c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3509).

Implantable Device Status

d. This code **MAY** contain zero or one [0..1] **@displayName**="Implantable Device Status" (CONF:4437-3510).

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHALL** be selected from ValueSet Implantable Device Status urn:oid:2.16.840.1.113762.1.4.1021.48 **STATIC** 2019-06-21 (CONF:4437-3504).

   a. This value **SHALL** contain exactly one [1..1] **@code** (CONF:4437-3511).

   b. This value **SHALL** contain exactly one [1..1] **@codeSystem** (CONF:4437-3512).

Figure 8: Implantable Device Status

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.305" extension="2019-06-21"/>
  <code  code="C160939" displayName="Implantable Device Status"
   codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
  <value xsi:type="CD" code="C160942"   codeSystem="2.16.840.1.113883.3.26.1.1"
  displayName="Reduced Function" codeSystemName="NCI  Thesaurus"
  sdtc:valueSet="2.16.840.1.113762.1.4.1021.48">
  <originalText>
    <reference value="#ImplantableDeviceStatus_1"/>
  </originalText>
 </value>
</observation>
```

2.8   Latex Safety Observation

```
[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-
21 (open)]
```

Table 16: Latex Safety 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 **Latex Safety Status** of the patient's medical device. The UDI-DI of the medical device may be used to retrieve the Latex Safety status in accessGUDID, which should be considered the source of truth.

Table 17: Latex Safety Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-21)					
templateId	1..1	SHALL		4437-3491	
@root	1..1	SHALL		4437-3494	2.16.840.1.113883.10.20.22.4.314
@extension	1..1	SHALL		4437-3495	2019-06-21
code	1..1	SHALL		4437-3492	
@code	1..1	SHALL		4437-3496	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C160938
@codeSystem	1..1	SHALL		4437-3497	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3498	NCI Thesaurus
@displayName	0..1	MAY		4437-3499	Latex Safety Status
value	1..1	SHALL	CD	4437-3493	urn:oid:2.16.840.1.113762.1.4.1021.47 (Device Latex Safety)
@code	1..1	SHALL		4437-3500	
@codeSystem	1..1	SHALL		4437-3501	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3491).
   a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.314" (CONF:4437-3494).
      Note: template oid

Revision from "2018-05-01".

   b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3495).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3492).
   Note: Code for "Latex Status"

Code used to specify the **Latex Safety Status**

   a. This code **SHALL** contain exactly one [1..1] **@code**="C160938" Latex Safety Status (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3496).
   b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3497).

c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3498).

d. This code **MAY** contain zero or one [0..1] **@displayName**="Latex Safety Status" (CONF:4437-3499).

The value of the Latex Safety status.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHALL** be selected from ValueSet `Device Latex Safety` `urn:oid:2.16.840.1.113762.1.4.1021.47` **STATIC** 2019-06-21 (CONF:4437-3493).

a. This value **SHALL** contain exactly one [1..1] **@code** (CONF:4437-3500).

b. This value **SHALL** contain exactly one [1..1] **@codeSystem** (CONF:4437-3501).

Figure 9: Latex Safety Status

```
<observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.314"
            extension="2019-06-21"/>
        <code code="C160938" displayName="Latex Safety Status"
            codeSystem="2.16.840.1.113883.3.26.1.1"
            codeSystemName="NCI Thesaurus"/>
        <value xsi:type="CD" code="C106038"
            codeSystem="2.16.840.1.113883.3.26.1.1" displayName="Not Made with Natural
Rubber Latex"
            codeSystemName="NCI Thesaurus"
sdtc:valueSet="2.16.840.1.113762.1.4.1021.47">
            <originalText>
                <reference value="#LatexSafety_1"/>
            </originalText>
        </value>
    </observation>
```

2.9 *Lot or Batch Number Observation*

```
[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.315:2019-06-
21 (open)]
```

Table 18: Lot or Batch 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 **Lot or Batch Number** of the device. The Lot or Batch Number is parsed from the UDI value, if present.