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HL7 Cross Paradigm Implementation Guide: UDI Pattern, Release 2

June 2020

HL7 Normative Standard

**Sponsored by:
Orders and Observations Work Group**

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Document Scope and Change History

Initial version of the UDI Pattern document includes content for the following HL7 working documents:

- Harmonization Pattern for Unique Device Identification (March 14, 2016)
- HL7 Cross Paradigm Implementation Guide: UDI Pattern, Release 1 (February 22, 2019)
- Updates from UDI work completed on the base standards

This document intends to replace the reference documents noted above and be backwards compatible to all base standards and their conformance statements. That information will not be included in this document but shall be applicable to any implementation guide that is created using this as a reference pattern.

Introduction

The Unique Device Identifier (UDI) Pattern provides the guidelines for exchanging information about the use of and/or implantation of medical devices in patients. This document will not give specific implementation guidance, but will set the overarching guidelines for all working groups that need to exchange the unique device identification. The goal of the UDI Pattern is to enable semantic interoperability for recording medical devices used on or implanted in patients regardless of the information exchange standard used to move the information across (e.g., HL7 V2.x, HL7 V3 messages or CDA, HL7 FHIR).

Background

The Unique Device Identifier (UDI) is being driven at the international level even if the implementations are local. The document sets out to address regulations currently in place, in the United States (US) and the European Union (EU) in addition to be extensible to other regions and/or countries that are currently developing UDI regulations.

UDI in US Regulations.

The Office of the National Coordinator for Health Information Technology (ONC) and other national authorities require the reporting of device identifiers for implantable devices to meet electronic health record certification criteria (Refer to 78 FR 58785). Also, USFDA issued a mandate to label devices to include UDI, in order to actively promote the use of UDI in the information chain. UDI will enable recalls, CDS, post-market surveillance and research. Thus, there is an increased need to communicate UDI and its individual components unambiguously to enable downstream stakeholders to access that information for their business purposes. Therefore, the capture of the UDI at the point of care and storage in the electronic health records will facilitate this information being available for exchange between providers, institutions and other healthcare organizations.

UDI in EU Regulations

The Regulation (EU) 2017/745 And 746 Of The European Parliament And Of The Council set forth the requirements for UDI and a UDI system. As stated in that regulation, “The traceability of devices by means of a Unique Device Identification system (UDI system) based on international guidance should significantly enhance the effectiveness of the post-market safety-related activities for devices, which is owing to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against falsified devices. Use of the UDI system should also improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings.”

UDI and Associated Data Elements

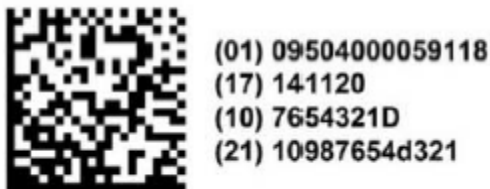
The UDI is made up of the Device Identifier, which indicates the type of device that is commercially distributed; and the Production Identifiers, which identifies the actual instance of the device with one or more of the following:

- lot or batch number,

- serial number,
- manufacturing date,
- expiration date, and
- distinct identification code (e.g., donation identification number).

The UDI may be present in *Automatic* Identification and Data Collection (AIDC) and/or Human Readable Format (HRF). AIDC format is meant to be read by equipment such as scanners and could be in the form of linear barcode, 2D barcode, or RFID. In absence of scanners, the HRF is expected to be used for recording of UDI. The AIDC and HRF format could be the same or different in the use of delimiters to separate the DI and PI's. Note that the partial or entire UDI may include a check-digit value based on issuing agency rules, and if it does it will be exchanged as part of the value. If there is no check-digit included, no additional information needs to be exchanged.

Sample UDI Barcode on a medical device label:



Label with UDI and associated data

Qty: 1 each	Size: 20mm x 12.5mm	REF Z1234
(0 1) 1 2 3 4 5 6 7 8 9 0 1 2 3 4 (1 7) 1 4 0 1 0 2 (1 1) 1 0 0 1 0 2 (1 0) A 1 2 3 4 (2 1) 1 2 3 4		
2014-01-02	2010-01-02	LOT A1234 SN 1234
<div style="display: flex; justify-content: space-around; align-items: center;"> <div> 45°C UPPER LIMIT OF TEMPERATURE </div> <div> KEEP DRY </div> <div> </div> </div>		
Manufacturer	CompuHyper GlobalMed, LTD 101 Innovation Drive, New Sales, MD 20999-0000	XXX-867-5309 (USA) XXX-555-3226 (Outside USA) http://www.compuhypergm.com

Single barcode Label

A label may contain the UDI in one barcode to indicate the entire value. There is a machine-readable version as well as a human-readable version of the UDI. Note that the barcode may include more than the UDI value displayed under the barcode in a human-readable manner, and barcode readers may pass additional information in the machine-readable version¹.



Multi-line Barcode Label

A label may contain a multi-line barcode for the UDI. In this case, parts of the UDI are broken down into multiple parts (i.e., two or more) to indicate the entire value. The example provided is only one of many patterns of how the manufacturer may label their device.

- GS1-128 non-concatenated (shared in 2 parts)



The example above may be shown on the label stacked or side-by-side. Refer to the issuing agency's guidance on how multi-line barcodes should be read and exchanged (i.e., as one value or multiple values). Most barcode technology will require the entire UDI to be scanned in order to be complete.

HRF (Human Readable Format)

The Human Readable Form is a rendering of the barcode contents, the data not the markup, using only printable ASCII characters. The HRF may allow different representations based upon standards established by each accredited issuing agency (GS1, HIBCC, ICCBBA, etc.).

(01)09504000059118(17)141120(10)7654321D(21)10987654d321 (GS1)

Examples:

{01}5102222233336{11}141231{17}150707{10}A213B1{21}1234 (GS1 HRF – exchangeable*)

+5102222233336/\$515187A213B1/S1234/16D20141231R (HIBCC HRF)

¹ IMDRF UDI Application Guide/N48 Sections 6.1 to 6.5 for additional globally harmonized reference on UDI format.

=/5102222233336=,1234/=A213B1=>015187=}014365

(ICCBBA HRF)

The first character of the UDI carrier determines the format (and issuing agency):

'('	GS1 Human Readable Format
'0' – '9'	GS1 DI (containing only the DI value);
'+'	HIBCC Human Readable style
'=' or '&'	ICCBBA Human Readable style

* Note: If the delimiters or separator characters (e.g., parentheses) are used for human-readable display, and exchanges by the message limit their use, the value should be exchanged according to the guidance provided by the issuing agency for transmitting this information to comply with the exchange standard's data type.

AIDC (Automatic Identification and Data Capture)

The AIDC format of the barcode contents includes both the data and the markup, and may contain unprintable ASCII characters. In the example below the <GS> stands for the unprintable character 29 (hex 1D). The actual standards organizations responsible for barcode standards should be consulted to understand the encoding of information into the various barcode standards.

The first character of the UDI carrier determines the format (and issuing agency):

'('	GS1 Human Readable Format
'0' – '9'	GS1 DI (containing only the DI value);
'+'	HIBCC Human Readable style
'=' or '&'	ICCBBA Human Readable style

The character checked is the first character after the barcode style identification string. In the examples below the barcode style string is the first 3 characters therefore the 4th character is examined.

]d2010950400005911817141120107654321D<GS>2110987654d321	(GS1 Data Matrix)
]C1015102222233336<GS>111412311715070710A213B1<GS>211234	{GS1 128}
]C1+5102222233336/\$\$515187A213B1/S1234/16D20141231R	(HIBCC 128)
]C1=/5102222233336=,1234/=A213B1=>015187=}014365	(ICCBBA 128)

Translating from the AIDC format to the HRF format is contingent on being aware of the issuing agency standard used to encode it and may require a current copy of the issuing agency's specification to be

maintained. The lengths, values of tags, and the list of valid tags may change with new releases of each issuing agency standard

The representation of the UDI in AIDC format will need to exchange its value with Base64 encoding using the method defined in RFC 4648 and may contain the complete set of UDI carrier formation that includes, but not limited to, the device identifier, production identifiers and any additional information contained in the AIDC version of the UDI.

The device identifier (DI) may be used to extract some of the associated identification information from the regulatory agency's UDI database, especially when it is not available. The following data elements may be reported by a patient and/or looked up with UDI information (specifically the DI) in Regional UDI databases as follows:

- Manufacturer/Device Company
- Brand Name
- Device Type
- Model Number
- Catalog Number
- Safety Information (e.g., MRI Safety and Latex Safety)

This information may or may not be available depending on the source of the information.

General Guidance and Recommendations

The full UDI carrier may contain Personally Identifying Information (PII) in the form of the **serial number**, **distinct identification code** or other elements, which may be used to link to other information on a patient. The US Health and Human Services (HHS), Office of Civil Rights (OCR) has taken the following position on the Production Identifier (PI) portion of the UDI and PII:

*"However, the PI portion of a UDI, which includes a serial number or other numbers that correspond to a specific device, would be a "device identifier" referred to in the HIPAA Privacy Rule provisions and, therefore, may not be included in a limited data set or data set that is de-identified in accordance with the "de-identification safe harbor" provisions at 45 CFR § 164.514(b)(2)."*²

Standard practice for exchanging potentially identifying content should be exercised when exchanging any type of UDI carrier. A recommended best practice is to use the UDI for validation purposes but to parse and store each of the UDI data components – DI and the applicable production identifiers represented on the device – (e.g., Lot Number, Serial Number, Expiration Date, Manufacturing Date, and/or Distinct Identification Code) – in separate fields. The separate fields provide valuable information and linkage to the regulatory authority meta-data associated with the DI of UDI. In addition, storing the PII as a separate field from other

² <https://www.hhs.gov/hipaa/for-professionals/faq/2071/can-device-identifier-di-portion-unique-device-identifier-udi-be-part-limited-or-de-identified/index.html>

parsed components of the UDI enables the ability to block PII while still exchanging the other important device identification components of UDI.

This section provides instructions for how UDI carriers and their components should be conveyed in various HL7 communication standards. Systems claiming conformance with this specification SHALL convey UDI information as described here when they are aware that they are conveying UDI information. Note that all guidance refers to where elements shall be transmitted if they are included in the instance. The base set of guidance does not assert when the UDI carrier, its constituent values or some combination of those need to be present (i.e., if the element is included in the UDI carrier it shall be provided).

This section provides recommended guidance for increased interoperability, but may not be practical for all systems or appropriate for all use-cases. It presumes that the system creating the instance:

- Is able to Base64 encode and decode the AIDC strings
- is able to convert the raw scanned barcode text to the UDI carrier Human Readable Form (HRF) string (including the check digit) by performing appropriate substitution for separator characters
- is able to parse the various forms of UDIs and can extract the various component elements
- is not transmitting in a bandwidth or size-constrained environment or other environment where including both the UDI and its associated component elements would be problematic
- is transmitting in an environment where exposing the UDI components would provide business value

Examples of where these rules may not make sense include instances created by automated devices with limited processing power or complexity as well as general-purpose systems for whom UDI is considered “just another identifier”.

The guidance that follows reflects implementer feedback and should be considered best-practice for systems and implementation guides that fall within the criteria listed above.

Profiles will be defined allowing systems and implementation guides to indicate whether they conform to these additional conformance requirements.

Conformance requirements

In accordance with the expressive capability of the HL7 standard being used to convey the instance and any standard-specific requirements (e.g., use of OID vs. URI):

1. Systems SHALL transmit the UDI value, SHALL do so using the Human Readable Form string (HRF) and SHALL ensure that the OID or URL identifying the UDI assigning system is specified. If the encoding format has both a regular and an exchangeable HRF syntax, the exchangeable syntax SHALL be used. Where a serial number is being conveyed and the intent of the instance is to identify a specific device, the UDI SHALL be included in the element which communicates that intention (if supported by the HL7 standard used)

2. Systems SHALL transmit all components found within the UDI for which data element locations are defined for the HL7 standard used and SHALL ensure that the data present within the components matches the data conveyed within the UDI
3. When conveying the DI components, the system SHALL ensure that the appropriate OID or URL is declared
4. Where the HL7 standard being used supports both OIDs and URLs (i.e., V2), the system SHALL be capable of recognizing both approaches and recognizing their equivalence.

HL7 V2

HL7 Version 2 field names may change between versions. For this reason, the implementer SHOULD rely on the segment name and field number instead of their descriptions.

Unique Device Identifier

The HRF or AIDC shall be communicated in either PRT-10 Device or PRT-22 Device Type. The HRF is preferred.

PRT-10 Device is used when the HRF contains the serial number, while PRT-22 Device Type is used when it does not.

Note that HL7 V2 supports either OIDs or URIs as a means of globally unique identification for identifiers, but only OIDs for code systems.

Within PRT-10 Device, the UDI carrier is sent in component 1 of the EI data type and the OID or URL is sent in component 3, with component 4 identifying whether the OID or URL approach was used.

PRT-10: |{01}00643169001763{17}160712{21}21A11F4855^^2.16.840.1.113883.3.3719^ISO|
or
PRT-10: |{01}00643169001763{17}160712{21}21A11F4855^^http://hl7.org/fhir/NamingSystem/fda-
udi^URI|

In PRT-22 Device Type, both a primary and a secondary code may be transmitted and which components are used depends on whether the value is being conveyed as a primary or secondary code. The UDI string value will go in either component 1 or 4. A code system name, if known, must be sent in either component 3 or 5.

PRT-22: |{01}00643169001763{17}160712^^FDAUDI^^^^^^^^^^2.16.840.1.113883.3.3719|

In HL7 V2 trading partners should either apply the escaping techniques described in Chapter 2 or use an alternative character set as described in Chapter 2 MSH-18 Character Set.

For the remaining elements, they SHALL be conveyed using PRT-16 UDI Device Identifier through PRT-21 Device Donation Identification. These elements are documented in V2.8.2 and later. Note that in versions before HL7 V2.9 the field names referenced in this guide included “Participant” as a prefix.

Device Identifier (DI)

The Device Identifier (DI) SHALL be included as follows:

- PRT-16 UDI Device Identifier – SHALL be placed in component 1. If known, the OID or URI for the namespace of the DI SHALL be placed in component 3, with component 4 set to either “ISO” (for OIDs) or “URI”.

Production Identifiers

The production identifiers in the UDI SHALL be conveyed using PRT-17 Device Manufacture Date through PRT-21 Device Donation Identification. These elements are documented in V2.8.2 and later. The correspondence is as follows:

- PRT-17 Device Manufacture Date – the Manufacture Date is expressed using the syntax `yyyymmdd[hh]`
- PRT-18 Device Expiry Date – the Expiration Date is expressed using the syntax `yyyymmdd[hh]`
- PRT-19 Device Lot Number – the Lot Number
- PRT-20 Device Serial Number – the Serial Number
- PRT-21 Device Donation Identification – the Distinct Identification Number (e.g., Donation Identification Number) goes into component 1. If known, the OID or URI for the namespace of the DIN goes into component 3, with component 4 set to either “ISO” (for OIDs) or “URI”.

Starting in HL7 V2.9, device information may also be conveyed in the Device segment. When the UDI is available, the UDI information SHALL be placed in the following fields:

- DEV-2 Unique Device Identifier – the HRF or AIDC if the UDI contains a serial number
- DEV-3 Device Type – the HRF or AIDC if the UDI does not contain a serial number
- DEV-10 Device Lot Number – the Lot Number
- DEV-11 Device Serial Number – the Serial Number
- DEV-12 Device Manufacture Date – the Manufacture Date is expressed using the syntax `yyyymmdd[hh]`
- DEV-13 Device Expiry Date – the Expiration Date is expressed using the syntax `yyyymmdd[hh]`
- DEV-15 Device Donation Identification – the Distinct Identification Number (e.g., Donation Identification Number) goes into component 1. If known, the OID or URI for the namespace of the DIN goes into component 3, with component 4 set to either “ISO” (for OIDs) or “URI”.

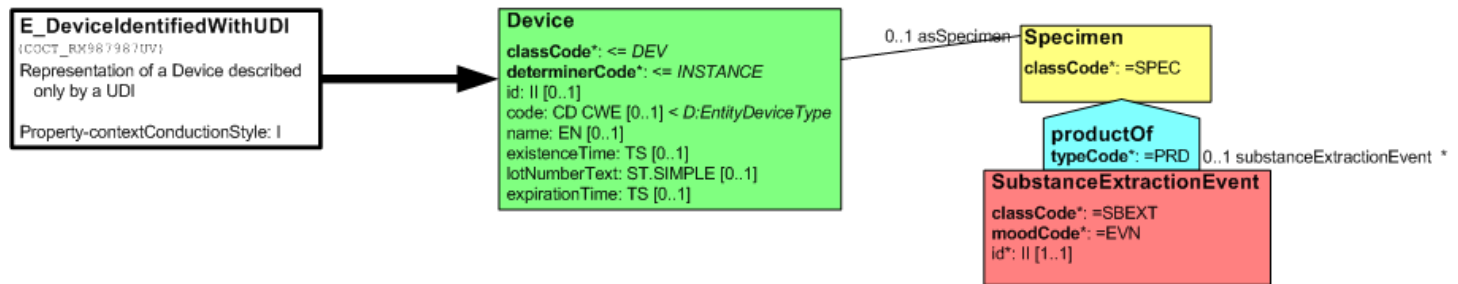
Other Device Identification Characteristics

The following information may be included on the HRF or AIDC, label, or retrieved using the device identifier from a regulatory authority database, e.g., GUDID in addition to the UDI to help identify the device or provide additional data about the device – especially in cases where the identifiers are not available. This data can only be conveyed using the Device segment in the following fields:

- DEV-4 Device Status - The device status indicates if the device is currently in use or not (e.g., active, inactive, reported in error). The implantable device active status shall be stored in the `activeStatus` element to indicate if the implanted device is functioning level/capacity of the device. If the device is implanted, the implantation status will be reported in DEV-17.
- DEV-5 Manufacture/Distributor - The manufacturer’s company name
- DEV-6 Brand Name - The brand name
- DEV-7 Model Identifier - The model number

- DEV-8 Catalogue Identifier - The catalog number
- DEV-14 Safety Characteristics - The safety status
- DEV-16 Software Version Number - The version number of the software that is part of the device.
- DEV-17 Implantation Status - This field contains the implantation status of the device, e.g., implanted, explanted.

HL7 Version 3



3

Unique Device Identifier

If the UDI has been parsed and contains a Serial Number or is otherwise known to represent a unique instance identifier, it shall be stored in the **Device.id** element using the “extension” for the UDI and the “root” for the OID. Otherwise, the UDI carrier shall be stored in the **Device.code** element either in the root or one of the translations with the UDI in the “code” element and the OID in the “system” element, with no display value.

Because of XML limitations, only the HRF representation can be stored. XML encoding rules prohibit transmission of control codes and there is no appropriate V3 element to transmit an escaped version of the AIDC. Note that a HRF may be used in a **Device.code** element even if it contains a serial number.

Device Identifier

The DI SHALL be exchanged in the **Device.code@code** element in either the root or as a CD.translation with the DI value as the “code” element and the OID conveyed in the “system” element.

Production Identifiers

The production identifiers contained in the UDI will be parsed as follows

- The manufacture date SHALL be exchanged in the low value of the **Device.existenceTime@value** element converted to the syntax `yyyymmdd[hh]`.
- The expiry date SHALL be exchanged in the high value of the **Device.expirationTime@value** element converted to the syntax `yyyymmdd[hh]`.
- The lot SHALL be exchanged in the **Device.lotNumberText@value** element.
- The Donation Identification Number SHALL be exchanged in the “element **SubstanceExtractionEvent.id@extension** with the root set to the OID and the extension to the actual Donation Identification Number.

³ V3 Model is missing some of the data elements in this version

- The **IdentifiedEntity.id@extension** element SHALL be used to exchange the serial number. The IdentifiedEntity.id root element MAY be omitted although it may be the Issuer OID or URL for the DI.

V3 Example

```
<someDevice classCode="DEV" determinerCode="instance">
  <id root="2.16.840.1.113883.3.3719"
extension="{01}0061414999996{17}910304{10}123ABC{21}1234567890" />
  <code system="2.51.1.1" code="0061414999996" />
  <lotNumberText value="123ABC" />
  <expirationTime value="19910304" />
  <asSpecimen classCode="SPEC">
    <substanceExtractionEvent classCode="SBEXT" moodCode="EVN">
      <id root="2.16.840.1.113883.6.18.2.1 " extension="the actual DIN
string" />
    </substanceExtractionEvent>
  </asSpecimen>
  <asIdentifiedEntity classCode="IDENT">
    <id extension="1234567890" />
    <code system="2.16.840.1.113883.5.111" code="[TBD - SERIAL NUMBER]" />
  </asIdentifiedEntity>
</someDevice>
```

Other Device Identification Characteristics

The following information may be provided in addition to the UDI and/or its components to help identify the device – especially in cases where the identifiers are not available:

- The manufacturer's company name SHALL be exchanged in the **manufacturer** element.
- The brand name SHALL be exchanged in the **manufacturedProduct.name** element.
- The model number SHALL be exchanged in the **asIdentifiedEntity** element.
- The version number SHALL be exchanged in the **asIdentifiedEntity** element.
- The catalog number SHALL be exchanged in the **asIdentifiedEntity** element.
- The device type SHALL be exchanged in the [asSpecializedKind.generalizedMaterialKind.code@code](#) element
- The safety status SHALL be exchanged in the **characteristic** element. See the value set for safety information. This includes the MRI Safety status and the latex safety information.
- The device status SHALL be exchanged in the **status** element. This indicates if the device is currently implanted or not. The implantable device active status SHALL be exchanged in the **activeStatus** element to indicate if the implanted device is functioning level/capacity of the device.

HL7 FHIR

When the medical device instance is the subject of the exchange, the FHIR Device resource provides all of the necessary elements and attributes for the unique device identifier and its component parts. The device resource should contain the unique device identifier when it is present.

However, note that when the UDI is not available (e.g., patient reported presence of a knee implant), the UDI may not be known to derive other identifying elements for that device, e.g., serial number or lot number. The Device resource is still appropriate to be used to reflect that an actual instance with the available identifying data (e.g., type of device, or brand), it may just not be as specific.

When the instance is not the subject, the kind of device can be described using the Device Definition resource.

Unique Device Identifier

The HRF shall be exchanged in the **carrierHRF** element with the appropriate repository **uri** as the system. The **identifier.type** should be set to "UDI". The **carrierAIDC** element will store the AIDC version of the UDI.

Device Identifier

When the UDI (either **carrierHRF** or **carrierAIDC**) is present, the Device Identifier SHALL be parsed and exchanged in the **Device.udiCarrier.deviceIdentifier** element and the classification or categorization SHOULD be placed in the **Device.entryType** element with the **uri** included as the **Device.udiCarrier.issuer**.

Production Identifiers

When the UDI is present, one or more production identifiers are exchanged using the Device resource as follows:

- The manufacture date SHALL be exchanged in the **Device.manufactureDate** element with the syntax converted to yyyy-mm-dd.
- The expiration date SHALL be exchanged in the **Device.expirationDate** element with the syntax converted to yyyy-mm-dd.
- The lot SHALL be exchanged in the **Device.lotNumber** element.
- The serial number SHALL be exchanged in the **Device.serialNumber** element without a system specified.
- The distinct identification code MAY be exchanged in the **Device.extension** (example extension used below for demonstration, for example:

```
<Device>
  <extension url=http://hl7.org/fhir/StructureDefinition/device-
donationIdentificationNumber>
    <valueIdentifier>
      <system value="http://hl7.org/fhir/NamingSystem/iccbba-dic"/>
      <value value="the actual DIC string"/>
    </valueIdentifier>
```

```
</extension>
<!--Additional attributes-->
</Device>
```

Other Device Identification Characteristics

The following information may be provided in addition to the UDI and/or its components to help identify the device – especially in cases where the identifiers are not available:

- The manufacturer's company name SHALL be exchanged in the **Device.manufacturer** element.
- The brand name SHALL be exchanged in the **Device.deviceName.name.name** element along with its **type**.
- The model number SHALL be exchanged in the **Device.modelNumber** element.
- The version number SHALL be stored in the **Device.version** element.
- The safety status SHALL be exchanged in the **Device.safety** element. See the value set for safety information, which includes codable concepts for the MRI Safety status and the latex safety.
- The device status SHALL be exchanged in the **Device.status** element. For implantable devices, this indicates if the device is currently implanted or not.

To exchange data that is not included in the device resource, and/or when the subject is not specific to the use or implant of a device instance, the Device Definition may be used to identify the kind of device as follows:

- The manufacturer's company name SHALL be exchanged in the **DeviceDefinition.manufacturer** element.
- The brand name SHALL be exchanged in the **DeviceDefinition.deviceName.name** element along with its type.
- The model number SHALL be exchanged in the **DeviceDefinition.modelNumber** element.
- The version number SHALL be exchanged in the **DeviceDefinition.version** element.
- The catalog number SHALL be exchanged in the **DeviceDefinition.deviceName.name** catalog element along with its type (NOTE: Only included in the Device Definition resource).
- The device type SHALL be exchanged in the **DeviceDefinition.type** element
- The safety status SHALL be exchanged in the **DeviceDefinition.safety** element. See the value set for safety information, which includes codable concepts for the MRI Safety status and the latex safety.

1 **Appendix A: Data Elements**

2 Refer to the base standards for mappings to the current resource elements and attributes.

3 **Appendix B: Representation of UDI in HL7 C-CDA**

4 For the representation of UDI in C-CDA R2.1 refer to the following documentHL7 CDA® R2 Implementation
5 Guide: C-CDA Supplemental Templates for Unique Device Identifier (UDI) for Implantable Medical Devices,
6 Release 1 - US Realm. It contains the instructions for how to represent each of the data element outlined in
7 this document.

8
9 Note: At this publication, the coverage of data elements should be consistent in the referenced document.