

- 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"
    sdct: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 17: 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 18: 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 19: 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.