

- 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:
<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.

Table 20: Lot or Batch Number Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.315:2019-06-21)					
templateId	1..1	SHALL		<a href="#">4437-3450</a>	
@root	1..1	SHALL		<a href="#">4437-3452</a>	2.16.840.1.113883.10.20.22.4.315
@extension	1..1	SHALL		<a href="#">4437-3453</a>	2019-06-21
code	1..1	SHALL		<a href="#">4437-3451</a>	
@code	1..1	SHALL		<a href="#">4437-3454</a>	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101672
@codeSystem	1..1	SHALL		<a href="#">4437-3455</a>	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		<a href="#">4437-3456</a>	NCI Thesaurus
@displayName	0..1	MAY		<a href="#">4437-3457</a>	Lot or Batch Number
value	1..1	SHALL	ED	<a href="#">4437-3458</a>	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3450).

- This **templateId** **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.315" (CONF:4437-3452).  
Note: template oid

Revision from "2018-05-01".

- This **templateId** **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3453).

2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3451).

Note: Code for "Lot or Batch Number"

Code used to specify the **Lot or Batch Number**.

- This code **SHALL** contain exactly one [1..1] **@code**="C101672" Lot or Batch Number (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3454).
- This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3455).
- This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3456).
- This code **MAY** contain zero or one [0..1] **@displayName**="Lot or Batch Number" (CONF:4437-3457).

The Lot or Batch Number can point to its corresponding narrative using the approach defined in CDA Release 2, section 4.3.5.1.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="ED" (CONF:4437-3458).

**Figure 10: Lot or Batch Number**

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.315" extension="2019-06-21"/>
  <code code="C101672" displayName="Lot or Batch Number"
    codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
  <value xsi:type="ED">
    <reference value="#LotOrBatchNumber_1"/>
  </value>
</observation>
```

## 2.10 Manufacturing Date Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.316:2019-06-21 (open)]

**Table 21: Manufacturing Date 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 **Manufacturing Date** of the device. The manufacturing date is parsed from the UDI value, if present.