

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="ST" (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:
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.

Table 22: Manufacturing Date Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.316:2019-06-21)					
templateId	1..1	SHALL		4437-3459	
@root	1..1	SHALL		4437-3462	2.16.840.1.113883.10.20.22.4.316
@extension	1..1	SHALL		4437-3463	2019-06-21
code	1..1	SHALL		4437-3460	
@code	1..1	SHALL		4437-3464	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101669
@codeSystem	1..1	SHALL		4437-3465	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3466	NCI Thesaurus
@displayName	0..1	MAY		4437-3467	Manufacturing Date
value	1..1	SHALL	TS	4437-3461	
@value	1..1	SHALL		4437-3468	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3459).
 - a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.316" (CONF:4437-3462).
Note: template oid

Revision from "2018-05-01".

- b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3463).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3460).
Note: Code for "Manufacturing Date"

Code used to specify the **Manufacturing Date**.

- a. This code **SHALL** contain exactly one [1..1] **@code**="C101669" Manufacturing Date (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3464).
Note: Manufacturing Date code
- b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3465).
- c. This code **MAY** contain zero or one [0..1] **@codeSystemName**="NCI Thesaurus" (CONF:4437-3466).

- d. This code **MAY** contain zero or one [0..1] **@displayName**="Manufacturing Date" (CONF:4437-3467).

The value of the Manufacturing Date as a time stamp.

3. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="TS" (CONF:4437-3461).
Note: Manufacturing Date as a time stamp

Manufacturing Date as a time stamp.

- a. This value **SHALL** contain exactly one [1..1] **@value** (CONF:4437-3468).

Figure 11: Manufacturing Date

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.316" extension="2019-06-21"/>
  <code code="C101669" displayName="Manufacturing Date"
    codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
  <value xsi:type="TS" value="20181015"/>
</observation>
```

2.11 Model Number Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.317:2019-06-21 (open)]

Table 23: Model 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 **Model Number** associated with the device. The UDI-DI of the medical device may be used to retrieve the **Model Number** in accessGUDID, which should be considered the source of truth.