

# **ISBT 128 Standard**

# Labeling of Human Tissues

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2

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## **Table of Contents**

1	Intro	Introduction			
	1.1 Purpose				
	1.2	Scope	6		
	1.3	Intended Audience	6		
	1.4	Normative References	7		
	1.5	Other References	7		
	1.6	Background	7		
	1.7	New in this Version	9		
2	Data	a Structures	10		
3	Labe	el Size	11		
4	Labe	el Access	12		
5	Elec	tronically Readable Symbols	13		
6	Text	Text14			
	6.1	Text for Linear Bar Codes	14		
	6.2	Text Associated with Electronically-Readable Information	14		
	6.2.	1 Donation Identification Number [Data Structure 001]	14		
	6.2.2	2 Product Descriptions	15		
	6.2.3	3 Dates	16		
7	Labe	el Design	17		
	7.1	Requirements for ISBT 128 Labels	17		
	7.2	Small Label Design	21		
	7.3	Tissue Labels Following the "Four Quadrant" Format	21		
	7.4	Labels with Non-ISBT 128 Electronically Readable Information	22		
	7.5	Labeling Formats	23		
	7.5.′	1 Basic Labeling Format	23		
	7.5.2	2 Special Labeling Format – Use of the FIN(P)	25		
	7.5.3	3 Tissues Labeled with a National Identification Number	27		

## Tables

## Figures

Figure 1	Comparison of a 2-D Symbol and Linear Bar Codes	.13
Figure 2	Representation of Flag Characters	.15
Figure 3	Example of Relative Text Sizes of Class and Attributes	.15
Figure 4	Minimum Information Content with Linear Bar Codes	.18
Figure 5	Minimum Information Content with a 2-D Symbol	.18
Figure 6	Label Example with Recommended ISBT 128 Information (Linear Bar Codes)	.19
Figure 7	Label Example with Recommended ISBT 128 Information (2-D Symbol)	.20
Figure 8	100 mm by 100 mm Label	.21
Figure 9	200 mm by 50 mm Label	.21
Figure 10	)Product Carton Label	.22
Figure 1 <sup>2</sup>	1 Large Vial Label	.22
Figure 12	2 Basic Labeling Format (2-D Symbol)	.24
Figure 13	3 Use of the Processing Facility Information Code [Data Structure 033]	.26

# 1 Introduction

## 1.1 Purpose

This document is intended to help facilities and software developers design appropriate ISBT 128 labels for tissue products.

## 1.2 Scope

This document provides guidance for the design of labels for tissue products following the standards described in the *ISBT 128 Standard Technical Specification* (ST-001).

Because the container size for tissue products varies considerably, only a sample of possible label designs is provided.

This document does not discuss all aspects of labeling of tissue products. Other aspects and where information may be found, are shown in Table 1. The documents referenced in the table can be found on the ICCBBA website (<u>www.isbt128.org</u>).

Product Group	Information found in:
Ocular Tissue	ISBT 128 Standard, Labeling of Ocular Tissue ( <u>ST-009</u> )
Single European Code (SEC)	ISBT 128 Standard, ISBT 128 and the Single European Code (SEC) ( <u>ST-012</u> )
Medical Device (For US Facilities)	ISBT 128 Standard, Coding and Labeling of Medical Devices Using ISBT 128 ( <u>ST-011</u> )
Medical Device (General)	ISBT 128 Standard, Coding and Labeling of Medical Devices Containing MPHO ( <u>ST-017</u> )
Medically Assisted Reproduction (MAR)	ISBT 128 Standard, Labeling of Reproductive Tissue and Cell Products ( <u>ST-019</u> )

Table 1 Information about Tissue Products Not Within the Scope of this Document

## 1.3 Intended Audience

The intended audience of this document is:

- staff at tissue banks and hospitals that receive tissue products (managers, information technology, quality, validation, and laboratory)
- software developers
- label vendors
- regulatory authorities in countries where ISBT 128 is used to label tissue products

## **1.4 Normative References**

ISBT 128 Standard Technical Specification (<u>ST-001</u>) ISBT 128 Standard Terminology for Medical Products of Human Origin (<u>ST-002</u>) ISBT 128 Standard Coding and Labeling of Medical Devices Using ISBT 128 (<u>ST-011</u>) ISBT 128 Standard, ISBT 128 and the Single European Code (SEC) (<u>ST-012</u>) ISBT 128 Standard Coding and Labeling of Medical Devices Containing MPHO (<u>ST-017</u>) ISBT 128 Standard Labeling of Reproductive Tissue and Cell Products (<u>ST-019</u>)

## 1.5 Other References

ICCBBA website (www.isbt128.org)

Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (<u>IG-014</u>) Implementation Guide: Use of Dimensions [Data Structure 029] (<u>IG-026</u>) Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033] (<u>IG-031</u>)

Note: The ICCBBA standards and implementation guidelines referred to throughout this document can be found on the ICCBBA website (<u>www.isbt128.org</u>).

#### International Standards Organization (ISO):

ISO 8601-1:2019(E) Date and time — Representations for information interchange —

## 1.6 Background

There is growing recognition at the global level that there is a need to move towards standardization of the coding and labeling used on tissue products in order to improve traceability and enhance patient safety. Existing requirements may ensure the use of distinct or unique identification numbers by a tissue facility, but do not necessarily require this uniqueness to extend outside the tissue bank. As a result, a hospital may receive identically numbered tissue products from two different tissue processors. With the widespread distribution of tissue products at both a national and international level there is increased risk of loss of traceability due to duplication of identifiers.

In May 2010, the World Health Assembly approved resolution WHA63.22, which urges Member States "to encourage the implementation of globally consistent coding systems for human cells, tissues, and organs as such in order to facilitate national and international traceability of materials of human origin for transplantation."

ISBT 128 is a well-established international standard for the coding and labeling of blood, cells, and tissues. It is used extensively for the coding and labeling of blood donations. Many hospitals are already equipped to handle ISBT 128 blood and cellular therapy products through their transfusion laboratories and software could be updated to accept ISBT 128 tissue products. Some major software and labeling suppliers are already developing tissue banking modules for tissue banks and hospital use.

The United Kingdom Blood Transfusion Services/National Institute for Biological Standards and Controls Standing Advisory Committee on Information Technology was the first to consider using a structure based on the ISBT 128 Product Code model for tissues. Intended initially as a national code, the proposal was taken forward by ICCBBA as an international standard. Over 160 facilities in 29 countries have since implemented ISBT 128 for tissues.

In some countries, there are unique requirements related to the labeling of human tissues:

- In member states of the European Union (EU) and European Economic Area (EEA), the Single European Code (SEC) is required on tissues and cells distributed in the EU, including imports from third countries (non-European Union countries), in accordance with EU legislation. ISBT 128 product codes are incorporated into the European Union (EU) Product Compendium making ISBT 128 fully compatible with the SEC. The *ISBT 128 Standard, ISBT 128 and the Single European Code* (SEC) (ST-012) explains how products may be labeled with the SEC and ISBT 128.
- In the United States, tissue products regulated as medical devices are required to be labeled with a unique device identifier (UDI). ICCBBA has developed a labeling format that is compliant with US regulations. The ISBT 128 Standard Coding and Labeling of Medical Devices Using ISBT 128 (ST-011) contains guidelines for the implementation of this labeling format.
- Numerous countries follow the International Medical Device Regulators Forum (IMDRF) UDI Guidance for labeling medical devices that contain medical products of human origin (MPHO). Therefore, ICCBBA has developed the *ISBT 128 Standard, Coding and Labeling of Medical Devices Containing MPHO* (ST-017) that satisfies international requirements of the IMDRF, and also carries the critical information required for biologics traceability and biovigilance.

Throughout the years, international professional societies and standards-setting organizations have had joint efforts in support of a standardized method of labeling for all MPHO.

In 2023, more than 5,700 facilities in over 70 countries across six continents were registered to use ISBT 128.

## **1.7** New in this Version

The following table indicates the major changes between Version 1.1.0 and Version 1.2.0. Actual changes or additions to requirements of the ISBT 128 Standard are in bold print; changes to formatting or organization, or additional guidance are in regular print. When changes were a result of a formal proposal, the proposal number is listed in the Rationale column.

ISBT 128 Standard Labeling of Human Tissues Version Control: Version 1.1.0 vs. Version 1.2.0.

	Version 1.1.0 Chapter, Section, Table, or Figure	Version 1.2.0 Chapter, Section, Table, or Figure	Change	Rationale
1.	1.2, 1.4, 1.6	1.2, 1.4, 1.6	Added reference to the <i>ISBT</i> 128 Standard, Coding and Labeling of Medical Devices Containing MPHO (ST-017).	This document is relevant to facilities that follow the International Medical Device Regulators Forum (IMDRF) requirements for the labeling of tissues regulated as medical devices.
2.	1.2, 1.4	1.2, 1.4	Added reference to the <i>ISBT</i> 128 Standard, Labeling of Reproductive Tissue and Cell Products (ST-019).	This is a new standard for use by facilities labeling reproductive tissue and cell products.
3.	1.5	1.5	Added reference to ISO 8601-1:2019(E).	For completeness. This reference was omitted in the previous version.
4.	7.1, 7.5.2	7.1, 7.5.2	Updated the requirements to refine when to use the Facility Identification Number of the facility that assigned the Product Code [FIN(P)].	To remove the complexities from previous specifications.
5.	Table 2	Table 2	Updated to include "ABO not specified" for the special messages T1, T2, and T3.	For clarification and to reflect current information in ST-001.
6.	N/A	End of document	Added "End of Publication"	For ICCBBA's document
7.	Throughout	Throughout	Updated the titles of referenced documents, updated references, and made minor edits to the document's text and label examples.	To reflect current information and improve clarity.

## 2 Data Structures

The data structures that will commonly be used to label tissue products include:

- Donation Identification Number [Data Structure 001],
- Product Code [Data Structure 003], and
- Expiration Date and Time [Data Structure 005].

Blood Groups [Data Structure 002] may be used to encode special messages for tissues. These messages, created for labeling of tissues, include:

Table 2 Special Messages Designed for Use with Tissues in Data Structure 002

T1	ABO not specified, RhD positive
T2	ABO not specified, RhD negative
Т3	ABO not specified, RhD not specified
T4	Autologous collection/in quarantine
T5	See outer packaging for product status
Т6	Must be sterilized before release

Additional bar codes, such as Dimensions [Data Structure 029], may also be useful. The Dimensions data structure can be used to encode specific tissue measurements (e.g., exact length, width, and depth). See the *Implementation Guide: Use of Dimensions [Data Structure 029]* (IG-026) for more information about the use of this data structure.

The Processing Facility Information Code [Data Structure 033] may be used by facilities required to identify the processing facility. This data structure encodes the Facility Identification Number of the facility that assigned the Product Code [FIN(P)] and the Facility-defined Product Code (FPC). See the *Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033]* (IG-031) for additional information.

Detailed information on all data structures is found in the *ISBT 128 Standard Technical Specification* (ST-001).

# 3 Label Size

The size of an ISBT 128 label for tissue will vary depending upon a range of factors, such as the size of the container, the amount of information that a facility wants to encode using ISBT 128 data structures, the symbology (linear versus 2-D symbols) chosen to convey electronically readable information, the number of languages that may be required for text, and the requirements for other information on the label. The ISBT 128 standard, therefore, does not specify a particular size of label.

## 4 Label Access

The ISBT 128 label should be available at the time of transplantation so that information can be directly scanned into patient records. This is essential to eliminate the risk of manual transcription errors at this critical point of information transfer. However, for tracking purposes, the label will need to be scanned at various other points in the production and supply chain. To ensure this visibility of the label throughout the pathway from product release to transplantation, it may be necessary to have multiple copies of the label on different levels of packaging or to make use of transparent outer packaging through which the underlying label can be scanned.

# 5 Electronically Readable Symbols

Either linear bar codes (Code 128) or two-dimensional (2-D) symbols (Data Matrix), or both, may be used to label tissue products. 2-D symbols have the advantage of allowing a great deal of information to be encoded into a very small amount of space. See Figure 1. They do, however, require an imaging scanner to be able to read them.

Specifications (quality, dimensions, etc.) for the printing of electronically readable symbols can be found in the *ISBT Standard Technical Specification* (ST-001). Information on the rationale for the selection of Data Matrix, as well as implementation guidance, can be found in the *Implementation Guide: Use of Data Matrix Symbols with ISBT 128* (IG-014).





## 6 Text

## 6.1 Text for Linear Bar Codes

Every Code 128 bar code on a container label shall be accompanied by text that corresponds to the data content, unless otherwise specified. Data identifiers shall not appear in the text unless otherwise specified. Text corresponding to the data content shall be printed left justified (in line with the leftmost bar of the bar code) immediately below, but not touching, a linear bar code, unless otherwise specified. Text shall be in a font that differentiates similar characters with a maximum height of 2 mm. The minimum size may be defined by national regulatory requirements but will also depend upon the printer; some printers cannot distinguish between certain letters (e.g., an "o" and an "e") below a height of about 1.5 mm.

The DIN and Product Code shall appear in text when Data Matrix symbols are used. This is necessary to ensure adequate traceability because a product is uniquely identified based on the DIN and the Product Code. It is, therefore, essential that manual entry of these codes be possible should the electronic capture of information not be possible.

## 6.2 Text Associated with Electronically-Readable Information

Text associated with electronically-readable information is nationally defined to allow for differences in language, regulatory requirements, and preferences. Where needed, text may appear in multiple languages on a label.

Particular font sizes and types are not specified for text but designers, after considering national regulatory requirements, shall ensure clarity of all text and use larger fonts to emphasize critical information. The font chosen should clearly differentiate between similar characters (e.g., "O" and "0"; "I" and "1").

## 6.2.1 Donation Identification Number [Data Structure 001]

A national authority should determine how the Donation Identification Number should be displayed, for example:

A9999 02 123456

V004399 499999

7004 203 123 456

All data characters shall be printed (in this instance only, the second data identifier character is also a data character).

The flag characters "ff" may be used to convey specific information other than the unique identification of the product and shall be distinguished from the Donation Identification Number. Refer to the *ISBT 128 Standard Technical Specification* (ST-001) for more details.

When Type 1 or Type 2 flag characters are used, they shall be printed as either:

- Alphanumeric Presentation: The two-character code representing the flags "ff" shall be printed rotated 90° clockwise to make them visually different from the Donation Identification Number.
- Non-alphanumeric Presentation: A graphical icon or other representation of the value of "ff", e.g., for flag "07" printing an icon showing a small test tube.

Figure 2 Representation of Flag Characters



Wherever the keyboard check character is printed, it shall be clearly distinguished from other information. When printed in association with the text of a code, a box shall be drawn around the keyboard entry check character as shown in Figure 2.

### 6.2.2 Product Descriptions

Class and Attributes (except default attributes) text shall be printed on the label, but this information is not required to be in the ISBT 128 area of the label.

The order and size of text relating to the Product Description should be based on the importance of the information to the end-user. In general, Class name will be in larger print than Attributes. However, this may not always be the case.

The use of uppercase or lower-case text is a decision that may be made at a national level.

The text printed on the label does not have to match exactly the wording found in the Product Description Code Database. The text may vary but should convey the same product information.

Figure 3 Example of Relative Text Sizes of Class and Attributes



### 6.2.3 Dates

When dates are within the ISBT 128 standardized area of the label, they shall be printed in compliance with ISO 8601-2019 extended format YYYY-MM-DD (e.g., 2023-03-17) or the format [DD] [MMM] [YYYY]. In the latter, the day shall be numerical, the month alphabetical using a three-letter abbreviation, and the year shall be a four-digit numerical representation (e.g., 17 MAR 2023).

Times shall be printed based on a twenty-four-hour clock with a colon placed between the hours and minutes.

## 25 JUN 2023 15:15 or 2023-06-25 15:15

When the default time of 23:59 is encoded, the time does not have to appear as text.

## 25 JUN 2023 or 2023-06-25

It is permissible to encode the expiration date within the ISBT 128 bar code, but print the text for the date in the non-ISBT 128 area of the label. In this situation, the format of the text date may be determined by the facility.

# 7 Label Design

Since human tissues are packaged in a large variety of containers with different sizes, shapes, materials, and characteristics, the Standard allows flexibility in designing labels. In order to provide a common presentation of key traceability information, it is recommended that an area of the label be standardized across all tissue products. The location and size/orientation of this standardized ISBT 128 area of the label can be adjusted to suit tissue bank requirements.

This document describes label designs that meet the ISBT 128 requirements but does not preclude other designs that meet the requirements.

National agencies may publish guidelines for labeling that adhere to the ISBT 128 Standard and which take local language and regulatory requirements into consideration.

The following general principles apply to label design:

- Primary considerations in label design shall include improving the safety of the product and the efficiency of processing/administering. If these two considerations conflict, safety shall take precedence over efficiency.
- Critical information on the container shall dominate the label via position and prominence and shall take precedence over information that is of lesser significance to the end-user (clinician, nurse, laboratory staff, and other hospital personnel).

## 7.1 Requirements for ISBT 128 Labels

The ISBT 128 label area shall have a white background.

The minimum information content of the ISBT 128 area of the label shall be:

- Bar coded Donation Identification Number (DIN) and Product Code;
- Text for the Donation Identification Number, flag characters when required (rotated 90° clockwise) and the boxed manual check character;
- Text for the Product Code (product description code and division code/pack number).

If the facility that assigns the Product Description Code (PDC) is different from the facility that assigns the Donation Identification Number (DIN), the label should include the Facility Identification Number of the facility that assigned the Product Code [FIN(P)].

The following examples illustrate the minimum information content when the FIN(P) is not required. For further explanation on the use of the FIN(P), refer to Section 7.5.2.

Figure 4 Minimum Information Content with Linear Bar Codes

- 1 The Product Code composed of the Product Description Code (PDC) T0140 and the Division Code 001 appears as text and is encoded in a linear bar code.
- 2 The Donation Identification Number (DIN) A999917123456 and flag characters (22) appear as text and are encoded in a linear bar code. The check character 9 appears as text only.

Figure 5 Minimum Information Content with a 2-D Symbol



THE 2-D SYMBOL ENCODES THE FOLLOWING INFORMATION:

- 1 The Product Code composed of the Product Description Code (PDC) T0427 and the Division Code 000.
- 2 The Donation Identification Number (DIN) A999917123456 and the flag characters (22). The check character 9 appears as text only.

In addition, the following text information shall appear on the label, and may or may not be in the ISBT 128 specific area of the label:

- The description of the product giving the product name (this will usually be in the local language, but for exported tissue, may be in the language of the recipient country);
- The expiration date.

The expiration date may be included in the bar code even if the text appears elsewhere on the label.



Figure 6 Label Example with Recommended ISBT 128 Information (Linear Bar Codes)

LABEL CONTENT:

- 1 Text corresponding to the data content in each linear bar code:
  - 0190222359

From the Expiration Date and Time [Data Structure 005]: &>0190222359

• T0266003

From the Product Code [Data Structure 003]: =<T0266003

• A999917123456 and flag characters 00 printed vertically

From the Donation Identification Number [Data Structure 001]: =A99991712345600 Note: The check character 9 is not encoded in the bar code; it appears as text only.

- 2 Text corresponding to the product information encoded in the linear bar codes:
  - BONE, GROUND Cortico-cancellous (description of the PDC T0266)
  - Pack 003 (Division Code 003)
  - 2019-01-22 (Expiration Date)

Note: In this example the default expiration time 2359 is not printed.

- T0266 003 (Product Code)
- Generis Tissue Bank A9999 (Tissue Facility Identification)

Additionally, data labels (Expiry Date, Product Code, and DIN) are used to identify the information encoded in each linear bar code.

Figure 7 Label Example with Recommended ISBT 128 Information (2-D Symbol)



LABEL CONTENT:

- 1 The 2-D symbol that encodes the following information: =+03000=A99911712345622=<T0328004&>0190261920
  - The Compound Message [Data Structure 023]: =+03000 It indicates that three data structures (03) are encoded in the string, and it also indicates that these data structures are not encoded in a specific order in the string (000).
  - Donation Identification Number [Data Structure 001]: =A99911712345622
  - Product Code [Data Structure 003]: =<T0328004
  - Expiration Date and Time [Data Structure 005]: &>0190261920
- 2 Text corresponding to the product information encoded in the 2-D symbol:
  - BONE PUTTY, Freeze Dried, Radiation Sterilization, Demineralized: Yes, Cortical (description of the PDC T0328)
  - Pack 004 (Division Code 004)
  - 2019-01-26 19:20 (Expiration Date and Time)
  - T0328 004 (Product Code)
  - Donation Identification Number (A999117123456) and flag characters (22) Note: The check character Z is not encoded in the 2-D symbol, it appears as text only.
  - Generis Tissue Bank A9991 (Tissue Facility Identification)

Additionally, data labels (Expiry Date, Product Code, and Donation Identification Number) are used to identify the type of product information.

The exact placement of electronically readable information on a label is dependent on the size and shape of the label and is therefore determined by the facility.

## 7.2 Small Label Design

If the size of the label does not support the information content required by this standard, the appropriate regulations and requirements of standards-setting organizations should be consulted. Some required information may need to appear on secondary packaging.

## 7.3 Tissue Labels Following the "Four Quadrant" Format

Tissue labels may follow the format used for blood components (a 100 mm x 100 mm label) if desired and when the size of the container and other constraints permit. This label includes the DIN, Product Code, ABO/Rh and Special Message, and Expiration Date and Time bar codes placed in the four-quadrant design specified by the *ISBT 128 Standard Technical Specification* (ST-001).



Figure 8 100 mm by 100 mm Label

Alternatively, a "horizontal" four quadrant label may be more suitable for some containers.

Figure 9 200 mm by 50 mm Label



# 7.4 Labels with Non-ISBT 128 Electronically Readable Information

Some tissues may be labeled with both ISBT 128 and non-ISBT 128 electronically readable information. Such additional non-ISBT 128 electronically readable information shall not appear in the ISBT 128 area of the label. When both ISBT 128 and non-ISBT 128 symbology are present on a tissue label, the text "ISBT 128" may be printed to identify the location of ISBT 128 information. See Figure 10 and Figure 11.

#### Figure 10 Product Carton Label



Figure 11 Large Vial Label



## 7.5 Labeling Formats

## 7.5.1 Basic Labeling Format

Tissue products labeled with the ISBT 128 basic labeling format shall contain, at a minimum, the following information:

- (1) The Donation Identification Number (DIN).
  - The DIN is encoded in the Donation Identification Number [Data Structure 001].
  - It may be assigned by a recovering or processing facility.
- (2) The Product Description Code (PDC) and Division Code.
  - The PDC and Division Code are encoded in the Product Code [Data Structure 003].
  - They may be assigned by a facility that recovers and processes tissues or by facilities that acquire tissues from recovering facilities.

Figure 12 illustrates a tissue label encoding the minimum required information [Data Structures 001 and 003] and additional product information such as the expiration date and time [Data Structure 005] in a 2-D symbol.





#### LABEL CONTENT:

- 1 The 2-D symbol that encodes the following information: =+03000=A99991712345622=<T0326003&>0180102359
  - The Compound Message [Data Structure 023]: =+03000 It indicates that three data structures (03) are encoded in the string, and it also indicates that these data structures are not encoded in a specific order in the string (000).
  - Donation Identification Number [Data Structure 001]: =A99991712345622
  - Product Code [Data Structure 003]: =<T0326003
  - Expiration Date and Time [Data Structure 005]: &>0180102359
- 2 Text corresponding to the product information encoded in the 2-D symbol.
  - SKIN, FULL WITH HYPODERMIS, Frozen, Decellularized, Radiation Sterilization (description of the PDC T0326)
  - Pack 003 (Division Code 003)
  - 2018-01-10 (Expiration Date)

Note: In this example the default expiration time 2359 is not printed.

- T0326 003 (Product Code)
- Donation Identification Number (A999917123456) and flag characters (22) Note: The check character 9 is not encoded in the 2-D symbol, it appears as text only.
- Generis Tissue Bank A9999 (Tissue Facility Identification)

The storage conditions in this example (Store at <-20 C) appear as text only.

## 7.5.2 Special Labeling Format – Use of the FIN(P)

The labeling format defined in this section applies to tissue products when the facility that assigns the Product Description Code (PDC) is not the same as the facility that assigns the Donation Identification Number (DIN).

The Processing Facility Information Code [Data Structure 033] should be used to ensure the unique identification of these tissue products. This data structure encodes the Facility Identification Number of the processing facility assigning the PDC [FIN(P)] and the Facility-defined Product Code (FPC).

The Processing Facility Information Code [Data Structure 033] shall be encoded in a 2-D symbol in conjunction with the Donation Identification Number [Data Structure 001] and the Product Code [Data Structure 003].

Tissue facilities may also use this labeling format to encode in the FPC the catalog number of the tissue product or any other product identifier used for internal purposes only.

Figure 13 illustrates the use of the FIN(P) in the following scenario:

- Tissue from the same donor (A999917111111) is processed at two different facilities (A9996 and A9997).
- The tissue products in both processing facilities are labeled with the same Donation Identification Number (A99991711111), same Product Description Code (T0266), and Division Code (000).
- It is only the inclusion of the FIN(P) in Data Structure 033 that ensures the unique identification and supports effective traceability of these tissue products.

www.isbt128.org





### 7.5.3 Tissues Labeled with a National Identification Number

ICCBBA permits the use of ISBT 128 data structures on tissues identified using an existing well-established national system of identification under governmental control where such an identification system is already in widespread use.

Tissues labeled with a national identification number and ISBT 128 data structures, do not encode the ISBT 128 Donation Identification Number (DIN), which is a required element for unique identification and traceability. Therefore, it shall be recognized that while these products may provide proper identification at a national level, they do not provide globally unique identification and care must be taken to ensure traceability if such products move outside of the country.

Organizations wishing to use ISBT 128 data structures in combination with a National Identification Number shall be covered by an ISBT 128 facility license.

ICCBBA recommends that such national systems be adapted to support the use of the ISBT 128 Donation Identification Number at the earliest opportunity.

The text "ISBT 128" shall not be included on tissue products labeled with both, a national identification number and ISBT 128 data structures.

END OF PUBLICATION

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ST-001 ISBT 128 Standard Technical Specification ST-002 ISBT 128 Standard Terminology for Medical Products of Human Origin ST-011 ISBT 128 Standard Coding and Labeling of Medical Devices using ISBT 128 ST-012 ISBT 128 and the Single European Code (SEC) ST-017 ISBT 128 Standard Coding and Labeling of Medical Devices Containing MPHO ST-019 ISBT 128 Standard Labeling of Reproductive Tissue and Cell Products IG-014 Use of Data Matrix Symbols with ISBT 128 IG-026 Use of Dimensions [Data Structure 029] IG-031 Use of the Processing Facility Information Code [Data Structure 033]