

The Model 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:4437-3420).

Figure 12: Model Number

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.317" extension="2019-06-21"/>
  <code code="C99285" displayName="Model Number"
    codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>
  <value xsi:type="ED">
    <reference value="#ModelNumber_1"/>
  </value>
</observation>
```

2.12 MRI Safety Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.318:2019-06-21 (open)]

Table 25: MRI 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 MRI Safety Status of the patient's medical device. The UDI-DI of the medical device may be used to retrieve the **MRI Safety Status** in accessGUDID, which should be considered the source of truth.

Table 26: MRI Safety Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.318:2019-06-21)					
templateId	1..1	SHALL		4437-3469	
@root	1..1	SHALL		4437-3471	2.16.840.1.113883.10.20.22.4.318
@extension	1..1	SHALL		4437-3472	2019-06-21
code	1..1	SHALL		4437-3470	
@code	1..1	SHALL		4437-3473	urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C106044
@codeSystem	1..1	SHALL		4437-3474	2.16.840.1.113883.3.26.1.1
@codeSystemName	0..1	MAY		4437-3475	NCI Thesaurus
@displayName	0..1	MAY		4437-3476	MRI Safety
value	1..1	SHALL	CD	4437-3477	urn:oid:2.16.840.1.113762.1.4.1021.46 (Device Magnetic resonance (MR) Safety)
@code	1..1	SHALL		4437-3478	
@codeSystem	1..1	SHALL		4437-3479	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3469).
 - a. This templateId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.318" (CONF:4437-3471).
Note: template oid

Revision from "2018-05-01".

- b. This templateId **SHALL** contain exactly one [1..1] **@extension**="2019-06-21" (CONF:4437-3472).
2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3470).
Note: Code for "MRI Safety Status"

Code used to specify the **MRI Safety Status**.

- a. This code **SHALL** contain exactly one [1..1] **@code**="C106044" MRI Safety (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3473).
- b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3474).

- c. This code **MAY** contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3475).
- d. This code **MAY** contain zero or one [0..1] @displayName="MRI Safety" (CONF:4437-3476).

The value of the MRI Safety status.

- 3. **SHALL** contain exactly one [1..1] value with @xsi:type="CD", where the code **SHALL** be selected from ValueSet Device Magnetic resonance (MR) Safety urn:oid:2.16.840.1.113762.1.4.1021.46 **STATIC** 2019-06-21 (CONF:4437-3477).
 - a. This value **SHALL** contain exactly one [1..1] @code (CONF:4437-3478).
 - b. This value **SHALL** contain exactly one [1..1] @codeSystem (CONF:4437-3479).

Figure 13: MRI Safety Status

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.318" extension="2019-06-21"/>
  <code code="C106044" displayName="MRI Safety Status"
    codeSystem="2.16.840.1.113883.3.26.1.1"codeSystemName="NCI Thesaurus"/>
  <value xsi:type="CD" code="C113844" codeSystem="2.16.840.1.113883.3.26.1.1"
    displayName="Labeling does not contain MRI Safety Information"
    codeSystemName="NCI Thesaurus" sdct:valueSet="2.16.840.1.113762.1.4.1021.46">
    <originalText>
      <reference value="#MRISafety_1"/>
    </originalText>
  </value>
</observation>
```

2.13 Serial Number Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.319:2019-06-21 (open)]

Table 27: Serial 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 **Serial Number** of the device. The serial number is parsed from the UDI value, if present.