID, which should be considered the source of truth.