

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:
<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 **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.

Table 8: Company Name Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21)					
templateId	1..1	SHALL		<a href="#">4437-3441</a>	
@root	1..1	SHALL		<a href="#">4437-3443</a>	2.16.840.1.113883.10.20.22.4.303
@extension	1..1	SHALL		<a href="#">4437-3444</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3442</a>	
@code	1..1	SHALL		<a href="#">4437-3445</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C54131
@codeSystem	1..1	SHALL		<a href="#">4437-3446</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3447</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3448</a>	Company Name
value	1..1	SHALL	ED	<a href="#">4437-3449</a>	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3441).

- This **templateId** **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.303" (CONF:4437-3443).  
Note: template oid

Revision from "2018-05-01".

- This **templateId** **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3444).

2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3442).

Note: Code for "Company Name"

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

- This code **SHALL** contain exactly one [1..1] **@code**="C54131" Company Name (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3445).
- This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3446).
- This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3447).
- This code **MAY** contain zero or one [0..1] **@displayName**="Company Name" (CONF:4437-3448).

The value of the Company Name as a text string.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="ED" (CONF:4437-3449).  
Note: Brand Name as a text value

**Figure 4: Company Name**

```
<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>
```

## 2.4 Device Identifier Observation

```
[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2019-06-
21 (open)]
```

**Table 9: Device Identifier Observation Contexts**

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

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 **Device Identifier** (also known as the "Primary DI Number") for a medical device marketed in the US. The device identifier is parsed from the UDI value.

The Device Identifier number can be used as a key to look-up device identification information in the publicly available version of the US FDA Global UDI Database (GUDID) - the AccessGUDID:

<https://accessgudid.nlm.nih.gov/resources/home>