IMPLEMENTATION GUIDE

Shipping ISBT 128 Labeled Products through a GS1 Supply Chain

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1 Introduction

1.1 Purpose

This document is intended to provide guidance to help users distribute ISBT 128 labeled products through a GS1 supply chain. It outlines how the ISBT 128 products can be packaged using a GS1 Serial Shipping Container Code (SSCC) and the associated ISBT 128 information can be incorporated into GS1 electronic dispatch information. It also provides a link to the associated GS1 guidance document that provides more detailed information.

1.2 Scope

This guideline applies to ISBT 128 registered facilities that need to distribute their products through a GS1 supply chain. It may also be used by distribution companies who need to distribute ISBT 128 labeled products as part of a GS1 shipment.

1.3 Intended Audience

The intended audience of this document is informatics, distribution, and supply chain management staff working for MPHO processing facilities, medical supply distributors, hospitals, and other locations of clinical application, and the application developers providing systems to support supply chain services.

1.4 Normative References

ISBT 128 Standard Technical Specification (ST-001)

1.5 Other References

ICCBBA:
Implementation Guide: Encoding Product Information [Data Structures 003, 032, 033, and 034]-Tissues (IG-020)
Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033] (IG-031)

GS1:
GS1 Distribution and Shipping of Biologicals Guideline
HTML: https://www.gs1.org/standards/gs1-distribution-and-shipping-biologicals-guideline/current-standard
PDF: https://www.gs1.org/docs/gsmp/healthcare/GS1_Biologicals_Guideline.pdf

1.6 Background

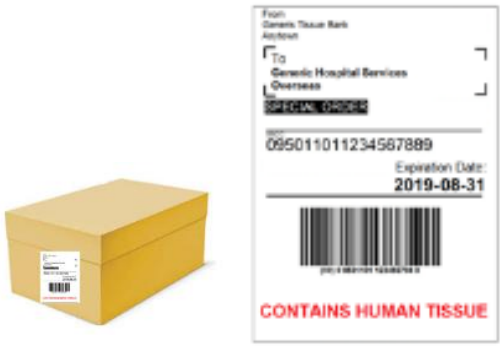
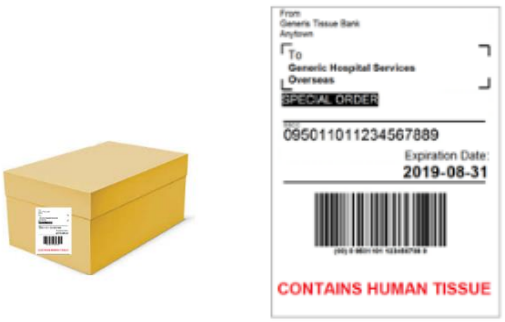
Facilities that identify their medical products of human origin (MPHO) using ISBT 128 labels need to distribute these products to sites of clinical application. Distribution may occur through dedicated supply chains equipped to handle ISBT 128 labeling, and in such cases, the ISBT 128 information is interpreted and stored at all stages in the distribution chain, ensuring traceability.

However, in some cases MPHO products need to enter the more general supply chain where GS1 identification is the recognized standard. Intermediaries, such as distribution companies, may not be able to interpret the ISBT 128 information, and therefore cannot use automated data transfer applications to capture and store important traceability information. GS1 labeling of the product would satisfy the supply chain actors, as their systems are designed for this standard, but GS1 does not provide the necessary traceability information required for MPHO products. In particular, GS1 does not support donation identification numbers or internationally standardized product codes.

To meet the needs of all stakeholders in these complex supply chains, a solution is required that allows the use of ISBT 128 identifiers at the points of product preparation and clinical application, but also supports the use of GS1 logistics in the intermediate supply chain. Working within the terms of an existing Memorandum of Understanding, GS1 and ICCBBA have developed such a solution based on the GS1 Serial Shipping Container Code (SSCC) and the GS1 EDI Trade Message – Despatch Advice.

The detailed specification “GS1 Distribution and Shipping of Biologicals Guideline” has been published by GS1 and provides additional information regarding the SSCC and Despatch Advice Message.

2 Process Summary

1. The MPHO processor assigns an ISBT 128 DIN linking to the donor record, prepares the MPHO product, packages and labels with an ISBT 128 label.	
2. The MPHO processor allocates the product to a shipment identified by a GS1 SSCC. The SSCC identifier is affixed to the outer container of the shipment. Information about the origin, destination, and contents of the shipment is placed in a GS1 Despatch Advice Message.	
3. The shipment travels through the GS1 supply chain with its associated Despatch Advice Message.	
4. The receiving healthcare facility receives the shipment and scans the SSCC. Information on the content is obtained from the Despatch Advice Message. MPHO products are forwarded to the Blood Bank, OR, or other site of clinical use.	
5. At the site of clinical application, the ISBT 128 information is scanned from the product label and the information is placed in the patient record. This provides essential traceability information, including the identity of the organization that assigned the DIN, and is responsible for holding the records providing traceability to the donor.	

3 Creating the SSCC Shipment

When the MPHO processor identifies that a product needs to be distributed via an intermediary using a GS1 supply chain, they can use a GS1 SSCC to create a "GS1 envelope," in which the product can travel through the supply chain. The SSCC is a shipment identifier and multiple ISBT 128 labeled products can be included in one single shipment. SSCC's can be nested; thus, multiple SSCC shipments can be placed in one consignment, itself identified by an SSCC (for example, a pallet may be identified by an SSCC and may be loaded with multiple containers, each carrying its own SSCC). The MPHO processor is responsible for maintaining records of the SSCC and the products it contains as part of its distribution records.

When creating the GS1 shipment identified by an SSCC, the processing facility will also need to create the accompanying Despatch Advice Message. This is a standard EDI message specified by GS1 and contains all of the information necessary to support the transfer of the shipment through the supply chain. It carries the SSCC as a key field to ensure a secure mapping between the shipment and the message, and information on the content of the shipment. It also has the capacity to carry a wide range of other shipping information.

Each item type in the shipment is identified in a separate line item referred to as AdditionalTradeItemIdentification in the GS1 specification, and it is at this level that the ISBT 128 identifiers are incorporated into the Despatch Advice Message. Multiple products of the same type can be included in one line item, or each can be given its own line item. The line item is defined using a data string for AdditionalTradeItemIdentification comprising the following:

Element	**Description**	**Example**
FIN(P)	Identification of the organization processing/labeling the product	A9999
FPC	Facility-defined Product Code	000037
PDC	Internationally standardized Product Description Code	T0122

The rules for creating this data string depend on the ISBT 128 data structures being used to label the product. Three options are defined:

- If the product label carries an ISBT 128 Processor Product Identification Code (PPIC – Data Structure 034), these three elements shall be taken directly from the PPIC data structure.

  e.g.
  PPIC data: =/A9999000037T0122
  DIN data: =A99971812345600
  AdditionalTradeItemIdentification: A9999000037T0122

- If the product label carries an ISBT 128 Processing Facility Information Code (PFIC – Data Structure 033), the FIN(P) and FPC shall be taken directly from this data structure and the PDC shall be the first five characters from the Product Code [Data Structure 003].

e.g.
PFIC data: &+A9999000003
DIN data: =A99971812345600
PC data: =<T0122001
AdditionalTradeItemIdentification: A9999000003T0122

- Where the ISBT 128 label does not carry either a PPIC or a PFIC, the data elements shall be derived as follows:

    - FIN(P) shall be the first five characters of the DIN [Data Structure 001]
    - FPC shall be set to six zeros
    - PDC shall be the first five characters from the Product Code [Data Structure 003]

    e.g.
    DIN data: =A99971812345600
    PC data: =<T0122001
    AdditionalTradeItemIdentification: A9997000000T0122

If the message has been constructed to create a line item for each individual product instance, then additional information can be included in the message, including the DIN, Division Number, and Expiration Date, but these are not required.

Hospital systems may also use the SSCC code at the point of goods receipt before forwarding them to the Blood Bank, Operating Room, or other site of clinical application. The products are then removed from the shipping container and the ISBT 128 information is scanned into the clinical information system. From this point on, the ISBT 128 identifiers are used to record the clinical application of the product in the patient record.

4 Traceability

Forward traceability is achieved by:

- tracking the MPHO product from donation to point of distribution using the ISBT 128 identifiers
- looking up the SSCC associated with the ISBT 128 identifiers
- tracking the consignment through the supply chain using the SSCC to final destination
- tracking the MPHO product from point of receipt at final destination to point of clinical application using the ISBT 128 identifiers

Backward traceability is achieved from the ISBT 128 identifiers in the patient record by taking the Facility Identification Number (FIN) that forms the first part of the Donation Identification Number, or the Processor FIN from Data Structure 033 or 034, and using this to identify the MPHO processor via the ICCBBA Facilities Database. This allows direct linking to the processor without the need to track back through the supply chain.

