

## 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:
<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 **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		<a href="#">4437-3491</a>	
@root	1..1	SHALL		<a href="#">4437-3494</a>	2.16.840.1.113883.10.20.22.4.314
@extension	1..1	SHALL		<a href="#">4437-3495</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3492</a>	
@code	1..1	SHALL		<a href="#">4437-3496</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C160938
@codeSystem	1..1	SHALL		<a href="#">4437-3497</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3498</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3499</a>	Latex Safety Status
value	1..1	SHALL	CD	<a href="#">4437-3493</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt))
@code	0..1	SHALL		<a href="#">4437-3500</a>	
@codeSystem	1..1	SHALL		<a href="#">4437-3501</a>	2.16.840.1.113883.3.26.1.1
@sdtc:valueSet	0..1	SHOULD		<a href="#">4437-3538</a>	2.16.840.1.113762.1.4.1021.47

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 CodeSystem NCI Thesaurus (NCIt) (urn:oid:2.16.840.1.113883.3.26.1.1) (CONF:4437-3493).

Allowed values from value set 2.16.840.1.113762.1.4.1021.47:

C106043 Natural Rubber Latex

C106038 Not Made with Natural Rubber Latex

- a. This value **SHALL** contain zero or one [0..1] @code (CONF:4437-3500).
- b. This value **SHALL** contain exactly one [1..1]  
@codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3501).
- c. This value **SHOULD** contain zero or one [0..1]  
@sdct:valueSet="2.16.840.1.113762.1.4.1021.47" (CONF:4437-3538).

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