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.

Table 19: 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		4437-3450	
@root	1..1	SHALL		4437-3452	2.16.840.1.113883.10.20.22.4.315
@extension	1..1	SHALL		4437-3453	2019-06-21
code	1..1	SHALL		4437-3451	
@code	1..1	SHALL		4437-3454	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101672
@codeSystem	1..1	SHALL		4437-3455	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3456	NCI Thesaurus
@displayName	0..1	MAY		4437-3457	Lot or Batch Number
value	1..1	SHALL	ED	4437-3458	

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

   b. 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**.

   a. 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).
   b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3455).
   c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3456).
   d. 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 20: Manufacturing Date 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 **Manufacturing Date** of the device. The manufacturing date is parsed from the UDI value, if present.