CDAR2\_IG\_CCDA\_COMPANION\_R3\_STU\_2022MAY\_AppxB



**HL7 CDA® R2 Implementation Guide:**

**C-CDA Templates for Clinical Notes STU Companion Guide**

**Release 3 (US Realm)**

**Standard for Trial Use**

**May 2022**

**Appendix B: UDI Organizer template from C-CDA Supplemental Templates for Unique Device Identifier (UDI)**

Publication of this standard for trial use (STU) has been approved by Health Level Seven International (HL7). This STU is not an accredited American National Standard. The feedback period on the use of this STU shall end 24 months from the date of publication. For information on submitting feedback see <http://www.hl7.org/permalink/?SpecificationFeedback>.

Following this 24 month feedback period, this STU, revised as necessary, may be resubmitted for further feedback or submitted to a normative ballot in preparation for approval by ANSI as an American National Standard. Implementations of this STU shall be viable throughout any subsequent normative ballot process and for up to six months after publication of the relevant normative standard.

Copyright © 2022 Health Level Seven International ® ALL RIGHTS RESERVED. The reproduction of this material in any form is strictly forbidden without the written permission of the publisher. HL7 International and Health Level Seven are registered trademarks of Health Level Seven International. Reg. U.S. Pat & TM Off**.**

**IMPORTANT NOTES:**

HL7 licenses its standards and select IP free of charge. **If you did not acquire a free license from HL7 for this document,** you are not authorized to access or make any use of it. To obtain a free license, please visit http://www.HL7.org/implement/standards/index.cfm.

**If you are the individual that obtained the license for this HL7 Standard, specification or other freely licensed work (in each and every instance "Specified Material")**, the following describes the permitted uses of the Material.

**A. HL7 INDIVIDUAL, STUDENT AND HEALTH PROFESSIONAL MEMBERS,** who register and agree to the terms of HL7’s license, are authorized, without additional charge, to read, and to use Specified Material to develop and sell products and services that implement, but do not directly incorporate, the Specified Material in whole or in part without paying license fees to HL7.

INDIVIDUAL, STUDENT AND HEALTH PROFESSIONAL MEMBERS wishing to incorporate additional items of Special Material in whole or part, into products and services, or to enjoy additional authorizations granted to HL7 ORGANIZATIONAL MEMBERS as noted below, must become ORGANIZATIONAL MEMBERS of HL7.

**B. HL7 ORGANIZATION MEMBERS,** who register and agree to the terms of HL7's License, are authorized, without additional charge, on a perpetual (except as provided for in the full license terms governing the Material), non-exclusive and worldwide basis, the right to (a) download, copy (for internal purposes only) and share this Material with your employees and consultants for study purposes, and (b) utilize the Material for the purpose of developing, making, having made, using, marketing, importing, offering to sell or license, and selling or licensing, and to otherwise distribute, Compliant Products, in all cases subject to the conditions set forth in this Agreement and any relevant patent and other intellectual property rights of third parties (which may include members of HL7). No other license, sublicense, or other rights of any kind are granted under this Agreement.

**C. NON-MEMBERS,** who register and agree to the terms of HL7’s IP policy for Specified Material, are authorized, without additional charge, to read and use the Specified Material for evaluating whether to implement, or in implementing, the Specified Material, and to use Specified Material to develop and sell products and services that implement, but do not directly incorporate, the Specified Material in whole or in part.

NON-MEMBERS wishing to incorporate additional items of Specified Material in whole or part, into products and services, or to enjoy the additional authorizations granted to HL7 ORGANIZATIONAL MEMBERS, as noted above, must become ORGANIZATIONAL MEMBERS of HL7.

Please see http://www.HL7.org/legal/ippolicy.cfm for the full license terms governing the Material.

**Ownership.** Licensee agrees and acknowledges that **HL7 owns** all right, title, and interest, in and to the Trademark. Licensee shall **take no action contrary to, or inconsistent with**, the foregoing.

**Licensee agrees and acknowledges that HL7 may not own all right, title, and interest, in and to the Materials and that the Materials may contain and/or reference intellectual property owned by third parties (“Third Party IP”). Acceptance of these License Terms does not grant Licensee any rights with respect to Third Party IP. Licensee alone is responsible for identifying and obtaining any necessary licenses or authorizations to utilize Third Party IP in connection with the Materials or otherwise. Any actions, claims or suits brought by a third party resulting from a breach of any Third Party IP right by the Licensee remains the Licensee’s liability.**

Following is a non-exhaustive list of third-party terminologies that may require a separate license:

| **Terminology** | **Owner/Contact** |
| --- | --- |
| Current Procedures Terminology (CPT) code set | American Medical Association https://www.ama-assn.org/practice-management/cpt-licensing |
| SNOMED CT | SNOMED International http://www.snomed.org/snomed-ct/get-snomed-ct or info@ihtsdo.org |
| Logical Observation Identifiers Names & Codes (LOINC) | Regenstrief Institute |
| International Classification of Diseases (ICD) codes | World Health Organization (WHO) |
| NUCC Health Care Provider Taxonomy code set | American Medical Association. Please see www.nucc.org. AMA licensing contact: 312-464-5022 (AMA IP services) |

Table of Contents

[1 entry 6](#_Toc103326487)

[1.1 UDI Organizer 6](#_Toc103326488)

[1.1.1 Properties 9](#_Toc103326489)

[2 subentry 17](#_Toc103326490)

[2.1 Brand Name Observation 17](#_Toc103326491)

[2.2 Catalog Number Observation 18](#_Toc103326492)

[2.3 Company Name Observation 20](#_Toc103326493)

[2.4 Device Identifier Observation (V2) 22](#_Toc103326494)

[2.5 Distinct Identification Code Observation 24](#_Toc103326495)

[2.6 Expiration Date Observation 26](#_Toc103326496)

[2.7 Implantable Device Status Observation 28](#_Toc103326497)

[2.8 Latex Safety Observation 30](#_Toc103326498)

[2.9 Lot or Batch Number Observation 32](#_Toc103326499)

[2.10 Manufacturing Date Observation 34](#_Toc103326500)

[2.11 Model Number Observation 36](#_Toc103326501)

[2.12 MRI Safety Observation 38](#_Toc103326502)

[2.13 Serial Number Observation 40](#_Toc103326503)

[3 Template Ids in This Guide 43](#_Toc103326504)

[4 Code Systems in This Guide 45](#_Toc103326505)

Table of Figures

[Figure 1: Unique Device Identifier (UDI) Organizer 13](#_Toc103326506)

[Figure 2: Brand Name Example 18](#_Toc103326507)

[Figure 3: Catalog Number Sample 20](#_Toc103326508)

[Figure 4: Company Name 22](#_Toc103326509)

[Figure 5: Device Identifier 24](#_Toc103326510)

[Figure 6: Distinct Identification Code 26](#_Toc103326511)

[Figure 7: Expiration Date 28](#_Toc103326512)

[Figure 8: Implantable Device Status 30](#_Toc103326513)

[Figure 9: Latex Safety Status 32](#_Toc103326514)

[Figure 10: Lot or Batch Number 34](#_Toc103326515)

[Figure 11: Manufacturing Date 36](#_Toc103326516)

[Figure 12: Model Number 38](#_Toc103326517)

[Figure 13: MRI Safety Status 40](#_Toc103326518)

[Figure 14: Serial Number 42](#_Toc103326519)

Table of Tables

[Table 1: UDI Organizer Contexts 6](#_Toc103326520)

[Table 2: UDI Organizer Constraints Overview 7](#_Toc103326521)

[Table 3: Brand Name Observation Contexts 17](#_Toc103326522)

[Table 4: Brand Name Observation Constraints Overview 17](#_Toc103326523)

[Table 5: Catalog Number Observation Contexts 18](#_Toc103326524)

[Table 6: Catalog Number Observation Constraints Overview 19](#_Toc103326525)

[Table 7: Company Name Observation Contexts 20](#_Toc103326526)

[Table 8: Company Name Observation Constraints Overview 21](#_Toc103326527)

[Table 9: Device Identifier Observation (V2) Constraints Overview 23](#_Toc103326528)

[Table 10: Distinct Identification Code Observation Contexts 24](#_Toc103326529)

[Table 11: Distinct Identification Code Observation Constraints Overview 25](#_Toc103326530)

[Table 12: Expiration Date Observation Contexts 26](#_Toc103326531)

[Table 13: Expiration Date Observation Constraints Overview 27](#_Toc103326532)

[Table 14: Implantable Device Status Observation Contexts 28](#_Toc103326533)

[Table 15: Implantable Device Status Observation Constraints Overview 29](#_Toc103326534)

[Table 16: Latex Safety Observation Contexts 30](#_Toc103326535)

[Table 17: Latex Safety Observation Constraints Overview 31](#_Toc103326536)

[Table 18: Lot or Batch Number Observation Contexts 32](#_Toc103326537)

[Table 19: Lot or Batch Number Observation Constraints Overview 33](#_Toc103326538)

[Table 20: Manufacturing Date Observation Contexts 34](#_Toc103326539)

[Table 21: Manufacturing Date Observation Constraints Overview 35](#_Toc103326540)

[Table 22: Model Number Observation Contexts 36](#_Toc103326541)

[Table 23: Model Number Observation Constraints Overview 37](#_Toc103326542)

[Table 24: MRI Safety Observation Contexts 38](#_Toc103326543)

[Table 25: MRI Safety Observation Constraints Overview 39](#_Toc103326544)

[Table 26: Serial Number Observation Contexts 40](#_Toc103326545)

[Table 27: Serial Number Observation Constraints Overview 41](#_Toc103326546)

[Table 28: Template List 43](#_Toc103326547)

[Table 29: Template Containments 44](#_Toc103326548)

[Table 30: Code Systems 45](#_Toc103326549)

# entry

UDI Organizer

[organizer: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.311:2019-06-21 (open)]

Table 1: UDI Organizer Contexts

| Contained By: | Contains: |
| --- | --- |
|  | [Distinct Identification Code Observation](#E_Distinct_Identification_Code_Observat) (optional)  [Serial Number Observation](#E_Serial_Number_Observation) (optional)  [Expiration Date Observation](#E_Expiration_Date_Observation) (optional)  [Brand Name Observation](#E_Brand_Name_Observation) (optional)  [Model Number Observation](#E_Model_Number_Observation) (optional)  [Catalog Number Observation](#E_Catalog_Number_Observation) (optional)  [Company Name Observation](#E_Company_Name_Observation) (optional)  [Lot or Batch Number Observation](#E_Lot_or_Batch_Number_Observation_2019) (optional)  [Manufacturing Date Observation](#E_Manufacturing_Date_Observation_2019) (optional)  [MRI Safety Observation](#E_MRI_Safety_Observation) (optional)  [Latex Safety Observation](#SE_Latex_Safety_Observation_2019) (optional)  [Implantable Device Status Observation](#SE_Implantable_Device_Status_Observation) (optional) |

This template is nested in an entryRelationship/Procedure Activity Procedure to record all the UDI-related templates to exchange the parsed UDI data elements and associated data.

* **Device Identifier**  
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.304: 2019-06-21 NCIt: C101722 SHALL be included in UDI Organizer
* **Lot or Batch Number**  
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.315: 2019-06-21 NCIt:C101672 SHOULD be included in UDI Organizer if present in UDI
* **Serial Number**  
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.319: 2019-06-21 NCIt: C101671 SHOULD be included in UDI Organizer if present in UDI
* **Manufacturing Date**  
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.316: 2019-06-21 NCIt:C101669 SHOULD be included in UDI Organizer if present in UDI
* **Expiration Date**  
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.309: 2019-06-21 NCIt: C101670 SHOULD be included in UDI Organizer if present in UDI
* **Distinct Identification Code**  
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.308: 2019-06-21 NCIt: C113843 SHOULD be included in UDI Organizer if present in UDI
* **Brand Name**  
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.301: 2019-06-21 NCIt: C71898 MAY be included in the UDI Organizer if available
* **Model Number**  
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.317: 2019-06-21 NCIt: C99285 MAY be included in the UDI Organizer if available
* **Catalog Number**  
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.302: 2019-06-21 NCIt: C99286 MAY be included in the UDI Organizer if available
* **Company Name**  
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.303: 2019-06-21 NCIt: C54131 MAY be included in the UDI Organizer if available
* **MRI Safety**  
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.318: 2019-06-21 NCIt: C106044 MAY be included in the UDI Organizer if available
* **Latex Safety**  
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.314: 2019-06-21 NCIt: C160938 MAY be included in the UDI Organizer if available
* **Implantable Device Status**  
  urn:hl7ii:2.16.840.1.113883.10.20.22.4.305 2019-06-21 NCIt: C160939 MAY be included in the UDI Organizer if available

Table 2: UDI Organizer Constraints Overview

| XPath | Card. | Verb | Data Type | CONF# | Value |
| --- | --- | --- | --- | --- | --- |
| organizer (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.311:2019-06-21) | | | | | |
| @classCode | 1..1 | SHALL |  | [4437-3482](#C_4437-3482) | CLUSTER |
| @moodCode | 1..1 | SHALL |  | [4437-3483](#C_4437-3483) | EVN |
| templateId | 1..1 | SHALL |  | [4437-3480](#C_4437-3480) |  |
| @root | 1..1 | SHALL |  | [4437-3484](#C_4437-3484) | 2.16.840.1.113883.10.20.22.4.311 |
| @extension | 1..1 | SHALL |  | [4437-3485](#C_4437-3485) | 2019-06-21 |
| id | 1..1 | SHALL |  | [4437-3541](#C_4437-3541) |  |
| @root | 1..1 | SHALL |  | [4437-3542](#C_4437-3542) |  |
| code | 0..1 | MAY |  | [4437-3481](#C_4437-3481) |  |
| @code | 0..1 | MAY |  | [4437-3486](#C_4437-3486) | urn:oid:2.16.840.1.113883.6.1 (LOINC) = 74711-3 |
| @codeSystem | 1..1 | SHALL |  | [4437-3487](#C_4437-3487) | 2.16.840.1.113883.6.1 |
| statusCode | 1..1 | SHALL |  | [4437-3490](#C_4437-3490) |  |
| @code | 1..1 | SHALL |  | [4437-3543](#C_4437-3543) | urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed |
| component | 1..1 | SHALL |  | [4437-3488](#C_4437-3488) |  |
| observation | 1..1 | SHALL |  | [4437-3489](#C_4437-3489) | Device Identifier Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2019-06-21 |
| component | 0..1 | SHOULD |  | [4437-3513](#C_4437-3513) |  |
| observation | 1..1 | SHALL |  | [4437-3514](#C_4437-3514) | [Lot or Batch Number Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.315:2019-06-21](#E_Lot_or_Batch_Number_Observation_2019) |
| component | 0..1 | SHOULD |  | [4437-3515](#C_4437-3515) |  |
| observation | 1..1 | SHALL |  | [4437-3516](#C_4437-3516) | [Serial Number Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.319:2019-06-21](#E_Serial_Number_Observation) |
| component | 0..1 | SHOULD |  | [4437-3517](#C_4437-3517) |  |
| observation | 1..1 | SHALL |  | [4437-3518](#C_4437-3518) | [Manufacturing Date Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.316:2019-06-21](#E_Manufacturing_Date_Observation_2019) |
| component | 0..1 | SHOULD |  | [4437-3525](#C_4437-3525) |  |
| observation | 1..1 | SHALL |  | [4437-3526](#C_4437-3526) | [Expiration Date Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.309:2019-06-21](#E_Expiration_Date_Observation) |
| component | 0..1 | SHOULD |  | [4437-3523](#C_4437-3523) |  |
| observation | 1..1 | SHALL |  | [4437-3524](#C_4437-3524) | [Distinct Identification Code Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.308:2019-06-21](#E_Distinct_Identification_Code_Observat) |
| component | 0..1 | MAY |  | [4437-3521](#C_4437-3521) |  |
| observation | 1..1 | SHALL |  | [4437-3522](#C_4437-3522) | [Brand Name Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.301:2019-06-21](#E_Brand_Name_Observation) |
| component | 0..1 | MAY |  | [4437-3519](#C_4437-3519) |  |
| observation | 1..1 | SHALL |  | [4437-3520](#C_4437-3520) | [Model Number Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.317:2019-06-21](#E_Model_Number_Observation) |
| component | 0..1 | MAY |  | [4437-3535](#C_4437-3535) |  |
| observation | 1..1 | SHALL |  | [4437-3536](#C_4437-3536) | [Company Name Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21](#E_Company_Name_Observation) |
| component | 0..1 | MAY |  | [4437-3527](#C_4437-3527) |  |
| observation | 1..1 | SHALL |  | [4437-3528](#C_4437-3528) | [Catalog Number Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21](#E_Catalog_Number_Observation) |
| component | 0..1 | MAY |  | [4437-3529](#C_4437-3529) |  |
| observation | 1..1 | SHALL |  | [4437-3530](#C_4437-3530) | [Latex Safety Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-21](#SE_Latex_Safety_Observation_2019) |
| component | 0..1 | MAY |  | [4437-3533](#C_4437-3533) |  |
| observation | 1..1 | SHALL |  | [4437-3534](#C_4437-3534) | [MRI Safety Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.318:2019-06-21](#E_MRI_Safety_Observation) |
| component | 0..1 | MAY |  | [4437-3531](#C_4437-3531) |  |
| observation | 1..1 | SHALL |  | [4437-3532](#C_4437-3532) | [Implantable Device Status Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21](#SE_Implantable_Device_Status_Observation) |

Properties

@classCode

The UDI Organizer contains the parsed components of the UDI included in the Product Instance.

1. SHALL contain exactly one [1..1] @classCode="CLUSTER" (CONF:4437-3482).
2. SHALL contain exactly one [1..1] @moodCode="EVN" (CONF:4437-3483).
3. SHALL contain exactly one [1..1] templateId (CONF:4437-3480) such that it
   1. SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.311" (CONF:4437-3484).

Revision from "2018-05-01".

* 1. SHALL contain exactly one [1..1] @extension="2019-06-21" (CONF:4437-3485).

The UDI Organizer identifier shall match the Product Instance identifier value. The identifier will tie the specific UDI information to an individual product instance.

1. SHALL contain exactly one [1..1] id (CONF:4437-3541).
   1. This id SHALL contain exactly one [1..1] @root (CONF:4437-3542).
2. MAY contain zero or one [0..1] code (CONF:4437-3481).
   1. The code, if present, MAY contain zero or one [0..1] @code="74711-3" Unique Device Identifier (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:4437-3486).
   2. The code, if present, SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CONF:4437-3487).

This is the status of the UDI Organizer. The value if fixed to "completed".

1. SHALL contain exactly one [1..1] statusCode (CONF:4437-3490).
   1. This statusCode SHALL contain exactly one [1..1] @code="completed" Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4437-3543).

**Device Identifier** - the mandatory part of the UDI

1. SHALL contain exactly one [1..1] component (CONF:4437-3488) such that it
   1. SHALL contain exactly one [1..1] Device Identifier Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2019-06-21) (CONF:4437-3489).

**Lot or Batch Number** - needed if present as a production identifier

1. SHOULD contain zero or one [0..1] component (CONF:4437-3513) such that it
   1. SHALL contain exactly one [1..1] [Lot or Batch Number Observation](#E_Lot_or_Batch_Number_Observation_2019) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.315:2019-06-21) (CONF:4437-3514).

**Serial Number** - needed if present as a production identifier

1. SHOULD contain zero or one [0..1] component (CONF:4437-3515) such that it
   1. SHALL contain exactly one [1..1] [Serial Number Observation](#E_Serial_Number_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.319:2019-06-21) (CONF:4437-3516).

**Manufacturing Date** - needed if present as a production identifier

1. SHOULD contain zero or one [0..1] component (CONF:4437-3517) such that it
   1. SHALL contain exactly one [1..1] [Manufacturing Date Observation](#E_Manufacturing_Date_Observation_2019) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.316:2019-06-21) (CONF:4437-3518).

**Expiration Date** - needed if present as a production identifier

1. SHOULD contain zero or one [0..1] component (CONF:4437-3525) such that it
   1. SHALL contain exactly one [1..1] [Expiration Date Observation](#E_Expiration_Date_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.309:2019-06-21) (CONF:4437-3526).

**Distinct Identification Code** - needed if present as a production identifier for HCT/P regulated as medical devices.

1. SHOULD contain zero or one [0..1] component (CONF:4437-3523) such that it
   1. SHALL contain exactly one [1..1] [Distinct Identification Code Observation](#E_Distinct_Identification_Code_Observat) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.308:2019-06-21) (CONF:4437-3524).

**Brand Name** - when it was extracted from accessGUDID at the time the information was entered in the patient's record.

1. MAY contain zero or one [0..1] component (CONF:4437-3521) such that it
   1. SHALL contain exactly one [1..1] [Brand Name Observation](#E_Brand_Name_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.301:2019-06-21) (CONF:4437-3522).

**Model Number** - when it was extracted from accessGUDID at the time the information was entered in the patient's record.

1. MAY contain zero or one [0..1] component (CONF:4437-3519) such that it
   1. SHALL contain exactly one [1..1] [Model Number Observation](#E_Model_Number_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.317:2019-06-21) (CONF:4437-3520).

**Company Name** - the name of the company that manufactured the device when it was extracted from accessGUDID at the time the information was entered in the patient's record.

1. MAY contain zero or one [0..1] component (CONF:4437-3535) such that it
   1. SHALL contain exactly one [1..1] [Company Name Observation](#E_Company_Name_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21) (CONF:4437-3536).

**Catalog Number** - specified by manufacturer or when it was extracted from accessGUDID at the time the information was entered in the patient's record.

1. MAY contain zero or one [0..1] component (CONF:4437-3527) such that it
   1. SHALL contain exactly one [1..1] [Catalog Number Observation](#E_Catalog_Number_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21) (CONF:4437-3528).

**Latex Safety Status** when it was extracted from accessGUDID at the time the information was entered in the patient's record.

1. MAY contain zero or one [0..1] component (CONF:4437-3529) such that it
   1. SHALL contain exactly one [1..1] [Latex Safety Observation](#SE_Latex_Safety_Observation_2019) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-21) (CONF:4437-3530).

**MRI Safety Status** when it was extracted from accessGUDID at the time the information was entered in the patient's record.

1. MAY contain zero or one [0..1] component (CONF:4437-3533) such that it
   1. SHALL contain exactly one [1..1] [MRI Safety Observation](#E_MRI_Safety_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.318:2019-06-21) (CONF:4437-3534).

**Implantable Device Status** - the status of the device in the body of the patient, it augments the information in **@status.**

1. MAY contain zero or one [0..1] component (CONF:4437-3531) such that it
   1. SHALL contain exactly one [1..1] [Implantable Device Status Observation](#SE_Implantable_Device_Status_Observation) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21) (CONF:4437-3532).

Figure 1: Unique Device Identifier (UDI) Organizer

<!-- UDI Organizer -->

<organizer classCode="CLUSTER" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.311"

extension="2019-06-21"/>

<id assigningAuthorityName="FDA" extension="(01)99994328998989(11)160330(10)ABC124(17)200712(21)2302991ABC210181" root="GS1"/>

<code code="74711-3" codeSystem="2.16.840.1.113883.6.1"

displayName="Unique Device Identifier"/>

<statusCode code="completed"/>

<!-- UDI components -->

<component>

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.304"

extension="2019-06-21"/>

<code code="C101722" displayName="Primary DI Number"

codeSystem="2.16.840.1.113883.3.26.1.1"

codeSystemName="NCI Thesaurus"/>

<!-- GS1 Device Identifier -->

<value xsi:type="II" root="1.3.160"

extension="99994328998989" displayable="true"

assigningAuthorityName="GS1"/>

</observation>

</component>

<component>

<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>

</component>

<component>

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.319"

extension="2019-06-21"/>

<code code="C101671" displayName="Serial Number"

codeSystem="2.16.840.1.113883.3.26.1.1"

codeSystemName="NCI Thesaurus"/>

<value xsi:type="ED">

<reference value="#SerialNumber\_1"/>

</value>

</observation>

</component>

<component>

<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>

</component>

<component>

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.309"

extension="2019-06-21"/>

<code code="C101670" displayName="Expiration Date"

codeSystem="2.16.840.1.113883.3.26.1.1"

codeSystemName="NCI Thesaurus"/>

<value xsi:type="TS" value="20221015"/>

</observation>

</component>

<component>

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.308"

extension="2019-06-21"/>

<code code="C113843"

displayName="Distinct Identification Code"

codeSystem="2.16.840.1.113883.3.26.1.1"

codeSystemName="NCI Thesaurus"/>

<value xsi:type="ED">

<reference value="#DistinctIdentificationCode\_1"/>

</value>

</observation>

</component>

<component>

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.301"

extension="2019-06-21"/>

<code code="C71898" displayName="Brand Name"

codeSystem="2.16.840.1.113883.3.26.1.1"

codeSystemName="NCI Thesaurus"/>

<value xsi:type="ED">

<reference value="#BrandName\_1"/>

</value>

</observation>

</component>

<component>

<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>

</component>

<component>

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.302"

extension="2019-06-21"/>

<code code="C99286" displayName="Catalog Number"

codeSystem="2.16.840.1.113883.3.26.1.1"

codeSystemName="NCI Thesaurus"/>

<value xsi:type="ED">

<reference value="#CatalogNumber\_1"/>

</value>

</observation>

</component>

<component>

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.303"

extension="2019-06-21"/>

<code code="C54131" displayName="Company Name"

codeSystem="2.16.840.1.113883.3.26.1.1"

codeSystemName="NCI Thesaurus"/>

<value xsi:type="ED">

<reference value="#CompanyName\_1"/>

</value>

</observation>

</component>

<component>

<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" sdtc:valueSet="2.16.840.1.113762.1.4.1021.46">

<originalText>

<reference value="#MRISafety\_1"/>

</originalText>

</value>

</observation>

</component>

<component>

<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>

</component>

<component>

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.305"

extension="2019-06-21"/>

<code code="C160939" displayName="Implantable Device Status"

codeSystem="2.16.840.1.113883.3.26.1.1"

codeSystemName="NCI Thesaurus"/>

<value xsi:type="CD" code="C160942"

codeSystem="2.16.840.1.113883.3.26.1.1" displayName="Reduced Function"

codeSystemName="NCI Thesaurus" sdtc:valueSet="2.16.840.1.113762.1.4.1021.48">

<originalText>

<reference value="#ImplantableDeviceStatus\_1"/>

</originalText>

</value>

</observation>

</component>

</organizer>

# subentry

Brand Name Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.301:2019-06-21 (open)]

Table 3: Brand Name Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [UDI Organizer](#E_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 **Brand Name**. The UDI-DI of the medical device may be used to retrieve the **Brand Name** in accessGUDID, which should be considered the source of truth.

Table 4: Brand Name Observation Constraints Overview

| XPath | Card. | Verb | Data Type | CONF# | Value |
| --- | --- | --- | --- | --- | --- |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.301:2019-06-21) | | | | | |
| templateId | 1..1 | SHALL |  | [4437-3403](#C_4437-3403) |  |
| @root | 1..1 | SHALL |  | [4437-3405](#C_4437-3405) | 2.16.840.1.113883.10.20.22.4.301 |
| @extension | 1..1 | SHALL |  | [4437-3406](#C_4437-3406) | 2019-06-21 |
| code | 1..1 | SHALL |  | [4437-3404](#C_4437-3404) |  |
| @code | 1..1 | SHALL |  | [4437-3407](#C_4437-3407) | urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C71898 |
| @codeSystem | 1..1 | SHALL |  | [4437-3408](#C_4437-3408) | 2.16.840.1.113883.3.26.1.1 |
| @codeSystemName | 0..1 | MAY |  | [4437-3409](#C_4437-3409) | NCI Thesaurus |
| @displayName | 0..1 | MAY |  | [4437-3410](#C_4437-3410) | Brand Name |
| value | 1..1 | SHALL | ED | [4437-3411](#C_4437-3411) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:4437-3403).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.301" (CONF:4437-3405).  
      Note: template oid

Revision from "2018-05-01".

* 1. This templateId SHALL contain exactly one [1..1] @extension="2019-06-21" (CONF:4437-3406).

1. SHALL contain exactly one [1..1] code (CONF:4437-3404).  
   Note: Code for "Device Brand Name"

Code used to specify the **Brand Name**.

* 1. This code SHALL contain exactly one [1..1] @code="C71898" Brand Name (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 STATIC) (CONF:4437-3407).
  2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3408).
  3. This code MAY contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3409).
  4. This code MAY contain zero or one [0..1] @displayName="Brand Name" (CONF:4437-3410).

The Brand Name can point to its corresponding narrative using the approach defined in CDA Release 2, section 4.3.5.1.

1. SHALL contain exactly one [1..1] value with @xsi:type="ED" (CONF:4437-3411).

Figure 2: Brand Name Example

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.301" extension="2019-06-21"/>

<code code="C71898" displayName="Brand Name"

codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>

<value xsi:type="ED">

<reference value="#BrandName\_1"/>

</value>

</observation>

Catalog Number Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21 (open)]

Table 5: Catalog Number Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [UDI Organizer](#E_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 **Catalog Number**. The UDI-DI of the medical device may be used to retrieve the Catalog Number in accessGUDID, which should be considered the source of truth.

Table 6: Catalog Number Observation Constraints Overview

| XPath | Card. | Verb | Data Type | CONF# | Value |
| --- | --- | --- | --- | --- | --- |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21) | | | | | |
| templateId | 1..1 | SHALL |  | [4437-3432](#C_4437-3432) |  |
| @root | 1..1 | SHALL |  | [4437-3434](#C_4437-3434) | 2.16.840.1.113883.10.20.22.4.302 |
| @extension | 1..1 | SHALL |  | [4437-3435](#C_4437-3435) | 2019-06-21 |
| code | 1..1 | SHALL |  | [4437-3433](#C_4437-3433) |  |
| @code | 1..1 | SHALL |  | [4437-3436](#C_4437-3436) | urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C99286 |
| @codeSystem | 1..1 | SHALL |  | [4437-3437](#C_4437-3437) | 2.16.840.1.113883.3.26.1.1 |
| @codeSystemName | 0..1 | MAY |  | [4437-3438](#C_4437-3438) | NCI Thesaurus |
| @displayName | 0..1 | MAY |  | [4437-3439](#C_4437-3439) | Catalog Number |
| value | 1..1 | SHALL | ED | [4437-3440](#C_4437-3440) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:4437-3432).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.302" (CONF:4437-3434).  
      Note: template oid

Revision from "2018-05-01".

* 1. This templateId SHALL contain exactly one [1..1] @extension="2019-06-21" (CONF:4437-3435).

1. SHALL contain exactly one [1..1] code (CONF:4437-3433).  
   Note: Code for "Device Catalog Number"

Code used to specify the **Catalog Number**.

* 1. This code SHALL contain exactly one [1..1] @code="C99286" Catalog Number (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 STATIC) (CONF:4437-3436).
  2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3437).
  3. This code MAY contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3438).
  4. This code MAY contain zero or one [0..1] @displayName="Catalog Number" (CONF:4437-3439).

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

1. SHALL contain exactly one [1..1] value with @xsi:type="ED" (CONF:4437-3440).

Figure 3: Catalog Number Sample

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.302" extension="2019-06-21"/>

<code code="C99286" displayName="Catalog Number"

codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>

<value xsi:type="ED">

<reference value="#CatalogNumber\_1"/>

</value>

</observation>

Company Name Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21 (open)]

Table 7: Company Name Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [UDI Organizer](#E_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 **Company Name**. The UDI-DI of the medical device may be used to retrieve the **Company Name** in accessGUDID, which should be considered the source of truth.

Table 8: Company Name Observation Constraints Overview

| XPath | Card. | Verb | Data Type | CONF# | Value |
| --- | --- | --- | --- | --- | --- |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21) | | | | | |
| templateId | 1..1 | SHALL |  | [4437-3441](#C_4437-3441) |  |
| @root | 1..1 | SHALL |  | [4437-3443](#C_4437-3443) | 2.16.840.1.113883.10.20.22.4.303 |
| @extension | 1..1 | SHALL |  | [4437-3444](#C_4437-3444) | 2019-06-21 |
| code | 1..1 | SHALL |  | [4437-3442](#C_4437-3442) |  |
| @code | 1..1 | SHALL |  | [4437-3445](#C_4437-3445) | urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C54131 |
| @codeSystem | 1..1 | SHALL |  | [4437-3446](#C_4437-3446) | 2.16.840.1.113883.3.26.1.1 |
| @codeSystemName | 0..1 | MAY |  | [4437-3447](#C_4437-3447) | NCI Thesaurus |
| @displayName | 0..1 | MAY |  | [4437-3448](#C_4437-3448) | Company Name |
| value | 1..1 | SHALL | ED | [4437-3449](#C_4437-3449) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:4437-3441).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.303" (CONF:4437-3443).  
      Note: template oid

Revision from "2018-05-01".

* 1. This templateId SHALL contain exactly one [1..1] @extension="2019-06-21" (CONF:4437-3444).

1. SHALL contain exactly one [1..1] code (CONF:4437-3442).  
   Note: Code for "Company Name"

Code used to specify the **Company Name**.

* 1. This code SHALL contain exactly one [1..1] @code="C54131" Company Name (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 STATIC) (CONF:4437-3445).
  2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3446).
  3. This code MAY contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3447).
  4. This code MAY contain zero or one [0..1] @displayName="Company Name" (CONF:4437-3448).

The Company Name can point to its corresponding narrative using the approach defined in CDA Release 2, section 4.3.5.1.

1. SHALL contain exactly one [1..1] value with @xsi:type="ED" (CONF:4437-3449).

Figure 4: Company Name

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.303" extension="2019-06-21"/>

<code code="C54131" displayName="Company Name"

codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>

<value xsi:type="ED">

<reference value="#CompanyName\_1"/>

</value>

</observation>

Device Identifier Observation (V2)

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2022-06-01 (open)]



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 **Device Identifier** (also known as the "Primary DI Number") for a medical device marketed in the US. The device identifier is parsed from the UDI value.

The Device Identifier number can be used as a key to look-up device identification information in the publicly available version of the US FDA Global UDI Database (GUDID) - the AccessGUDID: <https://accessgudid.nlm.nih.gov/resources/home>

Table 9: Device Identifier Observation (V2) Constraints Overview

| XPath | Card. | Verb | Data Type | CONF# | Value |
| --- | --- | --- | --- | --- | --- |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2022-06-01) | | | | | |
| templateId | 1..1 | SHALL |  | [4524-3421](#C_4524-3421) |  |
| @root | 1..1 | SHALL |  | [4524-3424](#C_4524-3424) | 2.16.840.1.113883.10.20.22.4.304 |
| @extension | 1..1 | SHALL |  | [4524-3425](#C_4524-3425) | 2022-06-01 |
| code | 1..1 | SHALL |  | [4524-3422](#C_4524-3422) |  |
| @code | 1..1 | SHALL |  | [4524-3426](#C_4524-3426) | urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101722 |
| @codeSystem | 1..1 | SHALL |  | [4524-3427](#C_4524-3427) | 2.16.840.1.113883.3.26.1.1 |
| @codeSystemName | 0..1 | MAY |  | [4524-3428](#C_4524-3428) | NCI Thesaurus |
| @displayName | 0..1 | MAY |  | [4524-3429](#C_4524-3429) | Primary DI Number |
| value | 1..1 | SHALL | II | [4524-3423](#C_4524-3423) |  |
| @root | 1..1 | SHALL |  | [4524-3430](#C_4524-3430) |  |
| @extension | 0..1 | SHOULD |  | [4524-3431](#C_4524-3431) |  |
| @displayable | 1..1 | SHALL |  | [4524-3540](#C_4524-3540) | true |

1. SHALL contain exactly one [1..1] templateId (CONF:4524-3421).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.304" (CONF:4524-3424).
   2. This templateId SHALL contain exactly one [1..1] @extension="2022-06-01" (CONF:4524-3425).
2. SHALL contain exactly one [1..1] code (CONF:4524-3422).  
   Note: Primary DI Number Code from NCIt

Code used to specify the device identifier, one of the parsed UDI components known as the Primary DI Number (UDI-DI).

* 1. This code SHALL contain exactly one [1..1] @code="C101722" Primary DI Number (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 STATIC) (CONF:4524-3426).
  2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4524-3427).
  3. This code MAY contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4524-3428).
  4. This code MAY contain zero or one [0..1] @displayName="Primary DI Number" (CONF:4524-3429).

The value of the Device Identifier assigned using one of the FDA-accredited, UDI issuing agency: GS1, HIBCC, or ICBBA.

1. SHALL contain exactly one [1..1] value with @xsi:type="II" (CONF:4524-3423).  
   Note: This value is assigned by the Manufacturer by using an FDA-accredited UDI-issuing agency

The "root" specifies the assigning authority, i.e, the UDI issuing agency. The allowable OIDs include:

1.3.160 (GS1)

2.16.840.1.113883.6.18 (ICCBBA - ISBT-128)

2.16.840.1.113883.6.40 (HIBCC)

* 1. This value SHALL contain exactly one [1..1] @root (CONF:4524-3430).

The value of the Device Identifier.

* 1. This value SHOULD contain zero or one [0..1] @extension (CONF:4524-3431).

The Device Identifier can be used to look up device information entered by manufacturers in the FDA GUDID

* 1. This value SHALL contain exactly one [1..1] @displayable="true" (CONF:4524-3540).

Figure 5: Device Identifier

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.304" extension="2019-06-21"/>

<code code="C101722" displayName="Primary DI Number"

codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>

<!-- GS1 Device Identifier -->

<value xsi:type="II" root="1.3.160" extension="00999998998989" displayable="true"

assigningAuthorityName="GS1"/>

</observation>

Distinct Identification Code Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.308:2019-06-21 (open)]

Table 10: Distinct Identification Code Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [UDI Organizer](#E_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 **Distinct Identification Code** for an HCT/P product regulated as a device as cited in 21 CFR 1271.290(c). The distinct identification code is parsed from the UDI value, if present.

The distinct identification code may be equivalent to the serial number, lot or batch number, or the donation identification number. The appropriate value should be provided as the distinct identification code.

Table 11: Distinct Identification Code Observation Constraints Overview

| XPath | Card. | Verb | Data Type | CONF# | Value |
| --- | --- | --- | --- | --- | --- |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.308:2019-06-21) | | | | | |
| templateId | 1..1 | SHALL |  | [4437-3348](#C_4437-3348) |  |
| @root | 1..1 | SHALL |  | [4437-3350](#C_4437-3350) | 2.16.840.1.113883.10.20.22.4.308 |
| @extension | 1..1 | SHALL |  | [4437-3351](#C_4437-3351) | 2019-06-21 |
| code | 1..1 | SHALL |  | [4437-3349](#C_4437-3349) |  |
| @code | 1..1 | SHALL |  | [4437-3355](#C_4437-3355) | urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C113843 |
| @codeSystem | 1..1 | SHALL |  | [4437-3352](#C_4437-3352) | 2.16.840.1.113883.3.26.1.1 |
| @codeSystemName | 0..1 | MAY |  | [4437-3353](#C_4437-3353) | NCI Thesaurus |
| @displayName | 0..1 | MAY |  | [4437-3354](#C_4437-3354) | Distinct Identification Code |
| value | 1..1 | SHALL | ED | [4437-3340](#C_4437-3340) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:4437-3348).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.308" (CONF:4437-3350).  
      Note: template oid

Revision from "2018-05-01"

* 1. This templateId SHALL contain exactly one [1..1] @extension="2019-06-21" (CONF:4437-3351).

1. SHALL contain exactly one [1..1] code (CONF:4437-3349).  
   Note: Distinct Identification Code from NCIt

Code used to specify the Distinct Identification Code, one of the parsed UDI components.

* 1. This code SHALL contain exactly one [1..1] @code="C113843" Distinct Identification Code (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 STATIC) (CONF:4437-3355).
  2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3352).
  3. This code MAY contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3353).
  4. This code MAY contain zero or one [0..1] @displayName="Distinct Identification Code" (CONF:4437-3354).

The Distinct Identification Code can point to its corresponding narrative using the approach defined in CDA Release 2, section 4.3.5.1.

1. SHALL contain exactly one [1..1] value with @xsi:type="ED" (CONF:4437-3340).

Figure 6: Distinct Identification Code

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.308" extension="2019-06-21"/>

<code code="C113843" displayName="Distinct Identification Code"

codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>

<value xsi:type="ED">

<reference value="#DistinctIdentificationCode\_1"/>

</value>

</observation>

Expiration Date Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.309:2019-06-21 (open)]

Table 12: Expiration Date Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [UDI Organizer](#E_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 **Expiration Date** of the device. The expiration date is parsed from the UDI value, if present.

Table 13: Expiration Date Observation Constraints Overview

| XPath | Card. | Verb | Data Type | CONF# | Value |
| --- | --- | --- | --- | --- | --- |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.309:2019-06-21) | | | | | |
| templateId | 1..1 | SHALL |  | [4437-3393](#C_4437-3393) |  |
| @root | 1..1 | SHALL |  | [4437-3396](#C_4437-3396) | 2.16.840.1.113883.10.20.22.4.309 |
| @extension | 1..1 | SHALL |  | [4437-3397](#C_4437-3397) | 2019-06-21 |
| code | 1..1 | SHALL |  | [4437-3394](#C_4437-3394) |  |
| @code | 1..1 | SHALL |  | [4437-3398](#C_4437-3398) | urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101670 |
| @codeSystem | 1..1 | SHALL |  | [4437-3399](#C_4437-3399) | 2.16.840.1.113883.3.26.1.1 |
| @codeSystemName | 0..1 | MAY |  | [4437-3400](#C_4437-3400) | NCI Thesaurus |
| @displayName | 0..1 | MAY |  | [4437-3401](#C_4437-3401) | Expiration Date |
| value | 1..1 | SHALL | TS | [4437-3395](#C_4437-3395) |  |
| @value | 1..1 | SHALL |  | [4437-3402](#C_4437-3402) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:4437-3393).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.309" (CONF:4437-3396).  
      Note: template oid

Revision from "2018-05-01".

* 1. This templateId SHALL contain exactly one [1..1] @extension="2019-06-21" (CONF:4437-3397).

1. SHALL contain exactly one [1..1] code (CONF:4437-3394).  
   Note: Code for "Expiration Date"

Code used to specify the "Expiration Date", one of the parsed UDI components.

* 1. This code SHALL contain exactly one [1..1] @code="C101670" Expiration Date (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 STATIC) (CONF:4437-3398).  
     Note: Expiration Date code
  2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3399).
  3. This code MAY contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3400).
  4. This code MAY contain zero or one [0..1] @displayName="Expiration Date" (CONF:4437-3401).

The value of the Expiration Date as a time stamp.

1. SHALL contain exactly one [1..1] value with @xsi:type="TS" (CONF:4437-3395).  
   Note: Expiration Date as a time stamp

Expiration Date as a time stamp.

* 1. This value SHALL contain exactly one [1..1] @value (CONF:4437-3402).

Figure 7: Expiration Date

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.309" extension="2019-06-21"/>

<code code="C101670" displayName="Expiration Date"

codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>

<value xsi:type="TS" value="20221015"/>

</observation>

Implantable Device Status Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21 (open)]

Table 14: Implantable Device Status Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [UDI Organizer](#E_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 augment the parsed data from the a Unique Device Identifier (UDI). This template is used to exchange the status of the patient's implantable medical device. This status is only relevant to medical devices implanted in the patient's body.

Table 15: Implantable Device Status Observation Constraints Overview

| XPath | Card. | Verb | Data Type | CONF# | Value |
| --- | --- | --- | --- | --- | --- |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21) | | | | | |
| templateId | 1..1 | SHALL |  | [4437-3502](#C_4437-3502) |  |
| @root | 1..1 | SHALL |  | [4437-3505](#C_4437-3505) | 2.16.840.1.113883.10.20.22.4.305 |
| @extension | 1..1 | SHALL |  | [4437-3506](#C_4437-3506) | 2019-06-21 |
| code | 1..1 | SHALL |  | [4437-3503](#C_4437-3503) |  |
| @code | 1..1 | SHALL |  | [4437-3507](#C_4437-3507) | urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C160939 |
| @codeSystem | 1..1 | SHALL |  | [4437-3508](#C_4437-3508) | 2.16.840.1.113883.3.26.1.1 |
| @codeSystemName | 0..1 | MAY |  | [4437-3509](#C_4437-3509) | NCI Thesaurus |
| @displayName | 0..1 | MAY |  | [4437-3510](#C_4437-3510) | Implantable Device Status |
| value | 1..1 | SHALL | CD | [4437-3504](#C_4437-3504) | urn:oid:2.16.840.1.113762.1.4.1021.48 (Implantable Device Status) |
| @code | 1..1 | SHALL |  | [4437-3511](#C_4437-3511) |  |
| @codeSystem | 1..1 | SHALL |  | [4437-3512](#C_4437-3512) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:4437-3502).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.305" (CONF:4437-3505).  
      Note: template oid

Revision from "2018-05-01".

* 1. This templateId SHALL contain exactly one [1..1] @extension="2019-06-21" (CONF:4437-3506).

1. SHALL contain exactly one [1..1] code (CONF:4437-3503).  
   Note: Code for "Implantable Device Status"

Code used to specify the **Implantable Device Status**.

* 1. This code SHALL contain exactly one [1..1] @code="C160939" Implantable Device Status (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 STATIC) (CONF:4437-3507).
  2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3508).
  3. This code MAY contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3509).

Implantable Device Status

* 1. This code MAY contain zero or one [0..1] @displayName="Implantable Device Status" (CONF:4437-3510).

1. SHALL contain exactly one [1..1] value with @xsi:type="CD", where the code SHALL be selected from ValueSet Implantable Device Status urn:oid:2.16.840.1.113762.1.4.1021.48 STATIC 2019-06-21 (CONF:4437-3504).
   1. This value SHALL contain exactly one [1..1] @code (CONF:4437-3511).
   2. This value SHALL contain exactly one [1..1] @codeSystem (CONF:4437-3512).

Figure 8: Implantable Device Status

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.305" extension="2019-06-21"/>

<code code="C160939" displayName="Implantable Device Status"

codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>

<value xsi:type="CD" code="C160942" codeSystem="2.16.840.1.113883.3.26.1.1"

displayName="Reduced Function" codeSystemName="NCI Thesaurus"

sdtc:valueSet="2.16.840.1.113762.1.4.1021.48">

<originalText>

<reference value="#ImplantableDeviceStatus\_1"/>

</originalText>

</value>

</observation>

Latex Safety Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-21 (open)]

Table 16: Latex Safety Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [UDI Organizer](#E_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 **Latex Safety Status** of the patient's medical device. The UDI-DI of the medical device may be used to retrieve the Latex Safety status in accessGUDID, which should be considered the source of truth.

Table 17: Latex Safety Observation Constraints Overview

| XPath | Card. | Verb | Data Type | CONF# | Value |
| --- | --- | --- | --- | --- | --- |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-21) | | | | | |
| templateId | 1..1 | SHALL |  | [4437-3491](#C_4437-3491) |  |
| @root | 1..1 | SHALL |  | [4437-3494](#C_4437-3494) | 2.16.840.1.113883.10.20.22.4.314 |
| @extension | 1..1 | SHALL |  | [4437-3495](#C_4437-3495) | 2019-06-21 |
| code | 1..1 | SHALL |  | [4437-3492](#C_4437-3492) |  |
| @code | 1..1 | SHALL |  | [4437-3496](#C_4437-3496) | urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C160938 |
| @codeSystem | 1..1 | SHALL |  | [4437-3497](#C_4437-3497) | 2.16.840.1.113883.3.26.1.1 |
| @codeSystemName | 0..1 | MAY |  | [4437-3498](#C_4437-3498) | NCI Thesaurus |
| @displayName | 0..1 | MAY |  | [4437-3499](#C_4437-3499) | Latex Safety Status |
| value | 1..1 | SHALL | CD | [4437-3493](#C_4437-3493) | urn:oid:2.16.840.1.113762.1.4.1021.47 (Device Latex Safety) |
| @code | 1..1 | SHALL |  | [4437-3500](#C_4437-3500) |  |
| @codeSystem | 1..1 | SHALL |  | [4437-3501](#C_4437-3501) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:4437-3491).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.314" (CONF:4437-3494).  
      Note: template oid

Revision from "2018-05-01".

* 1. This templateId SHALL contain exactly one [1..1] @extension="2019-06-21" (CONF:4437-3495).

1. SHALL contain exactly one [1..1] code (CONF:4437-3492).  
   Note: Code for "Latex Status"

Code used to specify the **Latex Safety Status**

* 1. This code SHALL contain exactly one [1..1] @code="C160938" Latex Safety Status (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 STATIC) (CONF:4437-3496).
  2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3497).
  3. This code MAY contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3498).
  4. This code MAY contain zero or one [0..1] @displayName="Latex Safety Status" (CONF:4437-3499).

The value of the Latex Safety status.

1. 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).
   1. This value SHALL contain exactly one [1..1] @code (CONF:4437-3500).
   2. 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>

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](#E_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](#C_4437-3450) |  |
| @root | 1..1 | SHALL |  | [4437-3452](#C_4437-3452) | 2.16.840.1.113883.10.20.22.4.315 |
| @extension | 1..1 | SHALL |  | [4437-3453](#C_4437-3453) | 2019-06-21 |
| code | 1..1 | SHALL |  | [4437-3451](#C_4437-3451) |  |
| @code | 1..1 | SHALL |  | [4437-3454](#C_4437-3454) | urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101672 |
| @codeSystem | 1..1 | SHALL |  | [4437-3455](#C_4437-3455) | 2.16.840.1.113883.3.26.1.1 |
| @codeSystemName | 0..1 | MAY |  | [4437-3456](#C_4437-3456) | NCI Thesaurus |
| @displayName | 0..1 | MAY |  | [4437-3457](#C_4437-3457) | Lot or Batch Number |
| value | 1..1 | SHALL | ED | [4437-3458](#C_4437-3458) |  |

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

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

1. 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**.

* 1. 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).
  2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3455).
  3. This code MAY contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3456).
  4. 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.

1. 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>

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](#E_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 21: 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](#C_4437-3459) |  |
| @root | 1..1 | SHALL |  | [4437-3462](#C_4437-3462) | 2.16.840.1.113883.10.20.22.4.316 |
| @extension | 1..1 | SHALL |  | [4437-3463](#C_4437-3463) | 2019-06-21 |
| code | 1..1 | SHALL |  | [4437-3460](#C_4437-3460) |  |
| @code | 1..1 | SHALL |  | [4437-3464](#C_4437-3464) | urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101669 |
| @codeSystem | 1..1 | SHALL |  | [4437-3465](#C_4437-3465) | 2.16.840.1.113883.3.26.1.1 |
| @codeSystemName | 0..1 | MAY |  | [4437-3466](#C_4437-3466) | NCI Thesaurus |
| @displayName | 0..1 | MAY |  | [4437-3467](#C_4437-3467) | Manufacturing Date |
| value | 1..1 | SHALL | TS | [4437-3461](#C_4437-3461) |  |
| @value | 1..1 | SHALL |  | [4437-3468](#C_4437-3468) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:4437-3459).
   1. 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".

* 1. This templateId SHALL contain exactly one [1..1] @extension="2019-06-21" (CONF:4437-3463).

1. SHALL contain exactly one [1..1] code (CONF:4437-3460).  
   Note: Code for "Manufacturing Date"

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

* 1. 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
  2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3465).
  3. This code MAY contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3466).
  4. 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.

1. 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.

* 1. 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>

Model Number Observation

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

Table 22: Model Number Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [UDI Organizer](#E_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.

Table 23: Model Number Observation Constraints Overview

| XPath | Card. | Verb | Data Type | CONF# | Value |
| --- | --- | --- | --- | --- | --- |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.317:2019-06-21) | | | | | |
| templateId | 1..1 | SHALL |  | [4437-3412](#C_4437-3412) |  |
| @root | 1..1 | SHALL |  | [4437-3414](#C_4437-3414) | 2.16.840.1.113883.10.20.22.4.317 |
| @extension | 1..1 | SHALL |  | [4437-3415](#C_4437-3415) | 2019-06-21 |
| code | 1..1 | SHALL |  | [4437-3413](#C_4437-3413) |  |
| @code | 1..1 | SHALL |  | [4437-3416](#C_4437-3416) | urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C99285 |
| @codeSystem | 1..1 | SHALL |  | [4437-3417](#C_4437-3417) | 2.16.840.1.113883.3.26.1.1 |
| @codeSystemName | 0..1 | MAY |  | [4437-3418](#C_4437-3418) | NCI Thesaurus |
| @displayName | 0..1 | MAY |  | [4437-3419](#C_4437-3419) | Model Number |
| value | 1..1 | SHALL | ED | [4437-3420](#C_4437-3420) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:4437-3412).
   1. 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".

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

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

Code used to specify the **Model Number**.

* 1. 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).
  2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3417).
  3. This code MAY contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3418).
  4. This code MAY contain zero or one [0..1] @displayName="Model Number" (CONF:4437-3419).

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

1. 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>

MRI Safety Observation

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

Table 24: MRI Safety Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [UDI Organizer](#E_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 25: 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](#C_4437-3469) |  |
| @root | 1..1 | SHALL |  | [4437-3471](#C_4437-3471) | 2.16.840.1.113883.10.20.22.4.318 |
| @extension | 1..1 | SHALL |  | [4437-3472](#C_4437-3472) | 2019-06-21 |
| code | 1..1 | SHALL |  | [4437-3470](#C_4437-3470) |  |
| @code | 1..1 | SHALL |  | [4437-3473](#C_4437-3473) | urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C106044 |
| @codeSystem | 1..1 | SHALL |  | [4437-3474](#C_4437-3474) | 2.16.840.1.113883.3.26.1.1 |
| @codeSystemName | 0..1 | MAY |  | [4437-3475](#C_4437-3475) | NCI Thesaurus |
| @displayName | 0..1 | MAY |  | [4437-3476](#C_4437-3476) | MRI Safety |
| value | 1..1 | SHALL | CD | [4437-3477](#C_4437-3477) | urn:oid:2.16.840.1.113762.1.4.1021.46 (Device Magnetic resonance (MR) Safety) |
| @code | 1..1 | SHALL |  | [4437-3478](#C_4437-3478) |  |
| @codeSystem | 1..1 | SHALL |  | [4437-3479](#C_4437-3479) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:4437-3469).
   1. 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".

* 1. This templateId SHALL contain exactly one [1..1] @extension="2019-06-21" (CONF:4437-3472).

1. SHALL contain exactly one [1..1] code (CONF:4437-3470).  
   Note: Code for "MRI Safety Status"

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

* 1. 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).
  2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3474).
  3. This code MAY contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3475).
  4. This code MAY contain zero or one [0..1] @displayName="MRI Safety" (CONF:4437-3476).

The value of the MRI Safety status.

1. 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).
   1. This value SHALL contain exactly one [1..1] @code (CONF:4437-3478).
   2. 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" sdtc:valueSet="2.16.840.1.113762.1.4.1021.46">

<originalText>

<reference value="#MRISafety\_1"/>

</originalText>

</value>

</observation>

Serial Number Observation

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

Table 26: Serial Number Observation Contexts

| Contained By: | Contains: |
| --- | --- |
| [UDI Organizer](#E_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.

Table 27: Serial Number Observation Constraints Overview

| XPath | Card. | Verb | Data Type | CONF# | Value |
| --- | --- | --- | --- | --- | --- |
| observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.319:2019-06-21) | | | | | |
| templateId | 1..1 | SHALL |  | [4437-3373](#C_4437-3373) |  |
| @root | 1..1 | SHALL |  | [4437-3377](#C_4437-3377) | 2.16.840.1.113883.10.20.22.4.319 |
| @extension | 1..1 | SHALL |  | [4437-3368](#C_4437-3368) | 2019-06-21 |
| code | 1..1 | SHALL |  | [4437-3374](#C_4437-3374) |  |
| @code | 1..1 | SHALL |  | [4437-3378](#C_4437-3378) | urn:oid:2.16.840.1.113883.3.26.1.1 (NCI Thesaurus (NCIt)) = C101671 |
| @codeSystem | 1..1 | SHALL |  | [4437-3369](#C_4437-3369) | 2.16.840.1.113883.3.26.1.1 |
| @codeSystemName | 0..1 | MAY |  | [4437-3370](#C_4437-3370) | NCI Thesaurus |
| @displayName | 0..1 | MAY |  | [4437-3379](#C_4437-3379) | Serial Number |
| value | 1..1 | SHALL | ED | [4437-3372](#C_4437-3372) |  |

1. SHALL contain exactly one [1..1] templateId (CONF:4437-3373).
   1. This templateId SHALL contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.319" (CONF:4437-3377).  
      Note: template oid

Revision from "2018-05-01".

* 1. This templateId SHALL contain exactly one [1..1] @extension="2019-06-21" (CONF:4437-3368).

1. SHALL contain exactly one [1..1] code (CONF:4437-3374).  
   Note: Code for "Serial Number"

Code used to specify the **Serial Number**.

* 1. This code SHALL contain exactly one [1..1] @code="C101671" Serial Number (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 STATIC) (CONF:4437-3378).
  2. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.3.26.1.1" (CONF:4437-3369).
  3. This code MAY contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3370).
  4. This code MAY contain zero or one [0..1] @displayName="Serial Number" (CONF:4437-3379).

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

1. SHALL contain exactly one [1..1] value with @xsi:type="ED" (CONF:4437-3372).

Figure 14: Serial Number

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.22.4.319" extension="2019-06-21"/>

<code code="C101671" displayName="Serial Number"

codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"/>

<value xsi:type="ED">

<reference value="#SerialNumber\_1"/>

</value>

</observation>

# Template Ids in This Guide

Table 28: Template List

| Template Title | Template Type | templateId |
| --- | --- | --- |
| [UDI Organizer](#E_UDI_Organizer) | entry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.311:2019-06-21 |
| [Brand Name Observation](#E_Brand_Name_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.301:2019-06-21 |
| [Catalog Number Observation](#E_Catalog_Number_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21 |
| [Company Name Observation](#E_Company_Name_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21 |
| [Device Identifier Observation (V2)](#SE_Device_Identifier_Observation_V2) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2022-06-01 |
| [Distinct Identification Code Observation](#E_Distinct_Identification_Code_Observat) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.308:2019-06-21 |
| [Expiration Date Observation](#E_Expiration_Date_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.309:2019-06-21 |
| [Implantable Device Status Observation](#SE_Implantable_Device_Status_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21 |
| [Latex Safety Observation](#SE_Latex_Safety_Observation_2019) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-21 |
| [Lot or Batch Number Observation](#E_Lot_or_Batch_Number_Observation_2019) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.315:2019-06-21 |
| [Manufacturing Date Observation](#E_Manufacturing_Date_Observation_2019) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.316:2019-06-21 |
| [Model Number Observation](#E_Model_Number_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.317:2019-06-21 |
| [MRI Safety Observation](#E_MRI_Safety_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.318:2019-06-21 |
| [Serial Number Observation](#E_Serial_Number_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.319:2019-06-21 |

Table 29: Template Containments

| Template Title | Template Type | templateId | |
| --- | --- | --- | --- |
| [UDI Organizer](#E_UDI_Organizer) | entry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.311:2019-06-21 | |
| [Distinct Identification Code Observation](#E_Distinct_Identification_Code_Observat) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.308:2019-06-21 | |
| [Serial Number Observation](#E_Serial_Number_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.319:2019-06-21 | |
| [Expiration Date Observation](#E_Expiration_Date_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.309:2019-06-21 | |
| [Brand Name Observation](#E_Brand_Name_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.301:2019-06-21 | |
| [Model Number Observation](#E_Model_Number_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.317:2019-06-21 | |
| [Catalog Number Observation](#E_Catalog_Number_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.302:2019-06-21 | |
| [Company Name Observation](#E_Company_Name_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.303:2019-06-21 | |
| [Lot or Batch Number Observation](#E_Lot_or_Batch_Number_Observation_2019) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.315:2019-06-21 | |
| [Manufacturing Date Observation](#E_Manufacturing_Date_Observation_2019) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.316:2019-06-21 | |
| [MRI Safety Observation](#E_MRI_Safety_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.318:2019-06-21 | |
| [Latex Safety Observation](#SE_Latex_Safety_Observation_2019) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.314:2019-06-21 | |
| [Implantable Device Status Observation](#SE_Implantable_Device_Status_Observation) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21 | |
| [Device Identifier Observation (V2)](#SE_Device_Identifier_Observation_V2) | subentry | urn:hl7ii:2.16.840.1.113883.10.20.22.4.304:2022-06-01 | |

# Code Systems in This Guide

Table 30: Code Systems

| Name | OID |
| --- | --- |
| HL7ActStatus | urn:oid:2.16.840.1.113883.5.14 |
| LOINC | urn:oid:2.16.840.1.113883.6.1 |
| NCI Thesaurus (NCIt) | urn:oid:2.16.840.1.113883.3.26.1.1 |