# ISBT 128 STANDARD

# Coding and Labeling of Medical Devices Containing MPHO

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# 1 Introduction

## 1.1 Purpose

The purpose of this document is to provide requirements and guidance on using the ISBT 128 Standard for the coding and labeling of Medical Products of Human Origin (MPHO) that are regulated as a medical device, or medical devices containing a MPHO component. The guidance is designed to provide an ISBT 128 UDI solution that is compatible with the IMDRF UDI Guidance: Unique Device Identification (UDI) of Medical Devices (2013). The European Union requirement for a Basic UDI-DI is addressed in Appendix 1.

## 1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification* (ST-001). It provides specific requirements and guidance for facilities labeling medical devices that contain Medical Products of Human Origin (MPHO) that are regulated as medical devices. It focuses on Unique Device Identification (UDI) labeling.

## 1.3 Intended Audience

The intended audience of this document are:

- The staff (management, information technology, quality, validation, and laboratory) in tissue banks or cellular therapy facilities that produce MPHO products regulated as medical devices;
- Software developers and label vendors that provide products for these facilities;
- Regulators/Competent Authorities.

## 1.4 Normative References

*ISBT 128 Standard Technical Specification* (ST-001)

*ISBT 128 Standard Product Description Code Database* (ST-010)

IMDRF/UDI WG/N7 FINAL 2013 UDI Guidance: Unique Device Identification (UDI) of Medical Devices

ISO/IEC 15415:2011(E), Information technology — Automatic identification and data capture techniques — Bar code symbol print quality test specification — Two-dimensional symbols

ISO/IEC 15459-2:2015(E): Information technology — Unique identifiers — Part 2: Registration procedures

ISO/IEC 15459-4-2014(E): Information technology — Automatic identification and data capture techniques — Unique Identification — Part 4 Individual products and product packages

ISO/IEC 15459-3:2014(E): Information technology — Unique identifiers — Part 3: Common rules for unique identifiers

ISO/IEC 16022:2006(E), Information technology — Automatic Identification and data capture techniques — Data Matrix bar code symbology specification (and correction ISO/IEC 16022:2006/Cor 1:2008/Cor 2:2011)

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

## 1.5 Other References

ICCBBA Website (www.iccbba.org)

Implementation Guides:
*Use of Dimensions [Data Structure 029]* (IG-026)
*Use of the Donation Identification Number [Data Structure 001]* (IG-033)
*ISBT 128 Facility Identification Number* (IG-034)

## 1.6 Background

In some countries, MPHO may be classified as biologics, drugs, advanced medicinal therapies, medical devices, or be placed in other regulatory categories. This classification affects how the products are labeled.

However, from a traceability standpoint, it is essential that all MPHO, regardless of regulatory classification, be traceable from donor to recipient, and that all MPHO from a single donor can be readily cross-referenced to support effective recall. Effective biovigilance requires standardization of terminology and coding of products at a generic level.

This document will discuss the coding and labeling of products containing an MPHO that are classified as medical devices and fall within a regulatory requirement to carry a UDI. Regulations describe a unique device identifier (UDI) that consists of a device identifier (DI) and one or more production identifiers (PI). This information must appear on the label in two formats:

- Automatic Identification and Data Capture (AIDC) and
- Human Readable Interpretation (HRI).

The DI includes static elements related to the device. The DI is a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the manufacturer of that device.

ICCBBA has developed an ISBT 128 UDI that satisfies international requirements of the International Medical Device Regulators Forum (IMDRF), and also carries the critical information required for biologics traceability and biovigilance. Using ISBT 128

identification for MPHO across all regulatory classifications ensures a harmonized approach to identification and a seamless traceability pathway.

The ISBT 128 UDI is based on ISBT 128 data structures that contain data identifiers. ISBT 128 UDI data strings will include such data identifiers that will allow the parsing of the DI and PI elements.

The ISBT 128 DI includes three elements: a Facility Identification Number, a Facility-defined Product Code, and the ISBT 128 standardized Product Description Code (PDC).

The ISBT 128 Standard mandates the use of two production identifiers that are essential to ensure traceability back to the donor and to other products derived from the same donor:

- the Donation Identification Number and,
- the Product Divisions Code (serial number).

Other PIs may be optional, but if present on the label must be included in the UDI.

# 2 Device Identifier

Within ISBT 128, the Processor Product Identification Code [Data Structure 034] shall be used to encode the Device Identifier (UDI-DI). This data structure includes a facility identifier and an identifier specific to the type of product that is made up of two elements: a 6-character Facility-defined Product Code (FPC) and a 5-character standardized ISBT 128 Product Description Code (PDC).

## 2.1 Processor Product Identification Code (PPIC) [Data Structure 034]

**Purpose:** Data Structure 034 shall identify the processing or labeling facility, a Facility-defined Product Code (FPC), and a standardized Product Description Code (PDC).

**Structure:** =/nnnnnpppppppqqqqq

| Element | Length | Type |
|---|---|---|
| = | 1 | data identifier, first character |
| / | 1 | data identifier, second character |
| nnnnn | 5 | alphanumeric {A-N, P-Z, 0-9} |
| pppppp | 6 | alphanumeric {A-Z, 0-9} |
| qqqqq | 5 | alphanumeric {A–Z, 0-9} |

The 16-character data string, **nnnnnpppppppqqqqq**, shall be encoded and interpreted as follows:

**nnnnn** shall specify the Facility Identification Number, or the FIN(P), of the facility that assigned the PDC. For a UDI, this facility would be the manufacturer. The FIN(P) is issued by ICCBBA as the Issuing Agency for ISBT 128 identifiers and is encoded and interpreted by reference to the Registered Facilities Database published and maintained by ICCBBA in the password-protected area of the ICCBBA Website. The facility that assigned the PDC may, or may not, be the same facility that assigned the Donation Identification Number (DIN).

**pppppp** shall specify a Facility-defined Product Code (FPC) assigned by the processing or manufacturing facility indicating a catalog or other number that identifies the type of product within its system. If a value is not required, the default value 000000 (zeroes) shall be used. If the number is less than 6 characters, leading zeroes shall be used. The facility may choose to publish reference tables for use by the organizations receiving the product.

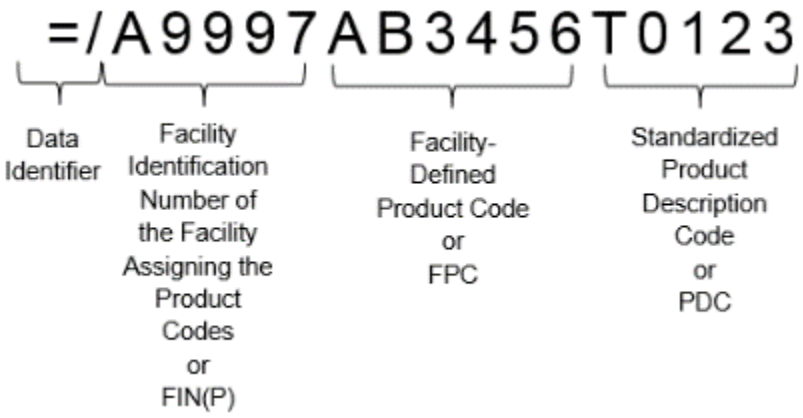
 

This code shall distinguish between two products that have the same standardized Product Description Code but require different DIs. This may be because two product lines are slightly different or because a product changes in a way that requires a new DI but not a new Product Description Code.

**qqqqq** shall specify the Product Description Code (PDC). This code shall be encoded and interpreted by reference to the ISBT 128 Product Description Code Database published and maintained by ICCBBA in the password-protected area of the ICCBBA Website.

See Chapter 7 for information on selection of a standardized PDC.

**Figure 1 Processor Product Identification Code Data Structure**



# 3 Production Identifiers

The IMDRF Guidance indicates that Production Identifiers (PIs) include:

- Serial number
- Lot/Batch number
- Manufacturing and/or Expiration date

For medical devices containing MPHO the donation identification number is an additional essential PI.

The data structures shown in Table 1 may be used for these identifiers.

**Table 1 Production Identifiers**

| UDI Identifier | ISBT 128 Data Structure [Data Structure Number] |
|---|---|
| Donation Identification Number | Donation Identification Number [001] |
| Serial Number | Product Divisions [032] |
| Expiration Date | Expiration Date [004] |
| Manufacturing Date | Production Date [008] |
| Lot/Batch Number | MPHO Lot Number [035] |

**To provide traceability for a MPHO, ISBT 128 requires that the PI shall include:**

- **The Donation Identification Number (DIN)**
- **The Product Divisions Code** (this code, in conjunction with the Product Description Code within the DI, is used to uniquely identify each product from a donation event)

The expiration date, manufacturing (production) date, and lot number shall be included as part of the PI if they are used on the label.

## 3.1 Donation Identification Number [Data Structure 001]

*Note: This is the only data structure in which the second character of the data identifier shall be part of the data content.*

Purpose: Data Structure 001 shall specify

- a Donation Identification Number (DIN) that is a unique identification of:
  (1) a donation event [collection or recovery];
  (2) a product pool;
  (3) for plasma derivatives, a unique identification of an aliquot from a pooled plasma derivative product; and
  (4) a fertilized oocyte/embryo formed through ART.
- flag character values

The DIN shall be globally unique for a one hundred year period.

Structure: =αppppyynnnnnnff

| Element | Length | Type |
|---|---|---|
| = | 1 | data identifier, first character |
| α | 1 | data identifier, second character, alphanumeric {A–N; P–Z; 1–9} |
| pppp | 4 | First two characters alphanumeric {A-N, P-Z, 0-9}; second two characters numeric {0-9}<br><br>Current usage is numeric for all 4 characters. Alpha characters may be introduced into positions 1 and 2 in the future<br>(e. g., if α = A and pppp = BC12, the αpppp will be ABC12) |
| yy | 2 | numeric {0–9} |
| nnnnnn | 6 | numeric {0–9} |
| ff | 2 | alphanumeric {0–9}, {A-H, J-N, P, R-Y} |

The fifteen (15)-character data content string, **αppppyynnnnnnff**, shall be encoded and interpreted as follows:

**αpppp** shall specify the Facility Identification Number (FIN) of the organization that assigned the DIN and shall be encoded and interpreted by reference to the Registered Facilities Database published and maintained by ICCBBA in the password-protected area of the ICCBBA Website.

**yy** shall specify the last two digits of the year in which the DIN was assigned.

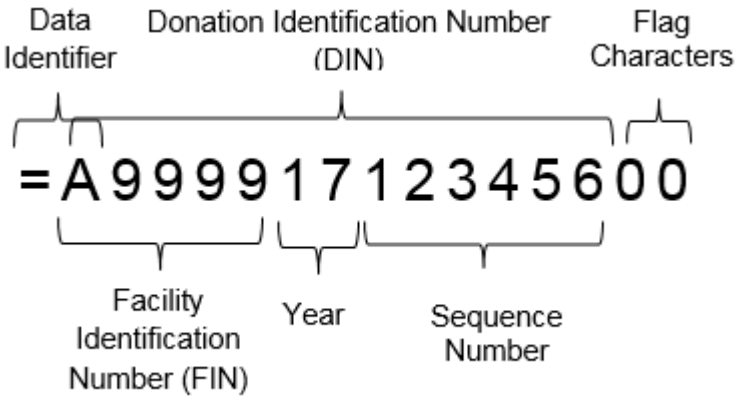
*Note: In practice, this is the "nominal" year. To cut down on wastage, DIN labels may be used for up to one month in the year before, and one month in the year after, the year shown on the label.*
*In the case of a tissue processing facility assigning a DIN, the DIN year code may be the year of the donation event OR the year in which the first product was processed. Usage shall be consistent within a facility. That is, if the DIN year code is the year the first tissue from the donation event was processed, the facility must always use the year the first tissue from a donation event was processed to determine the year code.*

**nnnnnn** shall specify a sequence number indicating the collection or recovery event, product pool, or aliquot from a pooled plasma derivative product, within the given year for the facility identified by the FIN.

**ff** are "flag characters."

At the current time, flag characters shall not be used for medical devices with an MPHO element and the value of ff shall be set to 00. Flag characters are intended for use in process control and, while are part of the DIN Data Structure, are not a part of the DIN itself.

**Figure 2 Donation Identification Number Data Structure**



## 3.2 Product Divisions [Data Structure 032]

Purpose: Data Structure 032 shall convey information about:

- Aliquots, or
- One or more individual collections from the donor within the same donation event.

The division code may represent:

- one of the subunits from a single container that has been divided. This can also be referred to as an aliquot or a split.
- one of the containers from a collection where the volume of product collected required the use of more than one container.
- a single collection into one container.

The Product Divisions shall serve as a serial number for MPHO regulated as medical devices.

Structure: =,dddddd

| Element | Length | Type |
|---|---|---|
| = | 1 | data identifier, first character |
| , | 1 | data identifier, second character |
| dddddd | 6 | alphanumeric {A-Z, 0-9} |

The 6-character data string, dddddd, shall be encoded and interpreted as follows:

**dddddd** shall specify the division code

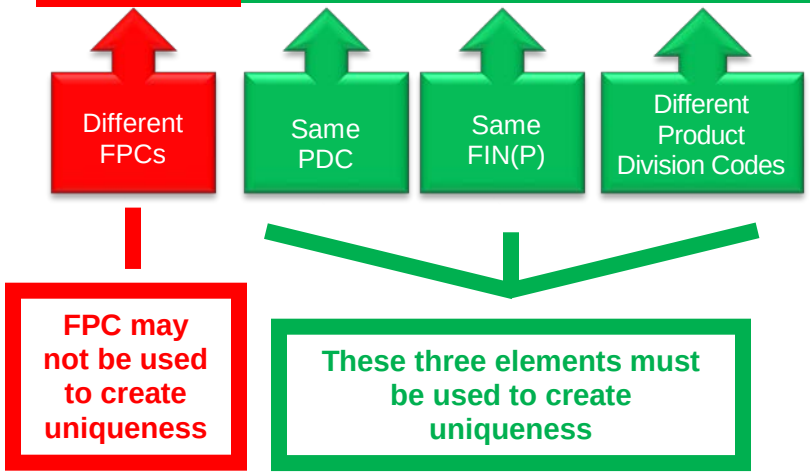
While ISBT 128 is used for all MPHO, not all MPHO use the same set of data structures as medical devices. Certain ISBT 128 identifiers, regardless of the data structure in which they are encoded, become essential for traceability across MPHO. Within medical devices, these essential identifiers are the FIN(P) and PDC from the DI and the DIN and Product Divisions Code from the PI.

The FPC is used to identify sub-categories of products that use the same ISBT 128 PDC. However the FPC is not part of the ISBT 128 traceability information and because it is not internationally standardized cannot be used as an element of the unique ISBT 128 product identification. If multiple FPCs map to one PDC, Product Division Codes must be used to uniquely identify each product. In the example in Table 2 (page 15) all products are from the same donation event (i.e., they all have the same DIN). The elements in bold font in the last column indicate how the Product Divisions Code is essential to ensure these products are uniquely identified (only the Division Codes differentiate the products). Although the FPC varies across the codes, it may not be used to create uniqueness. Therefore, the Product Divisions Code must be different for each of the four products since all have the same DIN (A9998 17 132343), FIN(P) (A9999), and PDC (T0475).

**Table 2 Use of Product Division Codes to Create Uniqueness**

| All Products Have the DIN A9998 17 132343 | | | | | |
|---|---|---|---|---|---|
| FPC | PDC | FIN(P) | Product Divisions Code | Description of Product | Data Structures 034 and 032 |
| XYZ123 | T0475 | A9999 | 000001 | BONE, PUTTY\|Radiation sterilization\|Demineralized:Yes\|Carrier and applicator, 2 mL | **A9999**XYZ123**T0475** and **000001** |
| XYZ124 | T0475 | A9999 | 000002 | BONE, PUTTY\|Radiation sterilization\|Demineralized:Yes\|Carrier and applicator, 5 mL | **A9999**XYZ124**T0475** and **000002** |
| XYZ125 | T0475 | A9999 | 000003 | BONE, PUTTY\|Radiation sterilization\|Demineralized:Yes\|Carrier and applicator, 10 mL | **A9999**XYZ125**T0475** and **000003** |
| XYZ126 | T0475 | A9999 | 000004 | BONE, PUTTY\|Radiation sterilization\|Demineralized:Yes\|Carrier and applicator, 15 mL | **A9999**XYZ126**T0475** and **000004** |




**For products with the same DIN: If the PDC and the FIN(P) are the same, the Product Divisions Code must be used to create uniqueness. *The FPC cannot be used for this purpose.***

***In this example, the FPC was used to encode volume, which is not included in the ISBT 128 PDC.***

## 3.3 Expiration Date [Data Structure 004]

Purpose: Data Structure 004 shall indicate the date at the end of which the item expires.

Structure: =>cyyjjj

| Element | Length | Type |
|---|---|---|
| = | 1 | data identifier, first character |
| > | 1 | data identifier, second character |
| c | 1 | numeric {0–9} |
| yy | 2 | numeric {0–9} |
| jjj | 3 | numeric {0–9} |

The six (6)-character data content string, **cyyjjj**, is encoded and interpreted as follows:

**c** shall specify the century of the year in which the item expires

**yy** shall specify the year within the century in which the item expires

**jjj** shall specify the ordinal number within the calendar year (Julian date) on which the item expires

## 3.4 Production Date [Data Structure 008]

Purpose: Data Structure 008 shall indicate the date on which the product was produced.

Structure: =}cyyjjj

| Element | Length | Type |
|---|---|---|
| = | 1 | data identifier, first character |
| } | 1 | data identifier, second character |
| c | 1 | numeric {0–9} |
| yy | 2 | numeric {0–9} |
| jjj | 3 | numeric {0–9} |

The six (6)-character data content string, **cyyjjj**, shall be encoded and interpreted as follows:

**c** shall specify the century of the year in which the product was produced

**yy** shall specify the year within the century in which the product was produced

**jjj** shall specify the ordinal number within the calendar year (Julian date) on which the product was produced

## 3.5 MPHO Lot Number [Data Structure 035]

Purpose: Data Structure 035 shall be used for the lot number of medical products of human origin

Structure: &,1xxxxxxxxxxxxxxxxx

| Element | Length | Type |
|---|---|---|
| & | 1 | data identifier, first character |
| , | 1 | data identifier, second character |
| 1 | 1 | data identifier, third character |
| xxxxxxxxxxxxxxxxx | 18 | alphanumeric {A–Z; 0–9} |

The data content string shall be up to 18 characters and shall be encoded and interpreted as follows:

**xxxxxxxxxxxxxxxxx** Facility-defined lot number

# 4 Compound Messages

In order to convey the full UDI (device identifier and production identifier information), in a single encoded message, a compound message is needed. This data structure allows multiple data structures to be combined into a single message and may be used with high capacity delivery mechanisms such as 2-D symbols and radio-frequency identification (RFID) tags.

## 4.1 Compound Message [Data Structure 023]

Purpose: Data Structure 023 shall allow multiple data structures to be combined into a single data string to facilitate use of newer technology delivery systems.

Structure: =+aabbb

| Element | Length | Type |
|---|---|---|
| = | 1 | data identifier, first character |
| + | 1 | data identifier, second character |
| aa | 2 | numeric {0-9} |
| bbb | 3 | numeric {0-9} |

The 5-character data content string, **aabbb**, shall be encoded and interpreted as follows:

**aa** shall specify the number of ISBT 128 data structures that follow;

**bbb** shall be either:

- all zeroes – indicating this is an undefined message, i.e. only the number of data structures is identified, but not what each one is or the order in which they occur.

a three-digit number referencing an entry in an ICCBBA-maintained table that defines the sequence of the data structures within a compound message. See Table W2, [RT017] ICCBBA-Specified Compound Messages described in the *ISBT 128 Standard Technical Specification* (ST-001). The reference table is found on the ICCBBA Website.

*Note: Because of the complexity created by multiple product categories and the many codes that would result from permutations of order of data structures, ICCBBA now encourages the use of undefined messages.*

Rules for constructing compound messages:

1. A compound message shall comprise a string of ISBT 128 data structures (excluding nationally defined structures), beginning with the Compound Message [Data Structure 023].

2. Data structures shall be combined with no intervening characters. Each data structure shall begin with its data identifier characters.

3. The string shall only contain ISBT 128 data structures (excluding nationally defined structures).

4. The number of data structures following the Compound Message Data Structure shall be indicated in element aa of the Compound Message Data Structure.

5. If the sequence of the message is unspecified, the Compound Message Data Structure shall have element bbb set to zeroes and element aa shall be set as specified in Rule 4.

6. If a specified sequence is used, the reference number of the selected message from Table RT017 shall be included in element bbb of the Compound Message Data Structure. The order of the data structures shall be that shown on Table RT017 for the reference number selected.

**To satisfy medical device regulations, the compound message shall always begin with the Processor Product Identification Code [Data Structure 034] (the DI).** In addition, to meet traceability requirements, the Product Divisions [Data Structure 032] and Donation Identification Number [Data Structure 001] shall also be present. If any additional PIs are present on the label then it shall be encoded. Additional PIs not present on the label may be included in the encoded message. If non-UDI data structures are included in the compound message, they must appear after the PIs.

Reading software should be able to interpret both unspecified sequence and specified sequence compound messages. The software should always verify the integrity of the data string, including checking that the correct number of data structures appears and, when specified sequence messages are used, that the sequence of data structures is correct. Data should only be interpreted if the integrity of the data structures has been confirmed.

## 4.2 Reference Table for Compound Messages (Specified Sequence)

A full list of specified sequence compound messages is found in Table W2, [RT017] ICCBBA-Specified Compound Messages on the ICCBBA Website. An excerpt of this table that includes some messages specific for MPHO devices is shown as Table 3. Additional specified sequence messages may be requested by contacting tech.manager@iccbba.org.

**Table 3 Specified Sequence Compound Messages for MPHO Devices**

| ICCBBA-Specified Message Number | Data Structures |
|---|---|
| 034 | Processor Product Identification Code [034], Product Divisions [032], Donation Identification Number [001] |
| 035 | Processor Product Identification Code [034], Product Divisions [032], Donation Identification Number [001], Expiration Date [004] |
| 036 | Processor Product Identification Code [034], Product Divisions [032], Donation Identification Number [001], Production Date [008] |
| 037 | Processor Product Identification Code [034],Product Divisions [032], Donation Identification Number [001], Expiration Date [004], Production Date [008] |

## 4.3 Creating Compound Messages

Compound Messages can be created using either an unspecified or a specified sequence of data structures. Facilities may select whichever type of message works best for them.

### 4.3.1 Creating a Compound Message (Unspecified Sequence)

The data structures and their sequence desired in the example compound message are:

- Processor Product Identification Code [034]
- Donation Identification Number [001]
- Product Divisions [032]
- Expiration Date [004]

The message desired is:

| Data Structure | Information to transfer | Data Identifier and Data Content |
|---|---|---|
| Processor Product Identification Code or PPIC (DI) | Facility: A9997<br>Facility-defined Product Code: XYZ100<br>Standardized Product Code: T0479 | =/A9997XYZ100T0479 |
| Donation Identification Number | Donation Identification Number: A999917123456 | =A99991712345600 |
| Product Divisions | 12 | =,000012 |
| Expiration Date | 31 JAN 2019 | =>019031 |

A compound message with this data is:

| Data Characters | Meaning of Data Characters |
|---|---|
| =+ | Data identifier |
| 04 | There are four data structures in the message |
| 000 | This is a message with an unspecified sequence of data structures |
| =/A9997XYZ100T0479 | Processor Product Identification Code is A9997XYZ100T0479 |
| =A99991712345600 | Donation Identification Number for the MPHO is A999917123456. Flag characters are set to 00. |
| =,000012 | Product division is 12 |
| =>019031 | Expiration date is 31 JAN 2019 |

The data string would therefore be:

=+04000=/A9997XYZ100T0479=A99991712345600=,000012=>019031

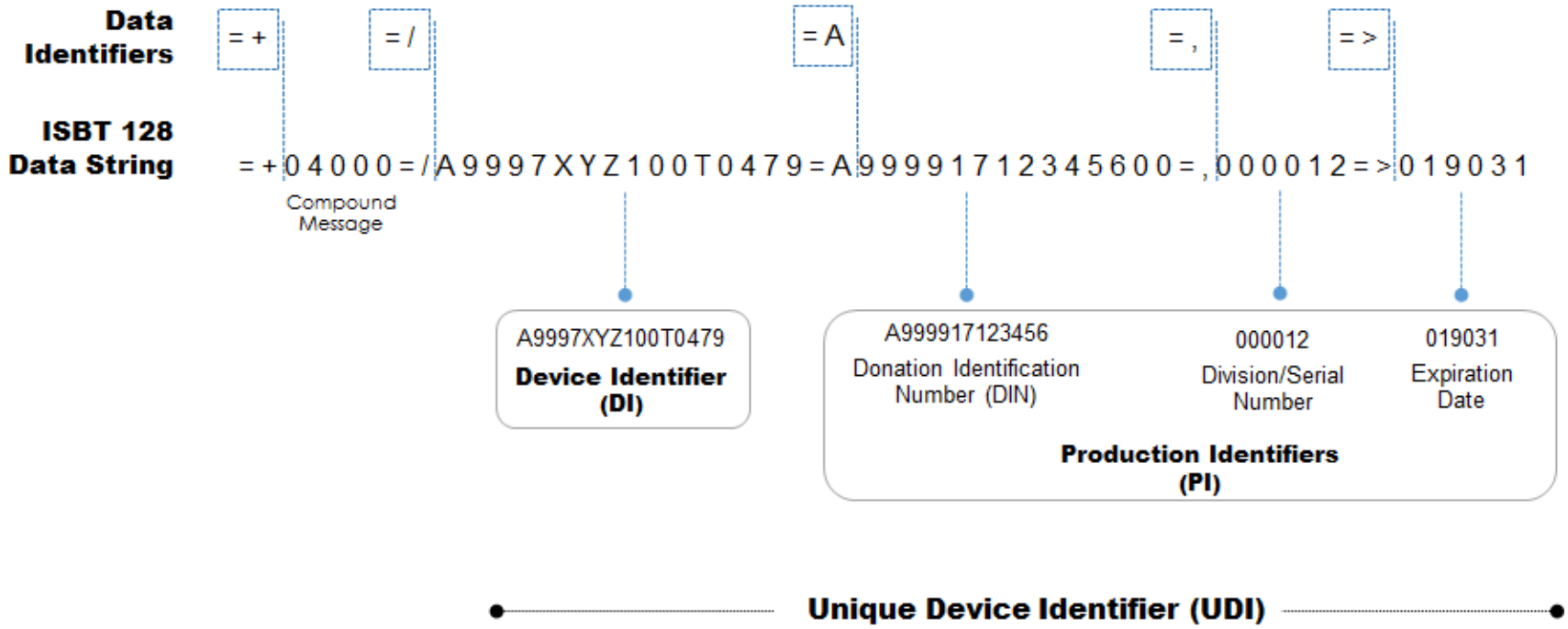
The Data Matrix symbol would be: 

This symbol, created with an X dimension of 0.36 mm has a size of approximately 9 mm by 9 mm.

Figure 3 shows how this message is parsed.

**Figure 3 Compound Message (Unspecified Sequence)**



### 4.3.2 Creating a Compound Message (Specified Sequence)

The data structures desired in the example compound message are:

- Processor Product Identification Code [034]
- Product Divisions [032]
- Donation Identification Number [001]
- Expiration Date [004]

Per Table W2 [RT017] - ICCBBA-Specified Compound Messages, these data structures are in the specified compound message #035.

**Table 4 Excerpt from RT017**

| ID | Number of Data Structures | Data Structure Numbers | Data Structures |
|---|---|---|---|
| 035 | 04 | [034];[032];[001];[004] | Processor Product Identification Code;Product Divisions;Donation Identification Number;Expiration Date |

The message desired in the example is:

| Data Structure | Information to transfer | Data Identifier and Data Content |
|---|---|---|
| Processor Product Identification Code or PPIC (DI) | Facility: A9997<br>Facility-defined Product Code: XYZ100<br>Standardized Product Code: T0479 | =/A9997XYZ100T0479 |
| Product Divisions | 12 | =,000012 |
| Donation Identification Number | Donation Identification Number: A999917123456 | =A99991712345600 |
| Expiration Date | 31 JAN 2019 | =>019031 |

A compound message with this data is:

| Data Characters | Meaning of Data Characters |
|---|---|
| =+ | Data identifier |
| 04 | There are four data structures in the message |
| 035 | This message has a sequence of data structures that is specified in line 035 from Table RT017 |
| =/A9997XYZ100T0479 | Processor Product Identification Code is A9997XYZ100T0479 |
| =,000012 | Product division is 12 |
| =A99991712345600 | Donation Identification Number for the MPHO is A999917123456. Flag characters are set to 00. |
| =>019031 | Expiration date is 31 JAN 2019 |

The data string would therefore be:

=+04035=/A9997XYZ100T0479=,000012=A99991712345600=>019031

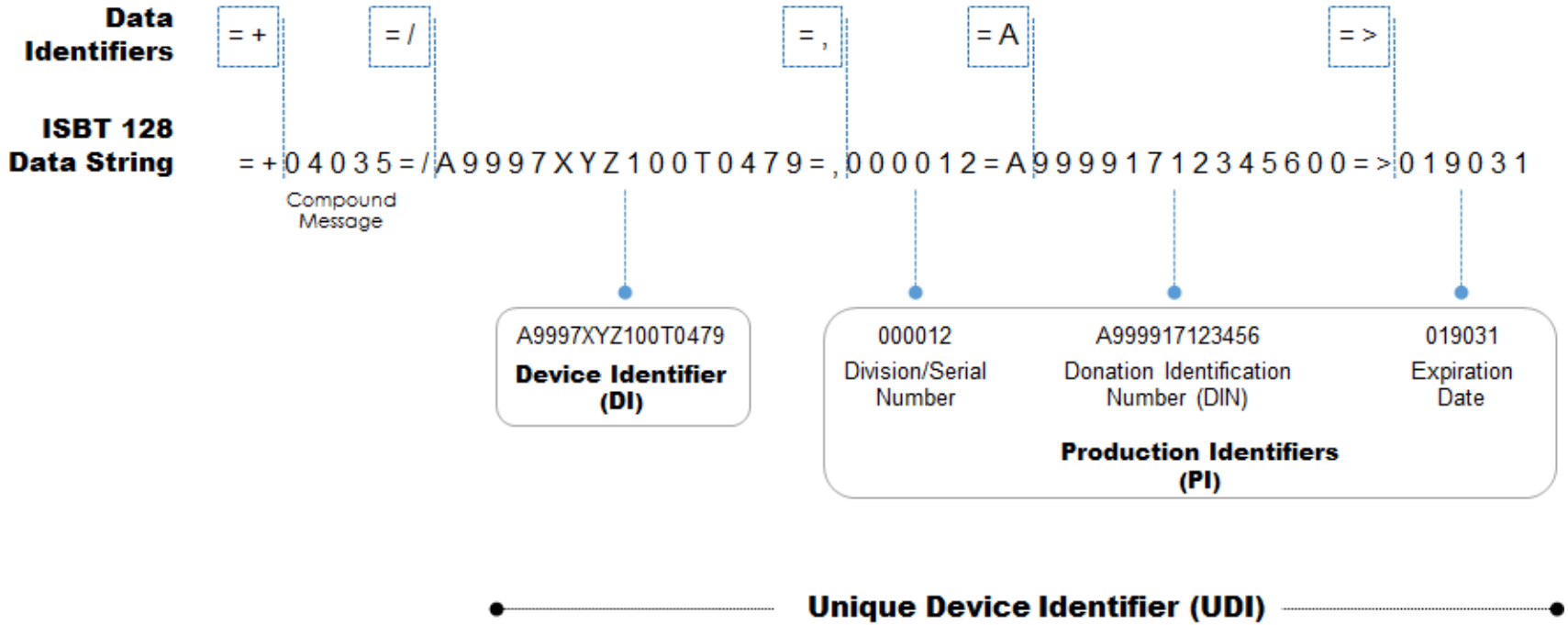
The Data Matrix symbol would be:

This symbol, created with an X dimension of 0.36 mm has a size of approximately 9 mm by 9 mm.

Figure 4 shows how this message is parsed.

**Figure 4 Compound Message (Specified Sequence)**



# 5 Parsing the ISBT 128 UDI to Extract the Data Items

The approved formats for an ISBT 128 UDI are shown in the table below. The ISBT 128 UDI is based on ISBT 128 data structures that contain data identifiers.

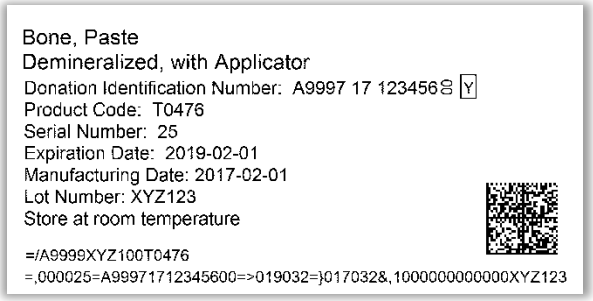
**Table 5 ISBT 128 UDI for Medical Devices Containing MPHO**

| Issuing Agency | Data Identifiers | Identifier | Data type | Human Readable Barcode Field Size | Database Field Size |
|---|---|---|---|---|---|
| ICCBBA | =/ | DI (Device Identifier) | Alphanumeric | 18 | 16 |
| ICCBBA | =, | Serial Number | Alphanumeric | 8 | 6 |
| ICCBBA | = | Donation Identification Number | Alphanumeric | 16 | 15 |
| ICCBBA | => | Expiration Date | numeric [YYYJJJ] | 8 | 6 |
| ICCBBA | =} | Manufacturing Date | numeric [YYYJJJ] | 8 | 6 |
| ICCBBA | &,1 | MPHO Lot Number | Alphanumeric | 21 | 18 |

Example of Human Readable Interpretation:

=/A9999XYZ100T0476=,000025=A99971712345600=>019032=}017032&,1000000000000XYZ123

**Figure 5 Example Label with 2-D Symbol**



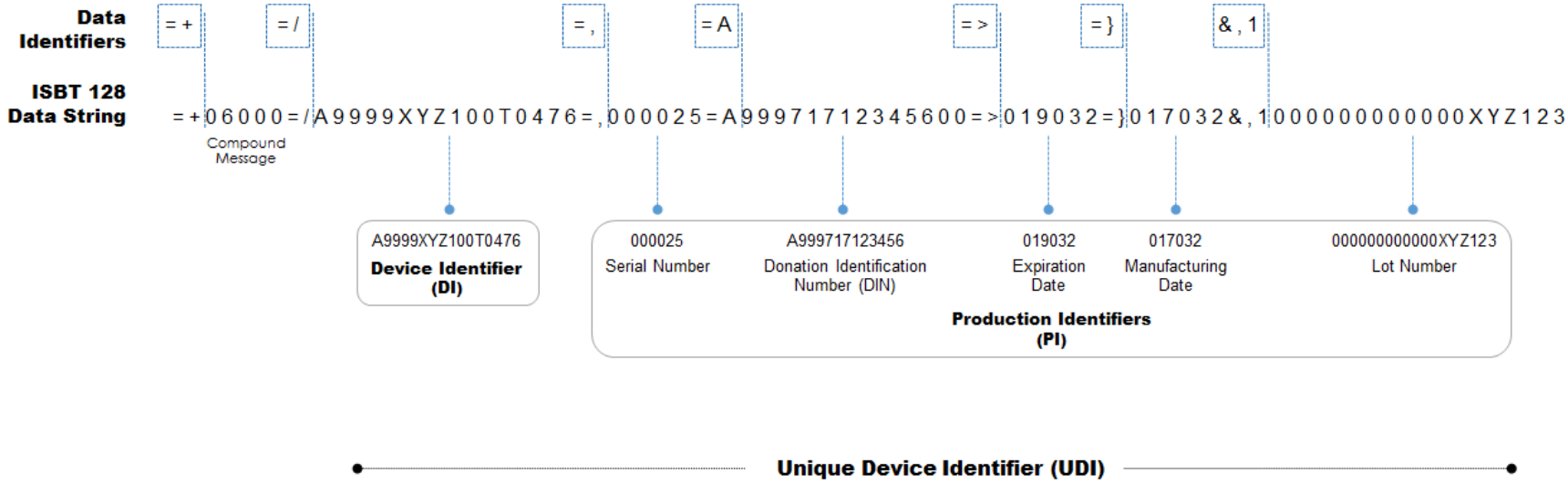

 

It is recommended that the ISBT 128 UDI be encoded within an ISBT 128 Compound Message in a 2-D Data Matrix symbol. However, the Standard does permit the use of Code 128 linear bar codes for compound messages.

When the UDI is encoded in a Data Matrix code the full UDI will be received as a single input string. An example is:

=+06000=/A9999XYZ100T0476=,000025=A99971712345600=>019032=}017032&,1000000000000XYZ123

**Figure 6 Parsing of an ISBT 128 UDI**



The initial “=” character indicates that this is an ISBT 128 data string. Elements of the message are divided either by the “=” or the “&” character.

The first element (=+06000) indicates that this is a compound message and the content can be interpreted in accordance with Section 4.1.

The second element is the Device Identifier (DI). This is identified by the data identifier “=/” and the 16 data characters following this data identifier comprise the device identifier (A9999XYZ100T0476).

The remaining elements are the production identifiers and may appear in any order. They are each identified by a data identifier. The Donation Identification Number and the Product Divisions Code (serial number) are mandatory PIs. If any other PIs appear on the label, then they too are required to be encoded.

In the above example the third element is the Product Divisions Code. It is identified by the data identifier “=,” and has six data characters (000025). This is the “serial number of a specific device”.

The fourth element is the Donation Identification Number. It is identified by the data identifier “=” followed by any alpha/numeric character. The “=” character is followed by 15 data characters, but only the first 13 of these are the Donation Identification Number. The last two characters are flag characters and should be ignored. Thus, in the example, the data characters A999717123456 form the Donation Identification Number.

The fifth element is the Expiration Date PI. This is identified by the data identifier “=>” and has six data characters. These are presented in an YYYJJJ format where the first three characters form a three-digit year and the next three characters are the ordinal number within the calendar year (Julian date). Thus, 019032 refers to 1 Feb 2019.

The sixth element is the Manufacturing Date PI. This is identified by the data identifier “=}” and has six data characters. These are presented in an YYYJJJ format where the first three characters form a three-digit year and the next three characters are the ordinal number within the calendar year (Julian date). Thus, 017032 refers to 1 Feb 2017. This is the date of manufacture.

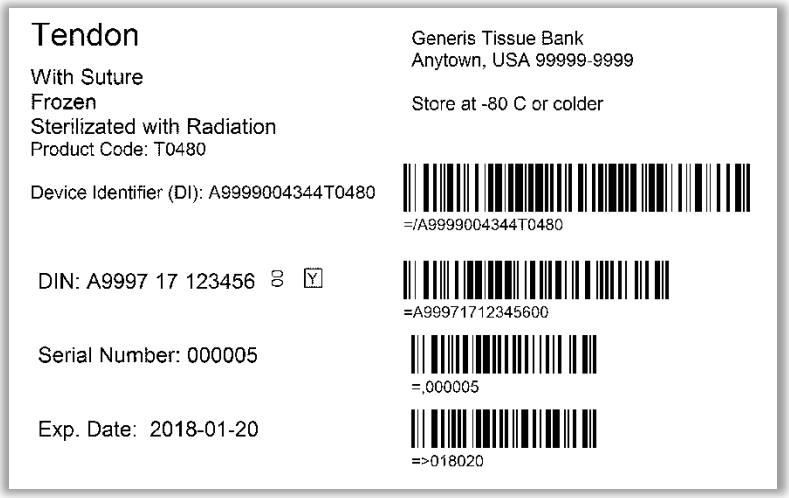
The seventh element is the Lot Number PI. This is identified by the data identifier “&,1” and the 18 data characters following this data identifier (000000000000XYZ123) are the lot or batch number.

*(Note: If non-UDI data structures are included in the message, they shall appear after the PIs.)*

If the UDI is presented as linear barcodes, each element shall be carried in an individual Code 128 linear code and will be identified by its data identifiers. The compound message data structure is not used in this situation. See Figure 7.

**Figure 7 Example Label with Multiple Linear Bar Codes**



# 6 Labeling

## 6.1 Bar Codes and 2-D Symbols

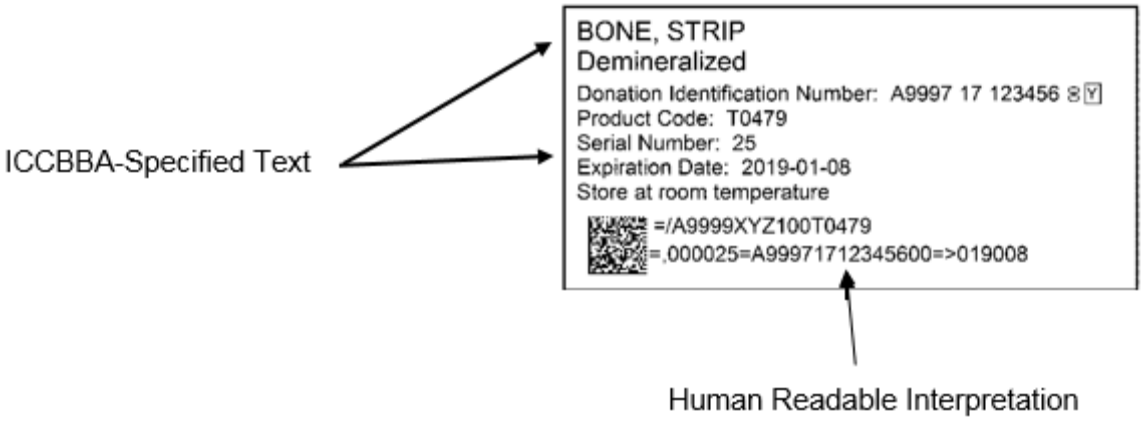
ISBT 128 specifies that linear bar codes shall use Code 128 and 2-D symbols shall use Data Matrix when printed on the label. Printing of the bar code or 2-D symbol shall follow appropriate ISO standards (listed in Section 1.4) and the *ISBT 128 Standard Technical Specification* (ST-001).

Linear bar codes may be used if space on the label permits. Because of the length of the bar codes, separate bar codes would be needed for the DI and the PI. Separate bar codes would also be needed for the various data structures within the PI.

## 6.2 Text

Both the human readable text that corresponds to the data characters encoded in the AIDC UDI and ICCBBA-specified text should be printed as shown in Figure 8.

**Figure 8 Label Example**




### 6.2.1 ICCBBA-Specified Text

ICCBBA-specified text corresponding to the UDI identifiers should be displayed in a way easily interpreted by humans. This text may be printed in any order and may omit leading zeroes. Font selected must allow differentiation between similar characters (e.g., 0/O and 1/I).

Information corresponding to identifiers essential for traceability in ISBT 128 should be near the electronically-readable symbol. At a minimum, this should include:

- The Donation Identification Number
- The Product Description Code
- The Product Divisions Code (serial number)

The identification of the processor (name of processor), also needed for traceability, should be present on the label, but the specific location is not mandated. This flexible placement is also true for the expiration date and the MPHO lot number.

The human readable interpretation should be identified with a label (e.g., “Donation Identification Number” and “Product Code”), but this label may be abbreviated if space is limited. See Table 6 for recommended abbreviations.

**Table 6 Abbreviations Found on Labels**

| Information | Recommended Abbreviation(s) |
|---|---|
| Donation Identification Number | DIN |
| Product Description Code | Prod Code or PC |
| Product Divisions Code | Pack, Serial Number, or SN |
| Expiration Date | Exp or Exp Date |
| Manufacturing or Production Date | Mnf Date or Prod Date |
| Lot Number | Lot No. or LN |

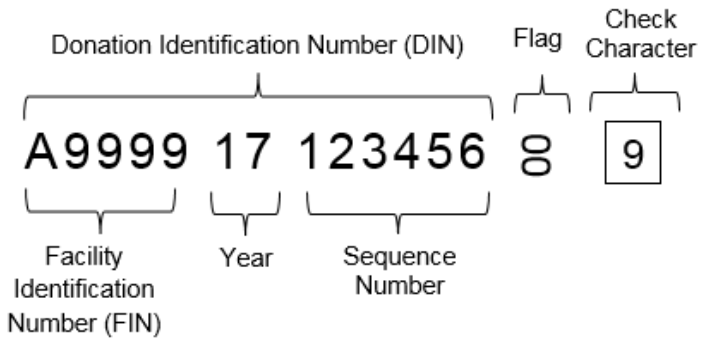
Requirements for printing specific text:

**Expiration Date:** The expiration date, if applicable, must be printed in the format YYYY-MM-DD (four-digit year, hyphen, two-digit month, hyphen, two-digit day).

**DIN:** When the DIN is printed within the ICCBBA-defined text, it should be printed in a standardized format. The printed DIN shall include a check character (see Figure 9). In some countries, the Facility Identification Number (FIN) is printed, followed by a space, the year code, a space, the sequence number, a space, the flag characters rotated 90 degrees clockwise, and the check character printed within a box. The first character of the data identifier is not printed; the second character of the data identifier is printed only because it is also the first character of the FIN. For calculating the check character, see *Use of the Donation Identification Number [Data Structure 001]* (IG-033).

**Figure 9 Printing of DIN in ICCBBA-Specified Text**




The ISBT 128 Class name and Attributes may be printed, but this is not required.

### 6.2.2 UDI Human Readable Interpretation

The format of human readable interpretation shall follow the ISBT 128-specified format.

Data structures within the UDI human readable text shall be in the order they appear within the electronically-readable symbol. The human readable text UDI should be displayed below or near the corresponding electronically-readable symbol or the AIDC form.

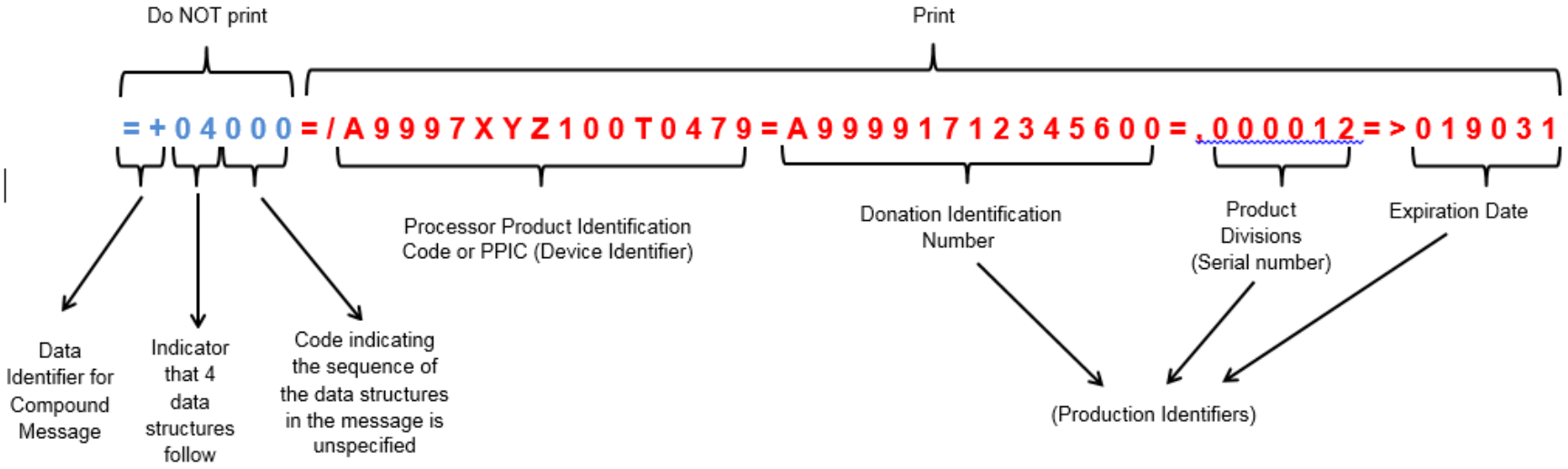
**Characters to print in human readable text:** Human readable text corresponding to UDI information shall be printed on the product label. The UDI information includes the data content and data identifiers for data structures comprising the DI and PI. See Figure 10.

**Characters NOT to print in human readable UDI text:** The characters corresponding to the compound message data identifier and message code. See Figure 10.

**Figure 10 Human Readable Text for UDI**

Bar coded message:




Human readable text for the code above should be as shown below (and as shown in red above):

**=/A9997XYZ100T0479=A99991712345600=,000012=>019031**

It is acceptable to print the device identifier on a separate line from the production identifier (with ISBT 128 data identifiers):
**=/A9997XYZ100T0479**
**=A99991712345600=,000012=>019031**

## 6.3 UDI on Higher Levels of Packaging

Most MPHO are shipped as individual devices (packages of one device). Organizations that package multiple devices as a routine packaging configuration should consult ICCBBA (email: iccbba@iccbba.org) for guidance on assigning a UDI for both the individual devices and the multi-device package.

# 7 Internationally Standardized Product Description Codes (PDCs)

Standardized PDCs are the last 5 characters in the Processor Product Identification Code [Data Structure 034], which is the device identifier (DI), and correspond to a standardized description of the MPHO product through a reference table. Products are described through the use of Class and Attributes. Each of the characteristics that make up the product description is defined in the document*: ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002)*.*

In general, the descriptions included in the ISBT 128 database tables are intended for use in final product labeling. A “final product” is defined as a product appropriate for transfer from the recovery and/or processing facility inventory to some other inventory. However, with the use of the “For Further Processing” Attribute, facilities may optionally use ISBT 128 Product Codes internally from the time of the recovery of tissue.

An outdate period is not defined in the description since each country determines the permissible period after collection, recovery, or further processing during which the product may be used.

The PDC does contain information about manufacturing, but is not intended to be a complete record of all processing steps; that is, it is not a portable data file of the manufacturing process.

## 7.1 Terminology

PDCs uniquely define MPHO in terms of their characteristics. All products have a Class and may have one or more Attributes.

### 7.1.1 Class

Class is a general description of products (such as Bone, Paste or Tendon, Achilles).

### 7.1.2 Attributes

Attributes provide additional information about MPHO. MPHO thus may be further described through the addition of one Attribute variable from one or more Attribute groups.

Attributes are organized into groups of mutually exclusive terms. Each group has a default value that applies if no Attribute variables are selected.

The document *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002) provides complete descriptions of currently defined Classes and Attributes.

## 7.2 Structure of Product Descriptions within the Database

Once defined, product descriptions are placed into a reference table database. Each description is assigned a unique five-character ISBT 128 Product Description Code (PDC) for electronic communication. Although there is no structure to the five-character PDC, the description of the product within the database is rigidly structured. Each product is defined in the ICCBBA database minimally in terms of its Class.

The Class and Attributes are separated in the product name by the "|" delimiter: CLASS|Attribute

For example:

| Product Description Code | Description |
|---|---|
| T0474 | BONE, PUTTY\|Demineralized:Yes |

Attributes may be used to further describe the product. Only one variable from each Attribute group may be used. Attributes are also separated by the "|" delimiter: CLASS|Attribute|Attribute

For example:

| Product Description Code | Description |
|---|---|
| T0475 | BONE, PUTTY\|Radiation sterilization\|Demineralized:Yes\|Carrier and applicator |
| T0476 | BONE, PASTE\|Demineralized:Yes\|Applicator |

The order in which the Attributes appear in the description field of the database is the order in which they appear in the Attribute table of the database.

The order in which text appears in the description field of the database does not specify the order in which Attributes will appear as label text. Since this can be country-specific, national guidelines as to the placement of label text should be consulted.

## 7.3 PDC Database

Details of the database structure may be found in *ISBT 128 Standard Product Description Code Database* (ST-010).

All ISBT 128 database tables are published in the password-protected area of the ICCBBA Website. This file is a Microsoft Access® file and is listed on the Website as:

ISBT 128 Product Description Code Database

## 7.4 Selecting PDCs

Tissue PDCs begin with the letter “T”. The codes are listed in alphabetical order in the full database so tissue codes are found near the end. To appropriately select product descriptions, it is important to understand the definitions of each term. These definitions are found in *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002).

### 7.4.1 “Retired” Codes

Over time, codes may become inappropriate, redundant, or errors may be discovered. As a result, a mechanism must exist to discontinue future use of these codes. However, because products may exist in inventories across the world, the codes must be retained in the database for backward compatibility.

To accomplish this goal, a column exists in the ICCBBA database to indicate such codes. This “Retired Date” column indicates the date on which ICCBBA recommended the codes no longer be used for new products. Software should be written to recognize these codes, but not assign them to newly created products. It is understood that facilities must be given time to retire codes after ICCBBA has made its recommendation.

### 7.4.2 Level of Detail

Following national guidelines, facilities can determine the level of detail that must be encoded into an electronically-readable format according to the needs of its customers.

*Note: For more detail about the dimensions of a product (volume, length, height, depth, etc.), another data structure, Dimensions [Data Structure 029] may be used. For more information on the use of this data structure, see the ISBT 128 Standard Technical Specification (ST-001) and Implementation Guide: Use of Dimensions [Data Structure 029]* (IG-026)*.*

### 7.4.3 Using the Product Code Lookup Tool to Locate PDCs

Searching for the correct PDC can be simplified by the use of the online ISBT 128 Product Lookup Program available on the ICCBBA Website.
https://www.iccbba.org/lookup-tools/find-product-information
It is refreshed with each new version of the ISBT 128 Product Description Code Database (approximately once a month).

The program can be used to lookup a description for a given PDC or lookup a PDC based on a description.

## 7.5 Requesting New PDCs

After performing a product search using the online Product Lookup Program, if the selected search criteria yields no exact match, the ISBT 128 Product Lookup Program allows for submitting a request to add the new product description to a future version of the ISBT 128 Product Description Code Database. Instructions for doing so are available on the ICCBBA website.
https://www.iccbba.org/lookup-tools/find-product-information

Codes that represent new combinations of existing Classes or Attributes will generally be added on the next database update. The database is updated approximately 10 times each year.

If a new Class, Attribute group, or variable within an Attribute group is needed, please contact the ICCBBA Technical Manager (tech.manager@iccbba.org). A definition compatible with the format of those in the *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002) must accompany such a request. Requests for new characteristics will be reviewed by appropriate technical advisory groups to ensure international consensus with the terminology chosen.

New PDCs must be compatible with the existing system. If there is a question of compatibility, the request may be referred to the Standards Committee of ICCBBA.

Updates to the PDCs will be regularly posted in the password-protected section of the ICCBBA Website and made apparent by a change in the Version Number of the ISBT 128 Product Description Code Database. Version control sheets describing the changes are published with each update.

# 8 Administrative Processes

## 8.1 Registration and Licensing

The scope of ISBT 128 is limited to coding MPHO. This means that only those medical devices with a MPHO component will be addressed in ISBT 128 coding. Manufacturers that distribute devices without a MPHO component should contact one of the other issuing agencies.

Each facility that implements ISBT 128, or plans to implement ISBT 128 and needs access to password-protected information from the ICCBBA Website, must register with ICCBBA. Specific requirements for registration and a form for this purpose may be found on the ICCBBA Website.

Before implementing ISBT 128, each registered facility shall pay the annual license fee. The annual license fee is set by the ICCBBA Board of Directors to cover the anticipated expenses for the fiscal year for which the fee is assessed. It is invoiced to every registered facility at its last known address early in each calendar year. The terms under which ISBT 128 is licensed for use are provided in the ICCBBA License Agreement, a copy of which can be found on the ICCBBA Website.

ICCBBA assigns Facility Identification Numbers (FINs) that are used in a number of data structures, including the one used for the DI (Data Structure 034), to identify the assigning organization. FINs are published in the password-protected area of the ICCBBA Website. An organization may have more than one FIN if it is useful for its operational needs. See Implementation Guide: ISBT 128 Facility Identification Number (IG-034) for further information about assignment of FINs, inactivation of FINs, the process to follow when an organization changes its name, etc.

## 8.2 Nonconformities with the ISBT 128 Standard

Regulations require the use of an approved coding and labeling system for medical devices. It is essential that facilities using ISBT 128 comply with the standard to meet these requirements and to ensure traceability. When requested, ICCBBA technical staff will provide technical support, including label review, through its help desk (iccbba@iccbba.org) to facilities implementing ISBT 128.

Should ICCBBA become aware of a facility utilizing ISBT 128 for UDI that is not in compliance with the Standard, it will work with the facility to bring it into compliance. It will follow-up with the facility by discussing the deficiency(ies) in their use of the Standard and provide educational materials as needed. If appropriate, an agreed Corrective Action Plan will be developed.

## 8.3 Suspension and Revocation of License

A facility's license to use ISBT 128 will be suspended if it is unable to substantially comply with the Standard in a reasonable period of time following notification of a problem. ICCBBA staff will work with facilities to resolve issues prior to suspending a license. If a facility has a suspended license for more than 12 months and no attempt is

made to come into compliance, the license to use ISBT 128 will be revoked. ICCBBA will notify a facility in writing via email or standard mail if its license to use ISBT 128 will be, or has been, suspended or revoked.

ICCBBA will notify appropriate competent authorities that a facility's license to use ISBT 128 will be, or has been, suspended or revoked.

# 9 Abbreviations

| | |
|---|---|
| AIDC | Automatic Identification and Data Capture |
| ASTM | Formerly known as American Society for Testing and Materials. Now is called ASTM International. |
| DI | Device Identifier |
| DIN | Donation Identification Number |
| EU | European Union |
| FIN | Facility Identification Number |
| FIN(P) | Facility Identification Number of the Processing Facility |
| FPC | Facility-Defined Product Code |
| GUDID | Global Unique Device Identification Database |
| HCT/P | Human Cells, Tissues, and Cellular and Tissue-Based Products |
| HRI | Human Readable Interpretation |
| IEC | International Electrotechnical Commission |
| IMDRF | International Medical Device Regulators Forum |
| ISO | International Standards Organization |
| MPHO | Medical Products of Human Origin |
| PDC | Product Description Code |
| PI | Production Identifier(s) |
| PPIC | Processor Product Identification Code |
| UDI | Unique Device Identifier |
| UDID | Unique Device Identifier Database |

# 10 Glossary

| Term | Definition |
|---|---|
| Data Content | The characters in a data structure that encode the information for which the data structure is named. The data content does not include the data identifier. (The Donation Identification Number is an exception to this rule. See Section 3.1, page 12.) |
| Data Identifier | The first two or three characters in a data structure that identify the data structure. These will always be present when the data structure is used as a bar code, but may be omitted when the data structure is used in situations in which the data structure identity is unambiguously and explicitly defined (e.g., electronic messaging). The Donation Identification Number is an exception to this rule. The second character of the data identifier can never be dropped because it is also part of the data content.) |
| Data Structure | Information content comprising the data identifier and data content. When a data structure is represented as a bar code, the term data structure does not include the symbology-specific start and stop codes that are always present, the symbology-specific check characters, or any specified control characters. |
| Device Identifier (DI) | A mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the Manufacturer of that device. |
| Medical Device | 'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:<br>• diagnosis, prevention, monitoring, treatment or alleviation of disease,<br>• diagnosis, monitoring, treatment, alleviation of or compensation for an injury,<br>• investigation, replacement, modification, or support of the anatomy or of a physiological process,<br>• supporting or sustaining life,<br>• control of conception,<br>• disinfection of medical devices,<br>• providing information by means of in vitro examination of specimens derived from the human body; |

| Term | | Definition |
|---|---|---|
| | | and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.<br><br>[Global Harmonization Task Force (revision of GHTF/SG1/N29:2005) Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'] |
| Ordinal Date | | A system for maintaining dates that numbers the first day of the year (January 1) as 1 and the last (December 31) as 365 or 366 (in a leap year). Also known as Julian Date. |
| Production Identifier (PI) | | A conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:<br>(i) The lot or batch within which a device was manufactured;<br>(ii) The serial number of a specific device;<br>(iii) The expiration date of a specific device;<br>(iv) The date a specific device was manufactured;<br>(v) For MPHO regulated as a device, the donation identification number. |
| Text | | The human-readable representation of information. |
| | Human Readable Interpretation (HRI) | Human Readable Interpretation is a legible interpretation of the data characters encoded in the UDI Carrier.<br>The HRI UDI must include the device identifier (DI), production identifiers (PIs), and data identifiers contained in the UDI. |
| | ICCBBA-specified text | Text corresponding to information required for traceability along with a label indicating the type of information (e. g., "Donation Identification Number"). Information required for traceability includes the FIN(P), the DIN, the Product Code, and the Product Divisions Code. |
| Unique Device Identifier (UDI) | | An identifier that adequately identifies a device through its distribution and use. A unique device identifier is composed of a device identifier and a production identifier. |

# Appendix 1: Basic UDI-DI

**Background**

UDI implementation in the European Union requires the use of a Basic UDI-DI identifier to act as the main key in the EU Database (EUDAMED). The purpose of the Basic UDI-DI is to link together products with different UDI-DI that have the same intended purpose, risk class, and essential design and manufacturing characteristics.

The European Commission has specified the following requirements for the Basic UDI-DI:
"In order to ensure, to the maximum possible extent, the quality of the code value entered in Eudamed, the Basic UDI-DI requirements on format should be as close as possible to the ones for the UDI-DI. In particular,

- the Basic UDI-DI code value shall have maximum 25 characters, so that it does not differ too significantly from the maximum length of the UDI-DI as established by the issuing entities;
- a check digit/character must be part of the Basic UDI-DI, based on an algorithm defined by the issuing entity. This algorithm shall be provided by the issuing entities to the Commission and to the manufacturers."

The following specification satisfies these requirements. The Basic UDI-DI format is identical to the UDI-DI format with the exception that it carries an additional two digits that form a mod-37,2 checksum.

Manufacturers are responsible for ensuring that they retain a mapping between the Basic UDI-DI and all the UDI-DI that relate to it.

Where there is a 1:1 mapping between the Basic UDI-DI and the UDI-DI, the data content (excluding checksum) should be the same in both identifiers.

Where there is a 1:many mapping between the Basic UDI-DI and the UDI-DI, but all the UDI-DI utilize the same ISBT 128 Product Description Code, then the Basic UDI-DI should carry the corresponding PDC in the qqqqq element.

Where there is a 1:many mapping between the Basic UDI-DI and the UDI-DI, and the UDI-DI utilize multiple ISBT 128 Product Description Codes, then the qqqqq element should be set to 00000.

**Purpose and Structure of the Basic UDI-DI**

Purpose: The Basic UDI-DI is the main key in the EU database (Eudamed) and in relevant documentation to connect devices with same intended purpose, risk class and essential design and manufacturing characteristics. It is independent/separate from the packaging/labelling of the device and it does not appear on any trade item.

Structure: nnnnnpppppppqqqqqbb

| Element | Length | Type |
|---|---|---|
| nnnnn | 5 | alphanumeric {A-N, P-Z, 0-9} |
| pppppp | 6 | alphanumeric {A-Z, 0-9} |
| qqqqq | 5 | alphanumeric {A–Z, 0-9} |
| bb | 2 | alphanumeric {A–Z, 0-9} |

The 18-character data string, **nnnnnpppppppqqqqqbb**, shall be interpreted as follows:

**nnnnn** shall specify the Facility Identification Number, or the FIN(P), of the facility that assigned the PDC. For a UDI, this facility would be the manufacturer. The FIN(P) is issued by ICCBBA as the Issuing Agency for ISBT 128 identifiers and is encoded and interpreted by reference to the Registered Facilities Database published and maintained by ICCBBA in the password-protected area of the ICCBBA Website. The facility that assigned the PDC may, or may not, be the same facility that assigned the Donation Identification Number (DIN).

**pppppp** shall specify a Facility-defined Product Code (FPC) assigned by the processing or labeling facility indicating a catalog or other number that identifies the type of product within its system. If a value is not required, the default value 000000 (zeroes) shall be used. If the number is less than 6 characters, leading zeroes shall be used. The facility may choose to publish reference tables for use by the organizations receiving the product.

This code shall distinguish between two products that have the same standardized Product Description Code but require different DIs. This may be because two product lines are slightly different or because a product changes in a way that requires a new DI but not a new Product Description Code.

**qqqqq** shall specify the Product Description Code (PDC). This code shall be encoded and interpreted by reference to the ISBT 128 Product Description Code Database published and maintained by ICCBBA in the password-protected area of the ICCBBA Website.

See Chapter 7 for information on selection of a standardized PDC.

Where the Basic UDI-DI maps to multiple UDI-DI with different PDCs this field shall be set to all zeroes.

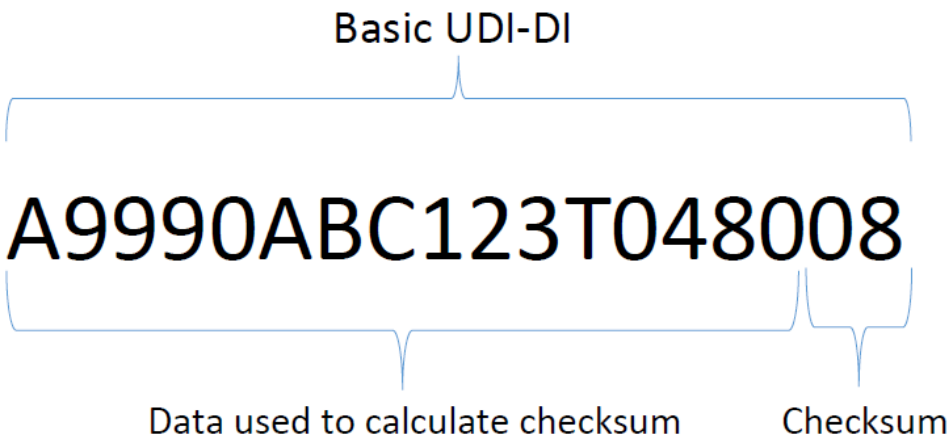
**bb** shall specify a two-digit modulus 37-2 checksum. The following section below describes how the checksum is calculated.

**Calculating the Basic UDI-DI Checksum**

The integrity of a Basic UDI-DI can be verified by performing a checksum calculation on the first sixteen characters of the Basic UDI-DI and ensuring that the resulting checksum matches the last two characters.

The checksum is based on the ISO 7064 Mod 37-2 algorithm. This section shows how the checksum shall be calculated for any given Basic UDI-DI.




The steps in the process are as follows:

1. For each character in the sixteen character string, determine its check value as required by ISO 7064 from Table 7 (e.g., character F has value 15);
2. For each character in the sixteen character string, determine its weighted check value by multiplying the check value from Table 7 by the $n^{th}$ power of 2 where n is the position of the character from the right-hand end of the string;
3. Sum the weighted check values from step 2;
4. Find the modulus 37 value of the sum from step 3;
5. Subtract the value obtained in step 4 from 38;
6. Find the modulus 37 value of the result of step 5;
7. If the value from step six is a single digit add a leading zero.
8. The calculated value is the modulo 37-2 checksum.

**Table 7 Character to ISO/IEC 7064 Check Values [RT061]**

| Character | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | A | B | C |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Value | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| | | | | | | | | | | | | | |
| Character | D | E | F | G | H | I | J | K | L | M | N | O | P |
| Value | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 |
| | | | | | | | | | | | | | |
| Character | Q | R | S | T | U | V | W | X | Y | Z | | | |
| Value | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | | | |

**Example of Checksum Calculation**

Calculation for **A9990ABC123T0480**

| Character in the string | STEP 1<br>ISO 7064 check value (a) | n<br>Position of the character from the right | $2^n$<br>(b) | STEP 2<br>Weighted check value (a x b) |
|---|---|---|---|---|
| A | 10 | 16 | 65536 | 655360 |
| 9 | 9 | 15 | 32768 | 294912 |
| 9 | 9 | 14 | 16384 | 147456 |
| 9 | 9 | 13 | 8192 | 73728 |
| 0 | 0 | 12 | 4096 | 0 |
| A | 10 | 11 | 2048 | 20480 |
| B | 11 | 10 | 1024 | 11264 |
| C | 12 | 9 | 512 | 6144 |
| 1 | 1 | 8 | 256 | 256 |
| 2 | 2 | 7 | 128 | 256 |
| 3 | 3 | 6 | 64 | 192 |
| T | 29 | 5 | 32 | 928 |
| 0 | 0 | 4 | 16 | 0 |
| 4 | 4 | 3 | 8 | 32 |
| 8 | 8 | 2 | 4 | 32 |
| 0 | 0 | 1 | 2 | 0 |

Step 3: sum of last column = 1211040

Step 4: modulo 37 of 1211040 = 30

Step 5: 38 – 30 = 8

Step 6: modulus 37 of 8 = 8

Step 7: Add leading zero if single digit. = 08

Thus, the mod 37-2 checksum is 08.

A9990ABC123T048008

# Appendix 2: Use Case for Medical Device Containing HCT/P in the United States

## Background

HCT/P products are derived from human donors. As such, they have unique characteristics that have implications throughout the supply chain. In particular, it is important to recognize that:

- A single donor can be the source of many different products. For example, one donor may donate skin, tendons, heart valves, and a wide range of bone products. All of these different products share a common history.

- HCT/P carry a risk of disease transmission. While this risk is minimized by testing and processing, it can never be entirely eliminated.

- It is therefore imperative that following detection of disease transmission by an HCT/P, all other products derived from the same donor can be rapidly removed from the supply chain and all patients who have received products from the donor can be followed up.

- Therefore, the traceability model for HCT/P has unique characteristics that are not present for other healthcare products. In particular, an identifier is required to allow tracking from recipient to donor and from donor to recipient. (FDA regulation uses the term “distinct identification code” – see 21CFR 1271.290(c)).

- This identifier needs to be captured at all point in the supply chain in order to allow rapid tracking and recall of products.

Effective traceability of HCT/P requires that the distinct identification code for the donor can be tracked throughout the supply chain from donor to recipient, and that other products from that donor, whether regulated as devices or biologics, can be identified and recalled.

Past experience has demonstrated that current traceability is sub-optimal with tracing being slow and sometimes incomplete. Reasons include a lack of standardization in the structure and presentation of the distinct identification code; lack of uniqueness of the distinct identification code throughout the supply chain; and lack of a standardized electronic format for the distinct identification code.

Within the ISBT 128 system the Donation Identification Number (DIN) fulfils the role of the distinct identification code. This identifier is standardized, globally unique, and identified in coding with its own PI to facilitate parsing from the UDI.

This use case identifies how traceability can be significantly improved using the distinct identification code PI.

## Use Case in the United States

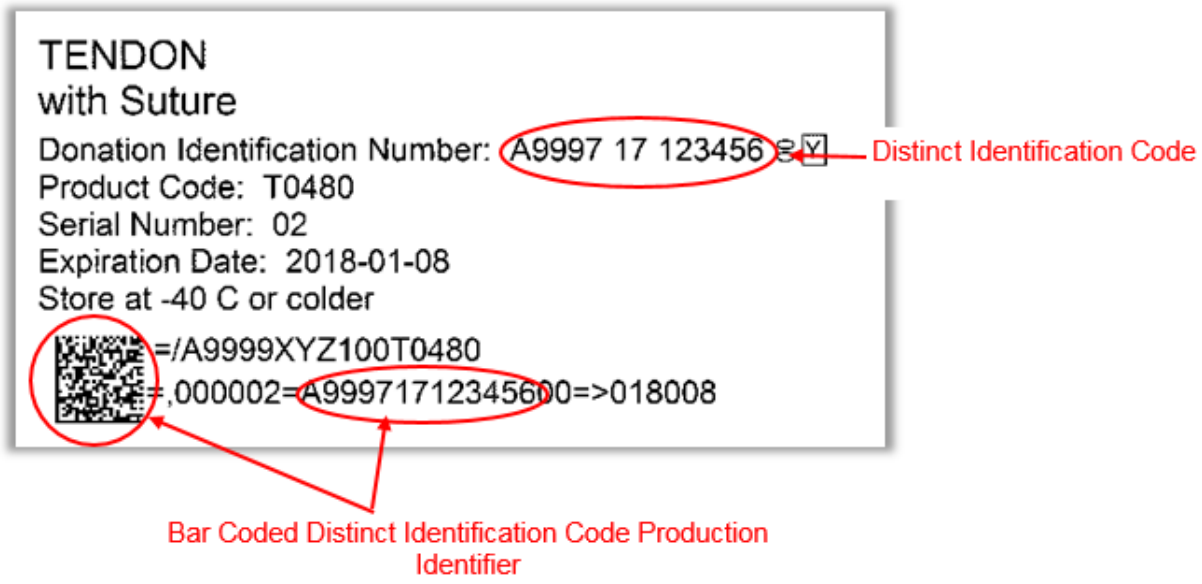
The use case illustrates what would happen when a medical device containing an HCT/P labeled with an ISBT 128 UDI is implicated in potential disease transmission.

*Note: The ISBT 128 Standard requires that the same distinct identification code (ISBT 128 Donation Identification Number) is used on all tissue products prepared from a particular donor by a specified tissue processor.*

Mr. Smith requires transplantation of a tendon with suture (a medical device containing an HCT/P) during an anterior cruciate ligament repair.

The product is received from a tissue bank, via a distributor and is entered into hospital materials management system by scanning of the ISBT 128 UDI barcodes [DI and PIs for distinct identification code (ISBT 128 Donation Identification Number), serial number, and expiration date]. See Figure 23.

Figure 11 Example HCT/P Label




When the product is to be transplanted, the UDI label is scanned and the product is removed from materials inventory. The record of the implant is recorded in Mr. Smith's electronic medical record using the UDI DI and PIs.

Some months following surgery Mr. Smith is found to be positive for Hepatitis C virus (HCV). The hospital informs the tissue processor and CDRH. CDRH, recognizing the infectious disease implications, pass the information on to CDC. The tissue processor performs additional testing on stored samples from the donor and detects very low levels of HCV. CDC conducts an epidemiologic and laboratory investigation and determines that there is a significant probability that the disease was transmitted by the implant. It alerts the public health and clinical and laboratory communities by issuing a Health Alert Network advisory for healthcare facilities to withdraw all HCT/P that carry the implicated distinct identification code. The manufacturer issues a voluntary recall. CDC works with the manufacturer to identify other hospitals which may

have received product from the same donor. Once these hospitals have been identified, CDC works with the state/local health departments who contact healthcare facilities to determine if the products have been used or are still in inventory.
Healthcare facilities enter the distinct identification code into their tissue/materials management systems and these systems search inventory and identify products to be withdrawn pending return to the supplier. The systems also add the distinct identification code onto a reference list which is checked each time new inventory is added, thus allowing the system to alert the user if an attempt is made to receive products that have been recalled.

Healthcare facilities also enter the distinct identification code into their electronic patient record systems. These systems search for patient records containing a UDI with this distinct identification code PI. Patients who have received these products are identified for follow up.