Appendix B: UDI Organizer template from C-CDA Supplemental Templates for UDI

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

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:
<u>UDI Organizer</u> (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.

XPath	Card.	Verb	Data Type	CONF#	Value	
observation (identifier: urn:hl7	ii:2.16.840.1.	113883.10.2	20.22.4.31	7:2019-06-2	21)	
templateId	11	SHALL		4437- 3412		
@root	11	SHALL		4437- 3414	2.16.840.1.113883.10.20.22.4 .317	
@extension	11	SHALL		4437- 3415	2019-06-21	
code	11	SHALL		4437- 3413		
@code	11	SHALL		<u>4437-</u> <u>3416</u>	urn:oid:2.16.840.1.113883.3.2 6.1.1 (NCI Thesaurus (NCIt)) = C99285	
@codeSystem	11	SHALL		<u>4437-</u> <u>3417</u>	2.16.840.1.113883.3.26.1.1	
@codeSystemName	01	MAY		<u>4437-</u> <u>3418</u>	NCI Thesaurus	
@displayName	01	MAY		<u>4437-</u> <u>3419</u>	Model Number	
value	11	SHALL	ED	4437-		

Table 24: Model Number Observation Constraints Overview

- 1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3412).
 - a. This templateId **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.317" (CONF:4437-3414). Note: template oid

Revision from "2018-05-01".

b. This templateId **SHALL** contain exactly one [1..1] @extension="2019-06-21" (CONF:4437-3415).

3420

2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3413). Note: Code for "Device Model Number"

Code used to specify the Model Number.

- a. This code **SHALL** contain exactly one [1..1] **@code=**"C99285" Model Number (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3416).
- b. This code **SHALL** contain exactly one [1..1] **@codeSystem=**"2.16.840.1.113883.3.26.1.1" (CONF:4437-3417).
- c. This code MAY contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3418).
- d. This code MAY contain zero or one [0..1] @displayName="Model Number" (CONF:4437-3419).

Appendix B: UDI Organizer template from C-CDA Supplemental Templates for UDI

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

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:
<u>UDI Organizer</u> (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.