I've completed my registration with ICCBBA and received my Facility Identification Number (FIN). Now what?

ICCBBA Website Access

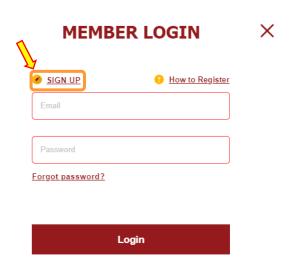
If you have not yet done so, you will need to create a new Website Members Account for the isbt128.org website, which uses your e-mail address as the log-in username. Log-in access will grant users permission to password-protected areas on the website. These areas include ISBT 128 databases and programs, such as the ISBT 128 Product Description Code Database, the Facility Identification Number Database and the ISBT 128 Product Lookup Program.

Please see the step-by-step explanation below on how to create your Website Member Account.

1. Users can register by clicking on the red "Member Login" button at the top of the page.



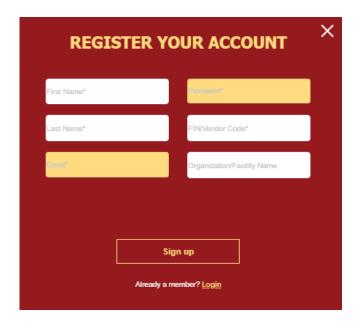
2. Next, click on the "SIGN UP" link







3. When prompted enter your credentials. You must enter your email address, your Facility Identification Number (FIN) or Vendor ID, as well as your desired password for your Website Member Account.



- 4. Once the submission has been completed, users will receive a confirmation email. Typically, there is a 24–48-hour period for approving user Website Member Accounts. Within this timeframe, ICCBBA staff members will review the submission and may contact the requesting individual if clarification is needed. Users who do not provide their FIN or do not respond to inquiries from ICCBBA staff will not have their accounts approved. Overdue registration/license fees will prevent users from account approval until their facility has paid.
- 5. Once your account has been approved, users will receive a second email notifying them that their Website Member Account is approved.

Users of the same facility may choose to share accounts if desired. If a facility or vendor has multiple users that are interested in creating Website Member Accounts, they must each use unique emails. Once an email is attached to an account, it cannot be changed by users. To change emails, please contact support@isbt128.org.

ISBT 128 Implementation

ICCBBA has provided a sample implementation plan with suggested activities and a step-by-step process for your facility to transition into implementing ISBT 128. The sample plan can be found on the ICCBBA website here: *ISBT 128 Implementation Plan* (IN-037). Your facility will need to revise it as necessary to



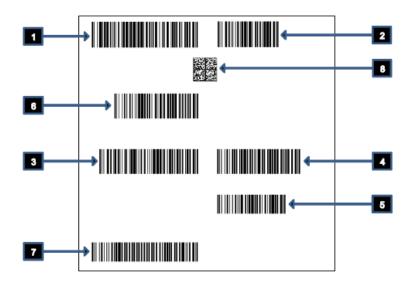
fit your specific processes and products. Not all portions of the example may apply, or conversely, additional sections that apply to your facility may need to be added.

Become Familiar with ISBT 128

When initiating the process of implementing ISBT 128, it is recommended to gain familiarity with the ISBT 128 Standard. The <u>Introductory Booklets</u> present a great and helpful introduction to ISBT 128. It is then recommended to gain familiarity with the required data structures for coding and labeling your products. Information regarding the various ISBT 128 Data Structures can be found in Section 2.4 of the *ISBT 128 Standard Technical Specification* (ST-001) document.

Get to Know the Required Information on the Label

Below illustrates how a 100mm by 100mm full ISBT 128 blood label with the required and optional bar codes. For blood products labeled with ISBT 128, it is required to encode items 1 through 4.



Required Bar Codes

- 1 Donation Identification Number
- 2 ABO/RhD
- 3 Product Code
- 4 Expiration Date and Time

Optional Bar Codes and Symbols

- 5 Special Testing
- 6 Collection (or Production) Date or Date and Time
- 7 Dimensions
- 8 Data Matrix symbol



The following sections in ST-001 provide specific information for the required bar codes:

- Section 2.4.1 Donation Identification Number [Data Structure 001]
- Section 2.4.2 Blood Groups [ABO and RhD] [Data Structure 002]
- Section 2.4.3 Product Code [Data Structure 003]
- Section 2.4.5 Expiration Date and Time [Data Structure 005]

At a Minimum, Traceability of Medical Products of Human Origin Labeled with ISBT 128 Requires the Following:

- ISBT 128-labeled products shall carry electronically-readable information required for traceability.
 - This includes the DIN (Data Structure 001), the standardized Product Description Code (Data Structure 003 or 034), and a divisions/pack code (Data Structure 003 or 032).
 - o If the processing facility identification code [FIN(P)] is required for traceability, this too shall be present in an electronically-readable format (Data Structure 033 or 034).
- Every ISBT 128-labeled product shall carry text corresponding to the required electronicallyreadable information.

Reference Documents that Pertain to Your Products

The following documents provide information and requirements on the labeling of specific products:

- ISBT 128 Standard Labeling of Human Tissues (ST-003)
- ISBT 128 Standard Labeling of Cellular Therapy Products (ST-004)
- ISBT 128 Standard Labeling of Blood Components (ST-005)
- ISBT 128 Standard Labeling of Ocular Tissue (ST-009)
- ISBT 128 Standard Labeling of Human Milk Banking Products (ST-013)

Selecting the Correct Product Description Code for Your Products

The following documents provide guidance for encoding product information:

- Implementation Guide: Encoding Product Information [Data Structures 003, 032, 033, and 034] – Tissues (IG-020)
- Implementation Guide: Use of Product Code [Data Structure 003] Blood (IG-021)
- Implementation Guide: Product Coding [Data Structures 003 and 032] Cellular Therapy (IG-022)
- o Implementation Guide: Use of Product Code [Data Structure 003] Ocular Tissue (IG-032)



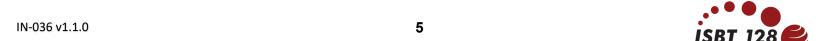
Upgrade or Purchase Equipment/Software from ISBT 128-licensed Vendors

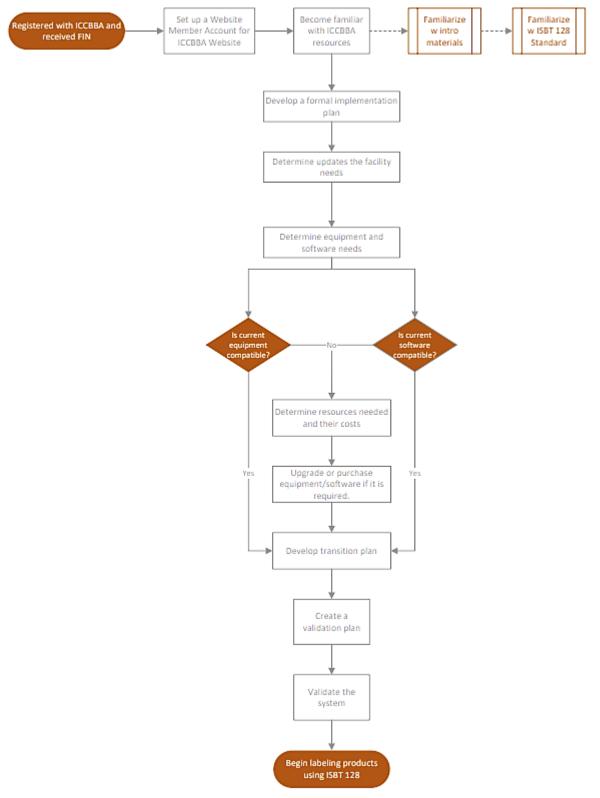
You can choose to purchase software from an ISBT 128-licensed vendor that best fits your facility's needs. https://www.isbt128.org/vendor-lookup-tool

If your facility has the resources to develop its own software, your programmers can use the specifications from the various ISBT 128 standards documents (e.g., ST-001) to create compatible software.

ICCBBA has created the Implementation Guide: Use of ISBT 128 in Resource-Limited Countries (IG-041) document to help users in resource limited countries.

The document provides guidance for implementation of the ISBT 128 Standard for blood transfusion in resource-limited countries. It is intended to provide options that allow facilities to promote safety, traceability, and efficiency without needing to implement all features of the ISBT 128 Standard. The document can be found at the following link: https://www.isbt128.org/IG-041







END OF PUBLICATION

FOR ICCBBA USE ONLY

These links are for internal document control and cannot be used externally:

ST-001 ISBT 128 Standard Technical Specification

ST-003 ISBT 128 Standard Labeling of Human Tissues

ST-004 ISBT 128 Standard Labeling of Cellular Therapy Products

ST-005 ISBT 128 Standard Labeling of Blood Components

ST-009 ISBT 128 Standard Labeling of Ocular Tissue

ST-013 ISBT 128 Standard Labeling of Human Milk Banking Products

IG-020 Encoding Product Information [Data Structures 003, 032, 033, and 034] - Tissues

IG-021 Use of Product Code [Data Structure 003] - Blood

IG-022 Product Coding [Data Structures 003 and 032] - Cellular Therapy

IG-032 Use of Product Code [Data Structure 003] - Ocular Tissue

IG-041 Use of ISBT 128 in Resource-Limited Countries

IN-037 ISBT 128 Implementation Plan

