

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:
UDI Organizer (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>

Table 10: Device Identifier Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2019-06-21)					
templateId	1..1	SHALL		4437-3421	
@root	1..1	SHALL		4437-3424	2.16.840.1.113883.10.20.22.4.304
@extension	1..1	SHALL		4437-3425	2019-06-21
code	1..1	SHALL		4437-3422	
@code	1..1	SHALL		4437-3426	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101722
@codeSystem	1..1	SHALL		4437-3427	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3428	NCI Thesaurus
@displayName	0..1	MAY		4437-3429	Primary DI Number
value	1..1	SHALL	II	4437-3423	
@root	1..1	SHALL		4437-3430	
@extension	1..1	SHALL		4437-3431	
@displayable	1..1	SHALL		4437-3540	true

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3421).
 - a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.304" (CONF:4437-3424).
Note: template oid

Revision from "2018-05-01"

- b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3425).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3422).
Note: Primary DI Number Code from NCIt

Code used to specify the device identifier, one of the parsed UDI components known as the Primary DI Number (UDI-DI).

- a. This code **SHALL** contain exactly one [1..1] **@code**="C101722" Primary DI Number (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3426).

- b. This code **SHALL** contain exactly one [1..1] `@codeSystem="2.16.840.1.113883.3.26.1.1"` (CONF:4437-3427).
- c. This code **MAY** contain zero or one [0..1] `@codeSystemName="NCI Thesaurus"` (CONF:4437-3428).
- d. This code **MAY** contain zero or one [0..1] `@displayName="Primary DI Number"` (CONF:4437-3429).

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:4437-3423).

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:4437-3430).

The value of the Device Identifier.

- b. This value **SHALL** contain exactly one [1..1] `@extension` (CONF:4437-3431).

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:4437-3540).

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>
```