



ISBT 128 STANDARD

ISBT 128 and the Single European Code (SEC)

Version 1.4.0

June 2021

Tracking Number ICCBBA ST-012

Endorsed by:



Published by:

ICCBBA

PO Box 11309, San Bernardino, CA 92423-1309 USA

ISBN-13: 978-1-933243-88-7

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1 Introduction

1.1 Purpose

This document specifies the way in which the Single European Code (SEC) should be formulated and printed on tissue and cell products labeled with ISBT 128. This standard has been developed based on currently available guidance from the European Commission (EC).

This standard must be read in conjunction with the relevant EC and national legislation and regulatory requirements. It is the responsibility of the tissue establishment (TE) applying the SEC to ensure that labels comply with applicable regulation.

The SEC will be required on all tissues and cells regulated under Directive 2004/23/EC of the European Parliament and of the Council released for circulation in the European Union unless specifically excluded in the regulation. The SEC does not apply to products regulated under advanced therapy medicinal product (ATMP) regulations. The implementing directive for the SEC is Commission Directive (EU) 2015/565 of 8 April 2015.

The purpose of this standard is to ensure that ISBT 128 Donation Identification Number, Product Code, Division Code, and Expiration Dates are represented in the SEC in a consistent manner.

1.2 Scope

This document provides specific rules and guidance in the implementation of the SEC for ISBT 128 labeled products. This document also addresses specifications for software developers. It is intended as a supplement to the *ISBT 128 Standard Technical Specification* (ST-001).

1.3 Intended Audience

The intended audience of this document is staff working at tissue establishments in the European Union, as well as software developers, label vendors, and other organizations that provide products or services to these facilities. The document may also be of interest to regulators in EU Member States and to cellular therapy facilities and tissue banks outside the EU that distribute products in the EU.

1.4 Normative References

ISBT 128 Standard Technical Specification (ST-001)
ISBT 128 Standard Labeling of Human Tissues (ST-003)
ISBT 128 Standard Labeling of Cellular Therapy Products (ST-004)
ISBT 128 Standard Labeling of Ocular Tissue (ST-009)

ISO 3166-1, Codes for the representation of names of countries and their subdivisions -
Part 1: Country codes http://www.iso.org/iso/country_codes.htm
ISO 8601 (2004)(E) Data elements and interchange formats — Information interchange
—Representation of dates and times

Directive 2004/23/EC of the European Parliament and of the Council
Commission Directive 2006/86/EC
Commission Directive (EU) 2015/565

1.5 Other References

ICCBBA Website (www.isbt128.org)
Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (IG-014)

1.6 Background

1.6.1 Single European Coding System

Directive 2004/23/EC of the European Parliament and of the Council required that the EC, in cooperation with Member States, design a single European coding system to provide information on the main characteristics and properties of tissues and cells.

In April 2015, the EC published Commission Directive (EU) 2015/565 which amends Directive 2006/86/EC and specifies the implementation requirements for the SEC. Legislation requiring Tissue Establishments to apply the SEC will take effect from 29 April 2017.

Commission Directive 2006/86/EC, as amended by Commission Directive 2015/565, requires that a Single European Code be applied to tissues and cells distributed for human application in the European Union. The directive further defines the Single European Code as comprising a Donation Identification Sequence (ISO Country Code, Tissue Establishment Number, and Unique Donation Number) and a Product Identification Sequence (Product Coding System Identifier, Product Number, Split Number, and Expiry Date).

In 2012, the EC awarded a contract to the Eurocet 128 Consortium to develop reference compendia for the application of a single European coding system for human tissues and cells. The Eurocet 128 Consortium was headed by the Istituto Superiore di Sanità of the Italian Ministry of Health. The other members of the Consortium were ICCBBA and Artman Technologies.

The deliverables from this contract comprise two compendia (tissue establishment compendium and tissue and cell products compendium) together with a web-based lookup program. In addition, a manual was developed specifying how the SEC should be applied.

1.6.2 Terminology

Terminology used by the Single European Coding System and ISBT 128 is not entirely harmonized. In some situations, different terms may have the same meaning. For example:

Instances Where Different Words Have Similar or the Same Meaning			
Single European Code		ISBT 128	
Term	Meaning	Term	Meaning
Unique Donation Number	A number that identifies a donation event. This number can be created at local, regional, national or international level	Donation Identification Number	The identifier that uniquely identifies a donation event globally
Expiry date	Date at the end of which the product may no longer be used	Expiration date	Date at the end of which the product may no longer be used
Split Number	Multiple products with the same Donation Identification Sequence and product code	Divisions	Multiple products with the same Donation Identification Number and Product Description Code
Product code	Code that maps to a product description in the EU Product Compendium	Product Description Code	Code that maps to a product description in the ISBT 128 Product Description Code Database

In other situations, the same term may have different meanings in the two systems.

Instance Where Same Word has Different Meaning			
Single European Code		ISBT 128	
Term	Meaning	Term	Meaning
Product code	A 7-character code that maps to either a product description in a different coding system or a generic product description defined by the European Union	Product Code	An 8-character data structure that comprises codes that map to a product description, divisions, and for cellular therapy, a donation type
In this document, “product code” (not capitalized) will refer to the Single European Coding System product code, while “Product Code” (capitalized) will refer to the ISBT 128 data structure.			

1.7 Changes in this Version

The following table indicates changes between Version 1.3.1 and Version 1.4.0. Bold print indicates a change to the ISBT 128 Standard; regular print indicates a clarification or additional guidance. When changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

ISBT 128 and the Single European Code (SEC) Version 1.3.1 vs. Version 1.4.0

	Version 1.3.1 Chapter, Section, Table, or Figure	Version 1.4.0 Chapter, Section, Table, or Figure	Change	Rationale
1.	Figures 6 and 7	Figures 6 and 7	Updated diagrams for clarification for the expiration date to match preceding text.	Provide consistency and clarification
2.		Chapter 4	Included Single European Code Builder Tool	Included for reference and clarification

2 Format of the SEC

2.1 Structure

The structure of the SEC developed by the EC Coding Working Group comprises two elements, the donation identification sequence and the product identification sequence.

The donation identification sequence is made up of three parts: a two-character ISO country identification code; a six-character tissue establishment identifier; and a thirteen-character unique donation number.

The product identification sequence is made up of four parts: a one-character coding system identifier; a seven-character product code; a three-character split (division) number; and an eight-character expiry date.

This structure is shown diagrammatically in Figure 1.

Figure 1 Structure of the SEC

DONATION IDENTIFICATION

<i>ISO Country Identifier</i>	<i>TE Code (TEC)</i>	<i>Unique Donation Number</i>
2 characters (alphabetic)	6 characters (alpha/numeric)	13 characters (alpha/numeric)

PRODUCT IDENTIFICATION

<i>Coding System Identifier</i>	<i>Product Code</i>	<i>Split Number</i>	<i>Expiry Date</i>
1 character (alphabetic)	7 characters (alpha/numeric)	3 characters (alpha/numeric)	8 characters (numeric)

2.2 Data Elements

2.2.1 Donation Identification Sequence

ISO Country Identifier: this code identifies the country of the TE issuing the SEC. The code used is the ISO 3166-1 alpha-2 country identifier.

TE Code: this is the identifier for the TE as listed in the EU Tissue Establishment Compendium. These codes will have been assigned by either the relevant Competent Authority (CA) or by the Eurocet 128 project. The TE Code shall be six characters long and if the assigned identifier is less than six characters, it shall be padded with leading zeroes.

Unique Donation Number: this is the donation number as allocated by the tissue establishment. This number may be locally defined or be aligned with national or international standards. The unique donation number shall be thirteen characters long and if the assigned identifier is less than thirteen characters, it shall be padded with leading zeroes.

2.2.2 Product Identification Sequence

Coding System Identifier: this is a single-character identifier which indicates the coding system being used for the product code. Three systems are approved for use in the SEC: ISBT 128, Eurocode, and the European Union Tissue Code (EUTC). Eurocode is a code used in Germany. The EUTC is the code provided by the EC. The coding system identifiers for these systems are:

Coding System	Identifier
ISBT 128	A
Eurocode	B
EUTC	E

Product code: this is the code that is mapped to the product description in the specified coding system. The product code shall be seven characters long and if the assigned identifier is less than seven characters, it shall be padded with leading zeroes.

Split number: this is an identifier for the split or division number of the product. It is used to uniquely identify each product where the donation identification sequence and product code are the same for multiple products (for example, multiple vials of bone chips derived from the same donor).

Expiry date: this is the expiration date of the product expressed as an eight-digit number using ISO 8601 international format (YYYYMMDD). Where a product does not have a specified expiration date, this field is set to eight zeroes. Expiry time is not encoded in the SEC.

2.3 Eye-Readable Presentation

The SEC shall be printed in eye-readable format and shall be preceded by the acronym "SEC". The SEC shall be printed with the Donation identification Sequence and the Product Identification Sequence separated by a single space or as two successive lines (see Figure 2).

The SEC shall appear on the product label where possible and in relevant accompanying documentation. Where the label size precludes the application of the SEC on the label, the code shall be unambiguously linked to tissues and cells packaged with such a label through the accompanying documentation.

In addition to the requirements of the Directive, ICCBBA recommends that the SEC should be printed in a minimum 6pt font using a font that distinguishes similar letters and numerals (O and 0, I and 1) as clearly as possible.

Figure 2 Eye-readable Presentation of the SEC

SEC: PL001499Z549917123456 A00T041600320171231

SEC: PL001499Z549917123456
A00T041600320171231

3 Creating the SEC

3.1 Donation Identification Sequence

Each TE in the EU will have an assigned country identifier and TE code and these shall be used for the first two parts of the donation identification sequence. The ISBT 128 Donation Identification Number (DIN) shall be placed directly into the unique donation number.

Thus, a product with ISBT 128 DIN Z5499 17 123456, labeled by a TE based in Poland (ISO Country Code PL) that is identified in the EU Tissue Establishment Compendium by the identifier 001499, would have the following donation identification sequence:

Figure 3 Donation Identification Sequence

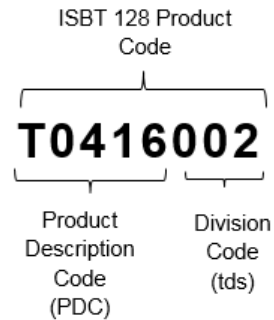


3.2 Product Identification Sequence

The coding system identifier shall be the letter “A” to specify ISBT 128 product coding.

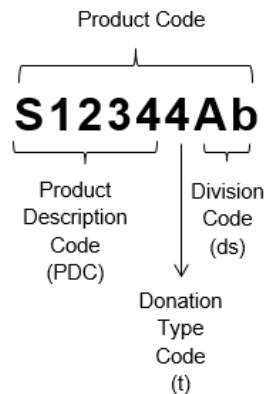
The product code shall be the five-character ISBT 128 Product Description Code (PDC) preceded by two leading zeroes to satisfy the seven-character length requirement. This code must be present in the EU Product Compendium. ISBT 128 PDCs are uploaded to the Product Compendium on a regular basis; however, there may be some delay between the issue of a code by ICCBBA and its appearance in the Product Compendium. It is the responsibility of each TE to ensure that they only use codes present in the Product Compendium. If the ISBT 128 code is not listed in the Product Compendium, see Section 3.3.

The split number will depend on the ISBT 128 product category. For tissues, ocular tissue, and reproductive categories, it shall be the division number as represented by the final three characters of the ISBT 128 Product Code (tds). (See Figure 4 for explanation of tds.)

Figure 4 Example ISBT 128 Tissue Product Code

For cellular therapy products, it shall be the two-character division code from the ISBT 128 Product Code (ds) preceded by a leading zero. (See Figure 5 for explanation of ds.)

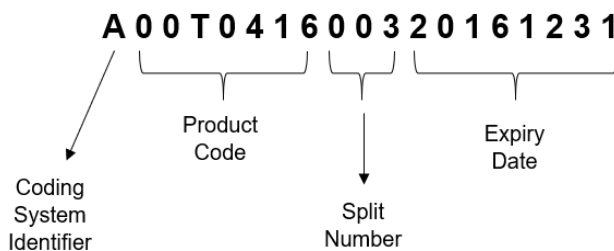
Note: The SEC does not currently support more than a three-character split code. At this time there is no recommendation on how to encode the longer division codes that are supported by ISBT 128 Product Division Codes (Data Structure 032). A TE intending to use this structure to encode divisions that cannot be accommodated within the three character split should consult the EC for advice.

Figure 5 Example ISBT 128 Cellular Therapy Product Code

The expiry date shall be the expiration date expressed in YYYYMMDD format.

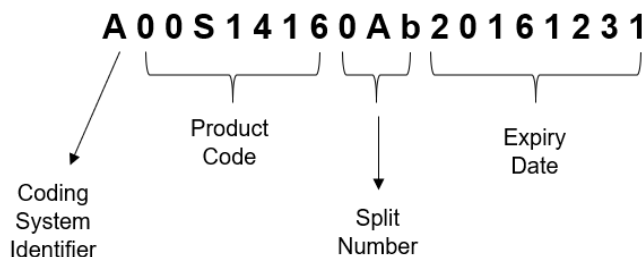
Thus a product with ISBT 128 PDC of T0416, a division number of 003, and an expiration date of 2016-12-31, would have the following product identification sequence:

Figure 6 Product Identification Sequence – Tissue Example



Similarly a product with ISBT 128 PDC of S1416, a division number of Ab, and an expiration date of 2016-12-31, would have the following product identification sequence:

Figure 7 Product Identification Sequence – Cellular Therapy Example



3.3 Using an EUTC in the SEC Product Code Element

An ISBT 128 PDC can be used on an ISBT 128 label as soon as the code has been published in the ISBT 128 Product Description Code Database. However, the ISBT 128 PDC must appear in the EU Product Compendium before it can be used in an SEC. In the event that a TE needs to issue a product prior to the ISBT 128 PDC being listed in the Product Compendium, it will be necessary to use the appropriate EUTC in the product code element of the SEC on a temporary basis.

EUTC are very high level codes that only describe tissues and cells at a generic level. The list of EUTC is maintained in the EU Product Compendium. The TE shall select the appropriate EUTC for the product and use this in the SEC. In this case, the Coding System Identifier shall be “E”.

Thus a product which is to be labeled with a newly-assigned PDC of T9999 that does not as yet appear in the EU Product Compendium, but which corresponds to EUTC 0000053, would be labeled with ISBT 128 in the normal manner using T9999 in the ISBT 128 Product Code, but would carry the EUTC in the product identification sequence of the SEC. If the product division number is 001, and the product expires on 2016-12-31, then the product identification sequence would be:

E000005300120161231

As soon as the new PDC appears in the EU Product Compendium, the TE should change to using the ISBT 128 PDC in the SEC.

3.4 Assignment of SEC to Imported Products

Tissues and Cells imported from outside the EU for distribution within the EU will, in most cases, need to have an SEC applied by the TE responsible for the import. In such cases the SEC is created as follows:

3.4.1 Donation Identification Sequence

The importing TE will have an assigned country identifier and TE code and these shall be used for the first two parts of the donation identification sequence.

If the imported product is already identified using an ISBT 128 DIN, this DIN should be used as the unique donation number. In all other cases, the importing TE shall assign an ISBT 128 DIN using its own Facility Identification Number and use this as the unique donation number. The TE shall maintain records to link the assigned DIN to the original donation number on the product for traceability purposes.

3.4.2 Product Identification Sequence

If the imported unit is already labeled using ISBT 128, the Product Description Sequence can be created using information from the original label and following Section 3.2.

If the imported unit is not labeled using ISBT 128, the importing TE may either assign an appropriate ISBT 128 PDC and generate the product identification sequence according to Section 3.2, or may map to the appropriate EUTC and generate the product identification sequence according to Section 3.3. In either case, the TE shall ensure the appropriate use of split numbers to ensure unique identification of the product.

4 Single European Code Builder Tool

The SEC Builder Tool can be located on the ISBT 128 website. The SEC Builder Tool allows a user to create an SEC for an ISBT 128 product by entering the various elements of the SEC.

SINGLE EUROPEAN CODE (SEC) BUILDER TOOL v1.1
This simple tool allows you to create the SEC for an ISBT 128 product.

ISBT 128
 More than Identification

Instructions:

1. Open the **Setup** tab located at the bottom of this program window, or **CLICK** the **SETUP** button:
 - a. Complete the Setup section by entering the two-character ISO Country Identifier and the six-character TE Code. These will be constant values for the SEC generated in the following step.
2. Open the **Create SEC** tab located at the bottom of this program window, or **CLICK** the **Create SEC** button:
 - a. Enter the information specific to the product.
 - i. The SEC can be viewed on that page.
 - ii. The SEC Barcode Data can be viewed on that page.

[Note: While the spreadsheet verifies the length of data entered in each cell, it is still the user's responsibility to check that the correct data has been entered.]

ICCBBA is an international non-governmental organization (NGO) in official relations with the World Health Organization (WHO) that manages, develops, and licenses ISBT 128; the international information standard for the terminology, coding and labeling of medical products of human origin.

Introduction | Setup | Create SEC

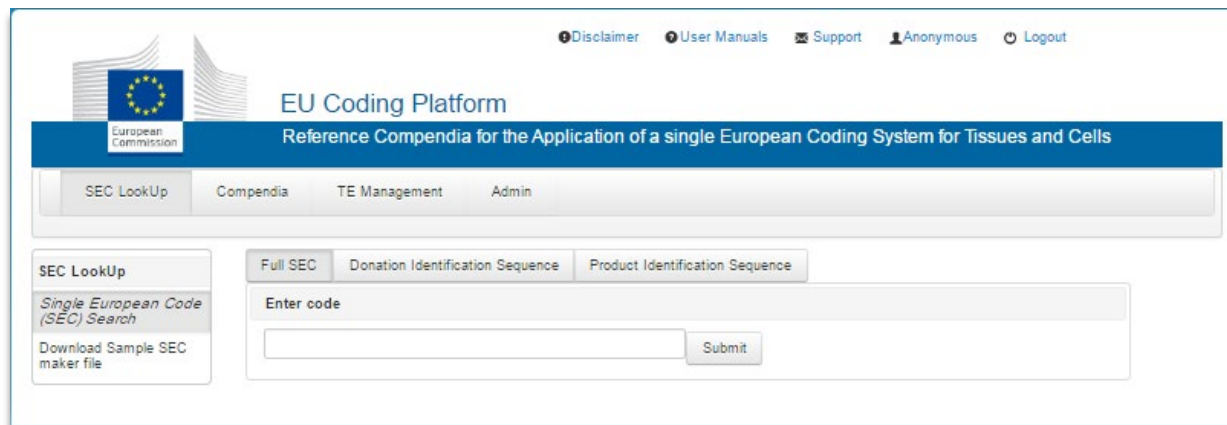
The program allows users to specify the Country Identifier and Tissue Establishment Code and provide supporting details such as the Donation Identification Number, Product Description Code, Split/ division code, and Expiry date for the program to populate an SEC accurately.

5 Using the SEC Lookup Program

The SEC lookup program will be made available by the EC. The program allows searching of the TE and Product Compendia and provides a lookup from an SEC to the corresponding TE and product information.

The look-up option allows entry of a full SEC, a donation identification sequence, or a product identification sequence (Figure 8).

Figure 8 SEC Lookup Program



The screenshot displays the 'EU Coding Platform' interface. At the top, there are navigation links for 'Disclaimer', 'User Manuals', 'Support', 'Anonymous', and 'Logout'. The main header includes the European Commission logo and the text 'EU Coding Platform Reference Compendia for the Application of a single European Coding System for Tissues and Cells'. Below the header is a navigation bar with tabs for 'SEC LookUp', 'Compendia', 'TE Management', and 'Admin'. The 'SEC LookUp' tab is active, showing a sub-menu with 'SEC LookUp', 'Single European Code (SEC) Search', and 'Download Sample SEC maker file'. The main content area has three tabs: 'Full SEC', 'Donation Identification Sequence', and 'Product Identification Sequence'. The 'Full SEC' tab is selected, showing an 'Enter code' input field and a 'Submit' button.

The SEC, or specific sequence, is entered and the corresponding information from the compendia is displayed.

The 'Full SEC' tab also supports bar code entry of ISBT 128 Data Structures for the DIN, Product Code, or Expiry Date and will display appropriate information from the compendia. In a future version, the lookup utility will be able to associate a Facility Identification Number (FIN) to an entry in the TE Compendium if the facility provides the CA with this information.

6 Electronically-Readable SEC

The SEC may be encoded into an ISBT 128 data structure in order to support electronic reading. Including the SEC in electronically-readable format is **optional**, but may be helpful for organizations responsible for human application that are required to capture and retain the SEC.

6.1 Single European Code [Data Structure 038]

Purpose: Data Structure 038 shall encode the Single European Code (SEC) as described in the EU Commission Directive 2015/565.

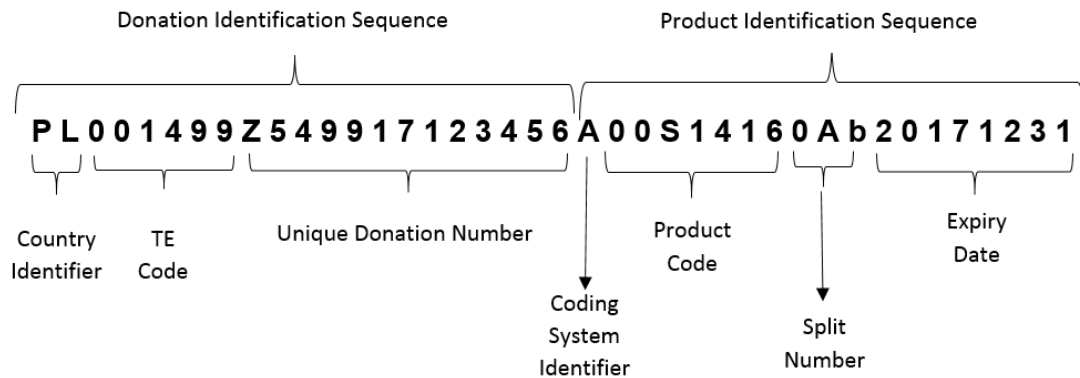
Structure: &4xx

Element	Length	Type
&	1	data identifier, first character
,	1	data identifier, second character
4	1	data identifier, third character
xx	40	alphanumeric {A-Z; a-z; 0-9}

The data content string shall be 40 characters and shall be encoded and interpreted as follows:

xx The SEC as described in EU Commission Directive 2015/565.

Figure 9 Example Data Content for SEC [Data Structure 038]



6.2 Options for Encoding Information

Because of the length of the SEC, a two-dimensional (2-D) symbol is strongly recommended. There are two options:

- Encode all the electronically-readable information (DIN, Product Code, Expiration Date, SEC, etc.) into the 2-D symbol using the Compound Message [Data Structure 023]. [See *ISBT 128 Standard Technical Specification (ST-001)* for more information on this data structure. See *Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (IG-014)* for more information on Data Matrix 2-D symbols.] This could either be instead of linear bar codes or in addition to linear bar codes. The advantage of this approach is that, for facilities able to decode the compound message, scanning the information is very efficient—a single scan instead of multiple scans. It also takes considerably less label space, which can be important for small labels. For example, in the 2-D symbol below, the DIN, Special Message within the Blood Groups data structure, the Product Code, the Expiration Date, and the SEC are encoded.

Note: Colors have been used in the text SEC in the examples below to help the reader separate the message into its elements



=+05000=Z54991712345600=%T300=<T0416003&>0183652359
&,4PL001499Z549917123456A00T041600320181231

- Encode only the SEC in the symbol which means a compound message would not be needed. This would be advantageous if receiving facilities are unable to decode a compound message. It can also be used as an additional code on existing linear bar coded ISBT 128 labels. While an imaging scanner would be needed to read the symbol, the message within the symbol is the same as it would be in a linear bar code. For example:



&,4PL001499Z549917123456A00T041600320181231

As the number of characters in the Data Matrix symbol increases, so does its size. The first symbol is approximately 10 mm by 10 mm and the second is 7 mm by 7 mm when the X dimension is set to 0.32 mm.

7 Label Design

The SEC shall be printed in accordance with the requirements specified in Commission Directive (EU) 2015/565 and Section 2.3. For more information about ISBT 128 label design options, see *ISBT 128 Standard Labeling of Human Tissues* (ST-003). The SEC should be added to the existing ISBT 128 label wherever possible. It should either be printed on one line with a single space between the elements (see Figure 10) or on two lines (see Figure 11). The SEC should be positioned towards the bottom of the label.

In Figure 10 and Figure 11, all ISBT 128 information, as well as the SEC, is encoded in the 2-D symbol.

Figure 10 Tissue Label with Electronically-Readable SEC

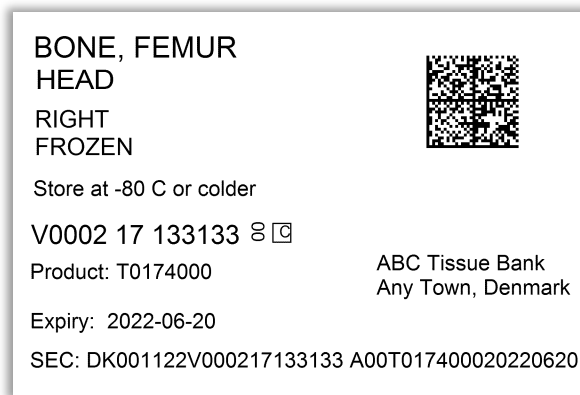
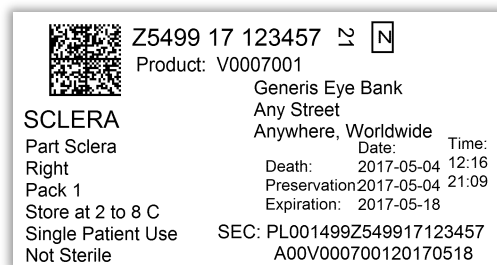











Figure 11 Ocular Tissue Label with Electronically-Readable SEC



For products labeled using 100 mm x 100 mm labels, the SEC should be printed as a single row of characters at the bottom of the label. In Figure 12, the height of the linear bar codes is reduced to the minimum recommended height of 15% of the length of the bar code in order to accommodate the electronically-readable 2-D symbol. This 2-D symbol includes only the SEC.

Figure 12 Cellular Therapy Label with Electronically-Readable SEC

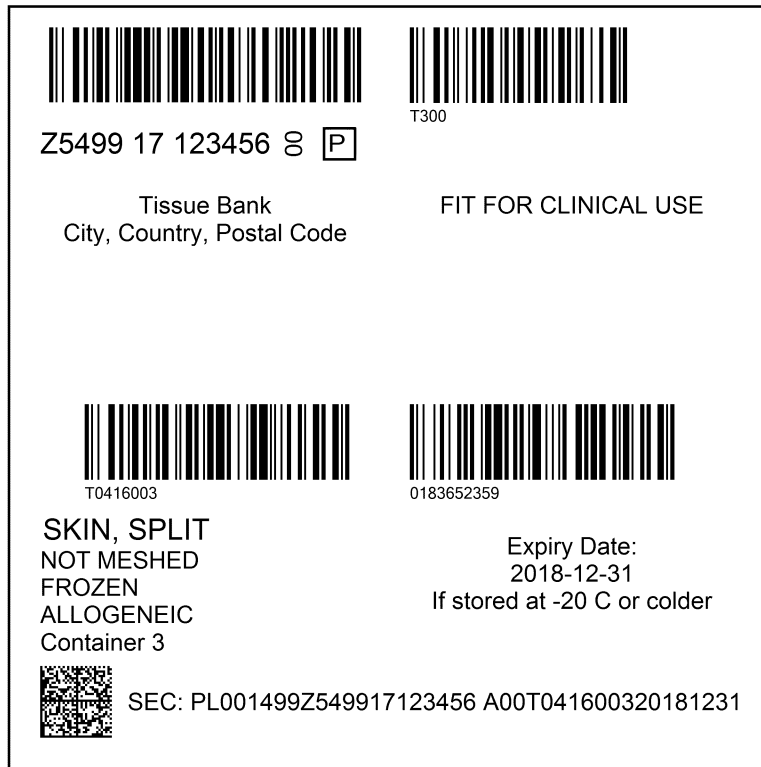
		
R0199 17 123456  	4700	RhD POSITIVE
Cell Therapy Facility City, Country, Postal Code		
Collection Date and Time		Related Donor
0170091330 2017-01-09 13:30 CET		O'Leary, Michael P Donor #: 123456789 Date of Birth: 1993-11-17
Do Not Irradiate Do Not Use Leukocyte Filtration		
		Expiry Date and Time
S1384400	0170101330	2017-01-10 13:30 CET
HPC, APHERESIS		
10% DMSO 3rd Party Component Present Other Additives Present Thawed, Mobilized Total Volume ___ mL containing approx ___ mL citrate Store at 1C to 10C	Intended Recipient: O'LEARY, DARA P Recipient ID: 123456789 Date of Birth: 1992-10-12	
	Processing Laboratory City, Country, Postal Code	
SEC: IE0TE999R019917123456 A00S138400020170110		

A horizontal line may be used to separate the SEC from the remainder of the label (see Figure 13).

Figure 13 Tissue Label with Text Only SEC

	
T0237000	
ACHILLES TENDON with BONE BLOCK	V0002 16 123456  
LEFT FROZEN Store at -80 C or colder	Expiry: 2022-06-20
ABC Tissue Bank Any Town, Denmark	 0221712359
SEC: DK001122V000216123456 A00T023700020220620	

Figure 14 Large Tissue Label with both Linear and 2-D Symbols



8 Software Developers

The SEC will become a mandatory requirement for all tissue establishments in the EU effective 29 April 2017. Considerable work has been carried out to ensure that the mapping from ISBT 128 information to the SEC is as simple as possible.

Software supporting the use of the SEC will need to address all of the sections above. The following information highlights some specific points for software developers.

8.1 Country Identifier and TE Code

The country identifier and TE code form the first two parts of the donation identification sequence. These will be constant for a particular TE and can therefore be maintained as reference information in the database. Where an organization has multiple sites, each site may have a separate TE code.

8.2 Split Number

The purpose of the split number is to ensure unique identification of each product where the donation identification sequence and product code are the same. When using the ISBT 128 Product Description Code in the SEC, the division number element of the Product Code should be used as the split number. For tissues, ocular tissue, and reproductive products this is a three-digit number in the tds portion of the Product Code.

For cell therapy products, the two characters in the ds position of the Product Code should be used with a leading zero (e.g., a cell therapy product with division code “Ac” would be given a split number of “0Ac”).

Where a division code is not used in ISBT 128, the split number shall be all zeroes.

If the SEC product identification sequence uses a EUTC (see 3.3), particular care has to be taken in the assignment of the split number. Multiple ISBT 128 Product Description Codes will be mapped to the same EUTC. It is theoretically possible that two different ISBT 128 products from the same donor could map to the same EUTC. If each of these products were identified with division number ‘001’ (acceptable with ISBT 128 as the PDCs are different) using these division codes for the split number in the SEC would lead to duplication. In this circumstance, software will need to be able to intelligently assign split numbers to maintain the uniqueness of the SEC and maintain appropriate records for traceability purposes.

8.3 2-D Symbol and Compound Message

The introduction of a data structure for the SEC introduces the use of 2-D symbols and the option of encoding all of the barcode information into a single compound message. Software developers should recognize this as a progressive trend in the use of ISBT 128 and should implement scanning solutions that can support both the scanning of individual data structures, and the capture of multiple data structures from a single compound message.

9 Abbreviations

2-D	Two-dimensional
ATMP	Advanced Therapy Medicinal Product
CA	Competent Authority
DIN	Donation Identification Number
EC	European Commission (or European Community when used in legislation identifiers)
EU	European Union
EUTC	European Union Tissue Code
FIN	Facility Identification Number
ISO	International Standards Organization
PDC	Product Description Code
SEC	Single European Code or Single European Coding
TE	Tissue Establishment