ICCBBA

ISBT 128 Standard for Traceability

ISBT 128
For Tissues

An Introduction

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IN-007

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1 Preface

Essential information is presented on the label of a tissue product. The information varies from country to country according to licensing regulations, language differences, and local practice but, in all cases, it is essential that it is recorded accurately, transferred correctly, and that critical items such as the identification number, product description, and expiration date are clearly understood by medical personnel transplanting the graft. In addition, robust audit trails must be in place to allow tracing between donor and recipient.

This need for accurate transfer of information goes beyond borders. Tissue collected in one country or region may be used in another. This creates a need for international agreement on product descriptions and a means of ensuring globally unique identification of the donation to support traceability requirements. These fundamental requirements are essential for effective traceability on a global scale.

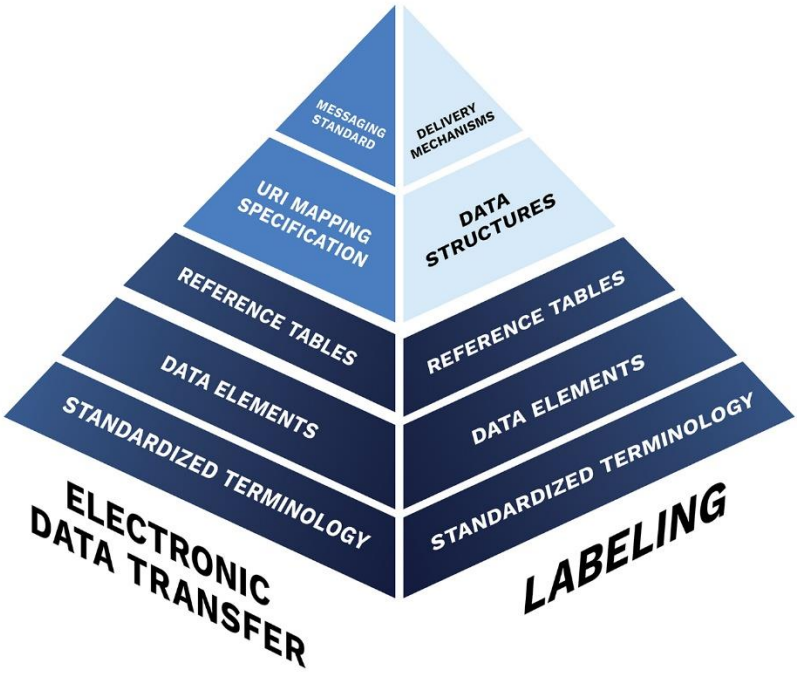
Tissue establishments frequently operate sophisticated computer systems to enhance safety and efficiency. Transfer of information between such facilities by electronic means ensures accuracy, but can only be effectively achieved in a global context by use of internationally agreed standards to define the information environment.

This is a high-level introduction to the ISBT 128 Standard. The Standard and additional information is available at www.iccbba.org.

2 The Information Environment

The information environment model describes how ISBT 128 organizes information to achieve standardization for both labeling and electronic messaging for medical products of human origin (MPHO).

The foundation of the information environment contains standardized terminology, data elements, and reference tables. These layers support the structures, mechanisms, specifications, and standards necessary to print labels and create electronic messages. These layers are illustrated and described below.



Standardized Terminology

Standardized terminology forms the base of the model. *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002) details a common understanding of terms. Without clarity at this level, any further attempt at standardization is futile. Obtaining agreement on standardized terminology at the necessary level of detail involves careful analysis and robust consensus. For example, glycerol may be used at different concentrations for different purposes.

A range of standardized terminology and associated values are required to accommodate these variations. Collaboration with experts from around the world is necessary to ensure that internationally standardized terminology is defined at the required level of granularity. This provides confidence in the consistency of both the information being transferred and the quality of the product described. The standardized terminology is accessible to all users of the ISBT 128 Standard.

Data Elements

Data elements are discrete pieces of information, common to both labeling and electronic data transfer. Examples of data elements include product description codes, expiration dates, and division identifiers. Detailed descriptions are provided in *ISBT 128 Dictionary of Standard Data Elements* (ST-027).

Reference Tables

Reference tables convert the clearly defined information into codes suitable for transmission via either delivery mechanisms on labels or electronic data transfer. These tables are built to map each item to a suitable coding. Reference tables can be large and complex, and they must be managed to ensure that they can be modified to meet the changing needs of clinical practice in a manner that maintains their integrity and avoids ambiguity or redundancy and retain backward compatibility.

Successful management of standardized terminology, data elements, and reference tables requires input from both clinical experts in the field and information specialists. The tables themselves need to be published in a manner that allows all users of the Standard to access the most up-to-date versions.

Data Structures

Data structures define the technical characteristics necessary for the interpretation of the information on a label. They specify the context and structure and provide links to the appropriate reference tables for conversion of embedded codes to meaningful information. Data structures may contain more than one data element.

Data structures need to be unambiguous and consider any constraints imposed by the anticipated delivery mechanisms.

Each ISBT 128 data structure is identified by and encoded with a distinct data identifier. All ISBT 128 data structures are defined in ISBT 128 Standard Technical Specification (ST-001).

Delivery Mechanism

The delivery mechanism is the means of delivering electronic information. The linear bar code has been used in blood transfusion practice for many years. There are several types of linear bar codes, including Code 128, a bar code standard widely used in coding standards such as GS1 and ISBT 128.

A range of delivery systems can sit at this level of the hierarchy. The standardized terminology, reference tables, and data structures of the information standard can be delivered as easily in a linear bar code as they can in 2-dimensional data matrix symbol or an RFID tag. The standards themselves need to be adaptable to make best use of new delivery mechanisms as they are developed.

Labeling

The layers of the information environment described above support the labeling of tissue. Although some labeling requirements fall outside the information environment described in this document, an effective system needs to consider the physical association between the information and the product. Whether incorporated into a bar code or an electronic tag, a mechanism is needed to ensure correct physical assignment of information to the product and confidence in the association between electronically stored information and eye-readable printed information. This latter requirement must not be overlooked in the enthusiasm to embrace remotely re-writable tags.

URI Mapping Specifications

For electronic data transfer, ISBT 128 data elements are identified by a uniform resource identifier (URI) in the form of a uniform resource locater (URL). This URL references a page on the ICCBBA website that carries the data element definition.

Messaging Standard

Messaging Standards define the rules for how systems exchange information. The ISBT 128 Standard can be used with multiple messaging standards, including but not limited to XML (Extensible Markup Language) and JSON (JavaScript Object Notation).

Electronic Data Exchange

The layers of the information environment described above support the transfer of MPHO information via electronic data exchange.

The Information Environment

Together, these elements form the information environment. For such a system to be and to remain effective, it must be carefully designed and managed. An on-going dialogue between clinical users, information specialists, and equipment and software vendors is critical to ensure that the standard continues to support rapidly developing clinical practice. ICCBBA routinely meets with a wide range of external experts via the ICCBBA Technical Advisory Groups and active collaboration with external organizations.

3 Application of the ISBT 128 Standard

The ISBT 128 Standard provides the specification for many of the elements of the information environment required in transfusion and transplantation. It defines the standardized terminology, data elements, reference tables, data structures, and URI mapping specifications. Minimum requirements are also defined for delivery mechanisms, labeling, and electronic data transfer. By complying with the ISBT 128 Standard, recovery and processing facilities can provide electronically readable information that can be read by any other compliant system.

ISBT 128 specifies:

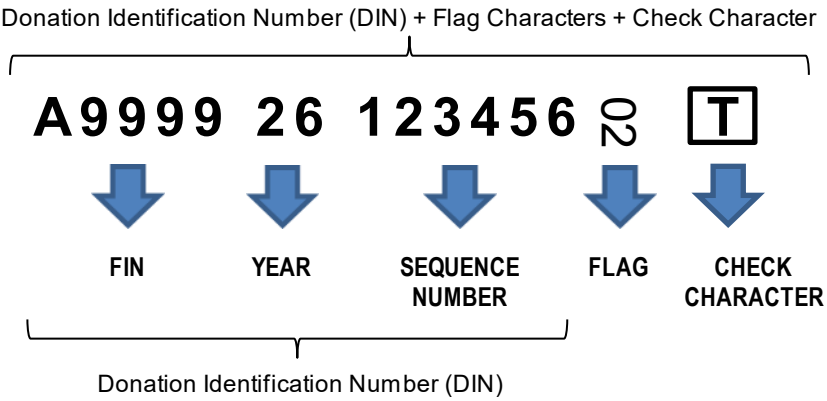
- the fundamental elements of traceability;
    - a donation numbering system that ensures globally unique identification
    - standardized product description coding
    - division identification
    - processing facility identification
- the information to be transferred, using internationally agreed reference tables;
- an international product reference database;
- the data structures in which this information is placed;
- bar coding system for transfer of the information on the product label;
- a standard layout for the product labels of some subject areas;
- a standard reference for use in electronic messaging.

The standard, originally accepted by the ISBT Council in 1994, has gained widespread acceptance. It has been extended beyond blood transfusion to include tissue and all MPHO. More than 6,000 facilities across six continents are registered to use ISBT 128, and this number continues to grow. Millions of blood, cell, and tissue products are labeled with ISBT 128 each year. The Eye Bank Association of North America (EBAA) required implementation of ISBT 128 labeling in 2017.

The most current version of the standard terminology is maintained on the ICCBBA website at www.iccbba.org.

4 Unique Donation Identification

ISBT 128 provides for unique identification of any donation event or zygote/embryo formed through ART worldwide. It does this by using a 13-character identifier built from three elements; the first element identifies the facility that assigned the number, the second the year, and the third a sequence number for the donation. For example:



where:

A9999 is the **F**acility **I**dentification **N**umber (FIN) of the facility that assigned the DIN;

26 identifies the year in which the DIN was assigned;

123456 is the 6-digit sequence number controlled and maintained by the facility assigning the DIN.

These first 13 characters comprise the **D**onation **I**dentification **N**umber (DIN).

The two digits printed vertically (the "flag" characters) allow individual bar codes in a number set to be discretely identified, providing an option to add process control into the collection and production processes.

An additional character is enclosed in a box at the end of the identifier. This is a checksum character used when a number is entered into a

computer system through the keyboard to verify the accuracy of the keyboard entry.

More information about the DIN can be found in the *ISBT 128 Standard Technical Specification* (ST-001).

FINs are assigned by ICCBBA, who maintains a database of all registered facilities on its website (www.iccbba.org). A lookup program allows lookup of individual facility codes, and ICCBBA-licensed facilities and vendors are able to download a full list of all licensed facilities.

5 Product Descriptions

ISBT 128 provides a comprehensive and highly flexible system for describing products and assigning product codes. The foundation of this system is a standard terminology which is constructed by international consensus to ensure global consistency in use and understanding. The standard terminology is maintained on the ICCBBA website and is publically available. Tissue terminology is currently managed through Technical Advisory Groups, (see section 10).

New products are defined by combining pieces of information from the standardized terminology in a way that unambiguously describes the product. This process is made easier by the use of the concepts of Class and Attributes.

This unique product description is assigned a product description code number that becomes incorporated into the ISBT 128 Product Description Database table, ensuring that the product will be accurately identified in any country in the world that is using ISBT 128.

New entries into the Product Description Code Database can be readily accommodated, allowing the system to expand to meet a growing range of products without losing the overall structure of the coding system.

The following example is taken from the database table:

Component Class:	SKIN, FULL WITH HYPODERMIS
Attribute:	Frozen
Attribute:	Cell reduction process:Yes
Attribute:	Radiation sterilization

has a Product Description Code of T0326.

While the description of a product in the Product Description Codes Database is standardized, the text that appears on the actual label of a product is under national control. This allows for differences in languages and regulatory requirements.

6 Other Data Structures

In addition to the donation identifier and product identifier, many other pieces of important information need to be provided with a product. These vary by the type of product being labeled, as well as by national requirements. The ISBT 128 Standard provides over thirty data structures that can be used to code product information such as:

- Chain of Identity Identification
- CMV and other test results
- Collection Container Catalog and Lot Number
- Collection Date and Time
- Division Identification
- Expiration Date and Time
- Type of Donation (Volunteer, Directed, Autologous, etc.)

7 Delivery Mechanisms

The delivery mechanism is how the information is represented in a machine-readable manner. ISBT 128 has traditionally been based on the linear bar code using Code 128 symbology. However, for tissue products a two-dimensional Data Matrix symbol may be a more suitable alternative.

A single Data Matrix symbol can carry the same information as encoded in multiple linear codes. This allows much more rapid scanning of tissues at the point of processing, issue, and receipt. In the tissue banking field, the need to use very small containers means that label size is severely restricted and in these situations the use of a Data Matrix symbol may replace linear codes.

Figure 1 Comparative Size of Code 128 and Data Matrix Symbols

The Data Matrix symbol on the left contains all of the information held in the three Code 128 bar codes on the right.

To use Data Matrix, or other high efficiency delivery mechanisms, ISBT 128 data structures must be strung together in a standardized way into a single message called a Compound Message. More information on Compound Messages may be found in the *ISBT 128 Standard Technical Specification* (ST-001).

RFID tag technology may provide significant benefits in some situations. ISBT 128 Compound Messages are compatible with RFID.

8 Product Labeling

In addition to specifying the requirements for the electronic coding of information, ISBT 128 provides a standard labeling format that ensures a consistent layout of the bar codes on “Four Quadrant” product labels. Critical eye readable information such as the Donation Identification Number, Product Code Description, and expiration date also appear in fixed positions on the label. This reduces the risk of confusion when products from multiple sources are being used.

When space is not an issue, two “Four Quadrant” label formats (see Figures 2 and 3) have been defined for tissues to ensure a consistent layout while retaining the flexibility to cater to a wide variety of container dimensions.

Figure 2 100 mm by 100 mm Label

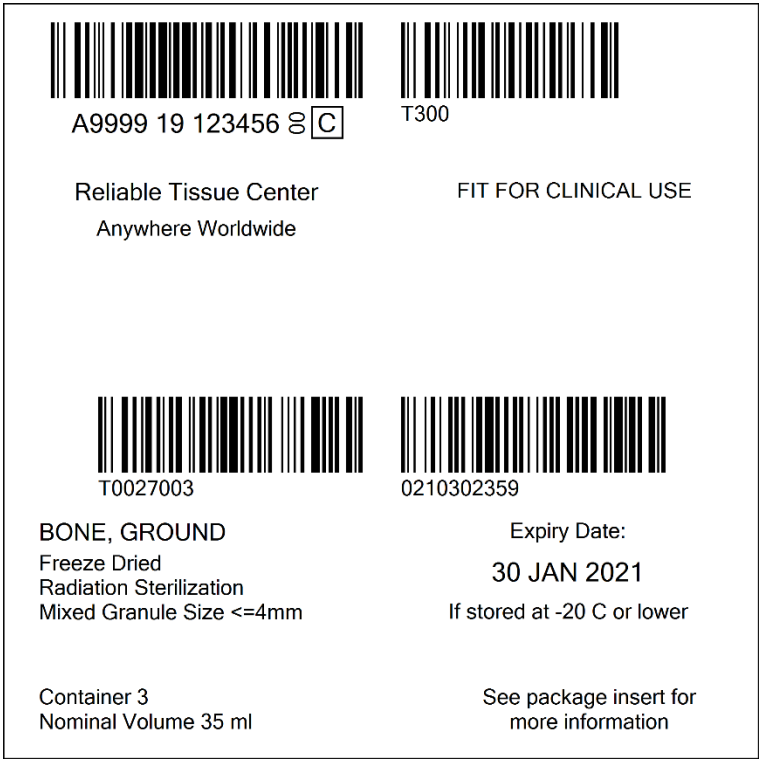
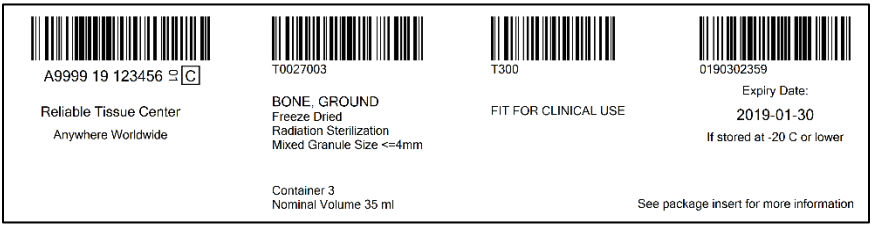


Figure 3 200 mm by 50 mm Label



When space is an issue, ISBT 128 information may be contained in a smaller area and two-dimensional symbols may be used in place of linear bar codes. These small labels may be used when the container is too small for a ”Four Quadrant” label.

Figure 4 65 mm by 34 mm Label with 2D Symbol

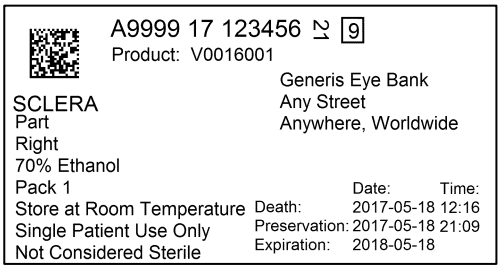
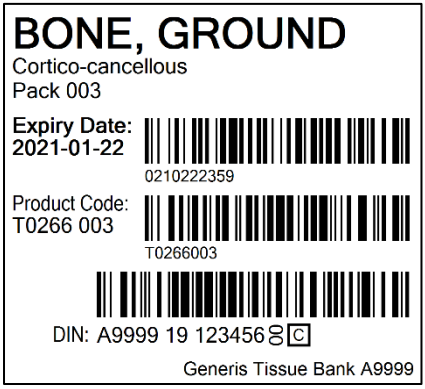
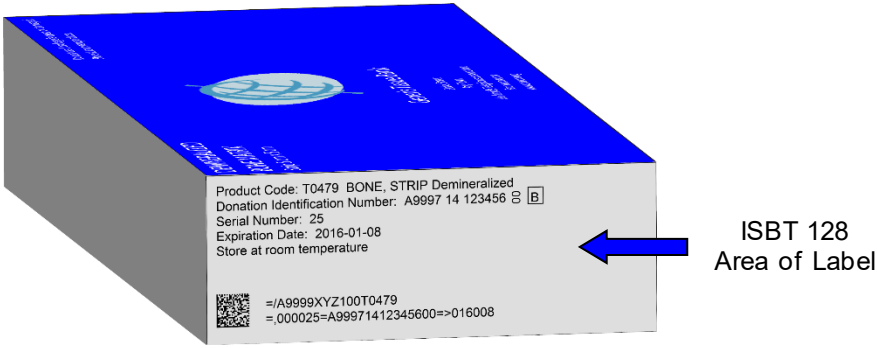


Figure 5 50 mm by 60 mm Label with Linear Bar Codes



Another situation in which a small label may be used is when the design of the label precludes devoting much space to the ISBT 128 information (e.g., when package label graphics and facility-determined text must be retained). In this case, a small ISBT 128 label can be placed anywhere on the package (front, back, side, end) where it will fit.

Figure 6 Use of Small Label on 360 mm by 100 mm Container



9 ISBT 128 and the Single European Code (SEC)

The SEC is a single European coding system that provides information on the main characteristics and properties of tissues and cells that fall under Directive 2004/23/EC and subsequently Regulation (EU) 2024/1938 of the European Parliament and of the Council. This directive applies to tissue and cell products released for circulation in the European Union unless specifically excluded in the regulation. It does not apply to products regulated under advanced therapy medicinal product regulations.

The implementing directive for the SEC is Commission Directive (EU) 2015/565. This directive further defines what elements comprise the SEC. Legislation requiring Tissue Establishments to apply the SEC took effect 29 April 2017.

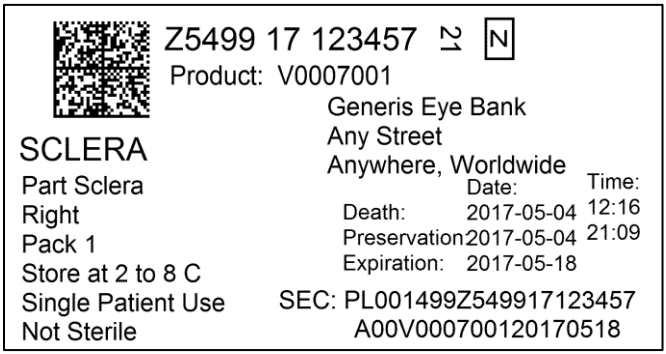
ISBT 128 is a voluntary standard in most countries, although it is mandated in some EU Member States. To comply with the SEC Directive, facilities that are currently using ISBT 128 can utilize data that is already bar coded to derive much of the required content.

To help in creating the SEC for products labeled with ISBT 128, ICCBBA has developed a tool that is now available on the ICCBBA website. The easy-to-use interface asks users to input specific product and Tissue Establishment information and will generate the eye-readable SEC as well as the required barcode content.

For organizations responsible for clinical application, ICCBBA has created a data structure that will allow the encoded SEC to be automatically captured.

For facilities not yet using ISBT 128, implementation of both SEC and ISBT 128 simultaneously would save both time and effort. Many changes required for the SEC will involve similar process steps to the implementation of ISBT 128.

Figure 7 Example Label that Includes SEC Information



10 The Role of Technical Advisory Groups

ICCBBA involves international volunteer experts in various MPHO fields (e.g., blood, tissue, cellular therapy, regenerative medicine, medically assisted reproduction, and milk banking) in the development and maintenance of the ISBT 128 Standard. These experts are organized into Technical Advisory Groups (TAGs) that meet regularly through asynchronous discussion forums, virtual meetings, and face-to-face meetings to further develop and expand the Standard, ensuring it continues to meet the needs of its users. The vital role of these groups cannot be overemphasized. Only through the involvement of such expert panels can ICCBBA be assured it has the knowledge base to anticipate the needs of its users in fields where change is constant. Hundreds of experts participate in the ICCBBA TAGs.

Advisory groups for tissues are listed below:

- Eye Bank Technical Advisory Group (EBTAG)
- Medically Assisted Reproduction Technical Advisory Group (MARTTAG)
- Tissue Technical Advisory Group (TTAG)

These international groups comprise experts in recovery and processing of tissues, surgeons, regulators, professional society representatives, and ICCBBA registered vendors.

The Standards Committee is comprised of TAG chairs and several Technical Experts. This committee reviews changes to the ISBT 128 Standard.

Additional information about the Standards Committee and each TAG and their activities can be found on the ICCBBA website (www.iccbba.org)

11 The Role of ICCBBA

ICCBBA is the not-for-profit, nongovernmental standards body responsible for the management, development, and distribution of the ISBT 128 Standard. It maintains a staff to manage the registration of facilities, update reference tables and databases, and develop additional functionality. It supports the Technical Advisory Groups that include experts from both the transfusion/transplantation community and relevant manufacturers of equipment or software that use ISBT 128.

Registration and license fees collected by ICCBBA are used to support these functions.

Through its activities, ICCBBA provides the management support essential to sustain standard coding in the complex environment of MPHO such as tissues. It delivers:

1) Stability – users can be confident in the stability of the Standard to satisfy the long time periods over which information must be retained (e.g., European Commission requirements for data to be stored and traceable for 30 years).
2) User focus – the user communities are the experts in their fields, and ICCBBA, through its Technical Advisory Groups, ensures that the information standard meets, rather than dictates, user needs.
3) Flexibility – as clinical and scientific knowledge grows, there is rapid development with changing information needs. ICCBBA ensures that the Standard is flexible enough to accommodate these needs.
4) Responsiveness – in these rapidly developing medical fields, ICCBBA ensures that the Standard can respond to user needs in a timely manner.
5) Globalization – ISBT 128 is an international standard with worldwide endorsement.
6) Compatibility – standards do not work in isolation but need to interface with equipment, software, and other standards. ICCBBA works with industry and other standards bodies to maximize compatibility and interoperability (e.g., the Single European Code).

Blood, cellular therapy, tissue, organ, banked human milk collection facilities, and manufacturers of equipment or software that uses ISBT 128, are required to register with ICCBBA and pay a registration and an annual license fee. Registered organizations obtain access to all ICCBBA documents and databases.

For further information on ISBT 128, visit the ICCBBA website at www.iccbba.org or contact our helpdesk at support@isbt128.org.

12 ISBT 128 Implementation Resources

Multiple resources are available to assist users on their implementation journey, whether they are beginning to plan their initial implementation or planning to maximize the benefits of new features of the Standard.

All ISBT 128 Standards and Implementation Guides are available to the public on our website. The material is copyrighted, and registration is required for organizations to utilize the Standard.

Guidance on planning implementation is available in *ISBT 128 Implementation Toolbox* (IG-047). Valid and invalid data structures to assist users in performing validation activities are available in *Implementation Guide: A Validation Tool for ISBT 128 Data Structures* (IG-043).

The website provides registered users with access to multiple lookup tools, including product code and vendor lookup.

The ICCBBA helpdesk is available to both current and potential users. The team can provide answers to questions, review labels, and facilitate one-on-one consultations as needed. Users are advised to consult regulatory authorities in their own countries for information regarding regulations and authorities from voluntary accrediting organizations for information concerning standards other than ISBT 128. Regulatory requirements supersede the requirements of the ISBT 128 Standard.

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ST-001 ISBT 128 Standard Technical Specification
ST-002 ISBT 128 Standard Terminology for Medical Products of Human Origin
ST-003 ISBT 128 Standard Labeling of Human Tissues
ST-012 ISBT 128 and the Single European Code (SEC)
ST-027 ISBT 128 Dictionary of Standard Data Elements
IG-014 Use of Data Matrix Symbols with ISBT 128
IG-043 A Validation Tool for ISBT 128 Data Structures
IG-047 Implementation Toolbox

