



Bar Coding Plasma Derivatives Implementation Guide

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0.5	21 May 2010	Tom Heist, Christian Hay, Pat Distler	Changed blood derivatives to plasma derivatives and added graphics agreed to during the 11 April call, adjusted Section 2 based on work group’s preferred version & proof read the document. Change introduction to section 2.
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1. Introduction

Currently, plasma derivatives in the healthcare supply chain are not consistently and uniformly marked/labelled to permit a global adoption of automatic identification and data capture (AIDC) due in part to the lack of a recognised global standard. To compensate for the lack of standardisation of data carriers being marked, some users choose to {re}-label the plasma derivative products and this is considerably inefficient, a possible source of errors and may increase patient risk.

GS1 and ICCBBA, two recognised and endorsed standards organisations, have worked together to develop a uniform global AIDC marking/labelling implementation guide. This guideline for the implementation of a global standard for AIDC for plasma derivatives would provide efficiencies in the healthcare supply chain and improvements toward patient safety.

This implementation guide does not set or modify the GS1 standards. Refer to the GS1 General Specification and the GS1 Global Data Dictionary (GDD) for current standards and definitions.

This implementation guide does not set or modify the ISBT 128 standard. Refer to ISBT 128 Standard Technical Specification for current standards.

1.1. Purpose of this document

To provide guidance for the labelling of plasma derivatives and recombinant products so healthcare supply chain partners responsible for encoding data into a data carrier (e.g. a bar code) can label their products by understanding the delimitation between the ICCBBA standard, ISBT 128 and the GS1 System of Standards without overlapping and without any “grey zone.”

Labelling guidance will also be helpful to the healthcare supply chain partners who must decode data (e.g. scan or read bar codes) at transfer points in the healthcare supply chain from point of supply or manufacture to point of care.

1.2. Who will use this document?

Healthcare supply chain partners that encode and/or decode AIDC data carriers on products from the origin and supply of plasma derivative products to the point of care:

- Blood Collection Centres
- Blood Services
- Distributors (Authorised)
- Fractionators
- Group Purchasing Organisations (GPO)
- Hospitals (Transfusion Services or Pharmacies)
- Manufacturers
- Patient Care Units
- Software Vendors

1.3. References

- ISBT 128 Standard Technical Specification, version 3.6.0
- GS1 General Specifications, version 10, issue 1, January 2010
- GS1 Healthcare GTIN Allocation Rules for Healthcare Products

- GS1 DataMatrix Introduction and Technical Overview
- GS1 AIDC Healthcare Implementation Guidelines for AIDC in Healthcare
- GS1 Global Traceability Standard for Healthcare and GS1 Traceability Implementation Healthcare
- GS1 Global Data Synchronisation Network (GDSN)



Note: Documents are published by GS1 on its global website (www.gs1.org); several documents are translated and made available by GS1 Member Organisations. ISBT 128 Standard Technical Specification is published by ICCBBA on its website (www.iccbba.org).

2. Business Scenario Overview

Traceability in the supply chain for blood, blood components, and plasma derivatives would provide further assurance that safe and effective products are being provided to the patients who need them. Traceability should be in place from “vein to vein”, in other words from the blood or plasma donation through any component processing and supply chain to the individual who receives a blood component (infusion) or receives a plasma derivative (transfusion).

Different standards have been developed to facilitate traceability for blood, blood components and plasma derivatives. Blood and blood components utilize the ISBT 128 Standard for labelling. Plasma derivatives, which go through a further manufacturing process, would generally use the GS1 standard. For some supply chain parties, such as blood collection facilities that distribute plasma derivatives, there is a need to have an IT system that can accommodate both the ISBT 128 standard and GS1 keys and attributes. This will avoid ambiguity and the need sometimes to re-label plasma derivatives. IT system alignment to GS1 standards enables the unique and unmistakable identification of these products so that patient safety can be assured. The following diagram illustrates where the ISBT 128 and GS1 standards are applicable.

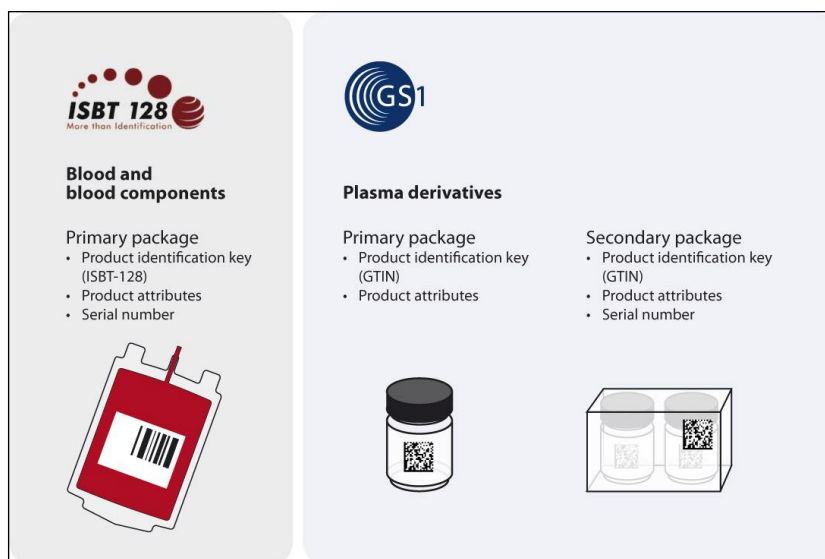


Figure 2-1 ISBT 128 and GS1 Product Identification

The graph demonstrates that one of the critical issues is to understand how blood components and plasma derivatives are distinguished. This is the purpose of the next paragraphs.

2.1. Delimitation of plasma derivative products

The following diagram demonstrates the criteria by which plasma derivatives are logically distinguished from blood products: that of pooling for future manufacture, and also by relevance of ABO group to the final product.

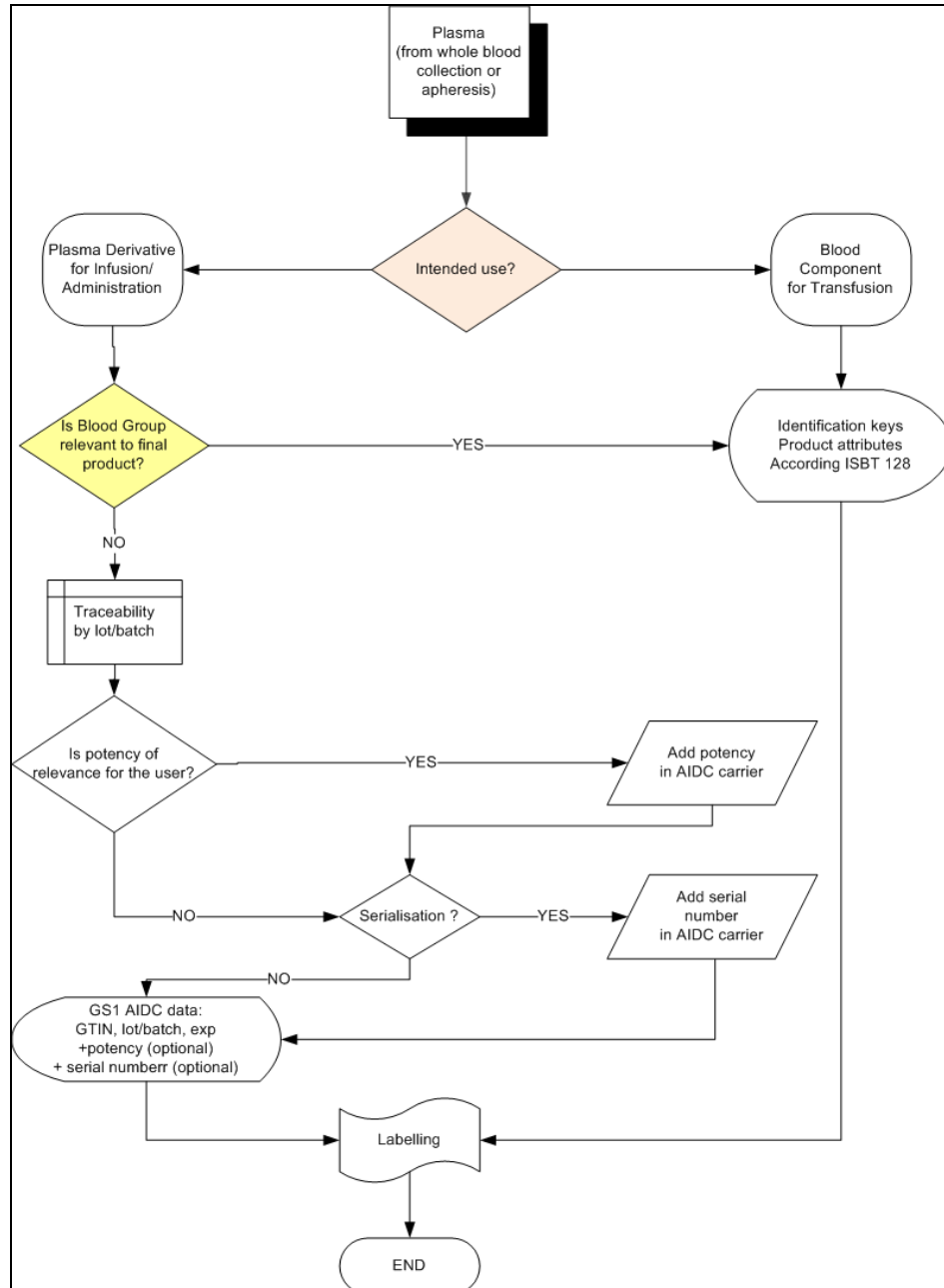


Figure 2.1-1 Delimitation of Plasma Derivative products

2.2. The case of plasma recombinant products

This is a different Plasma Derivative group of products, which has specific characteristics and is always labelled with GS1 System.

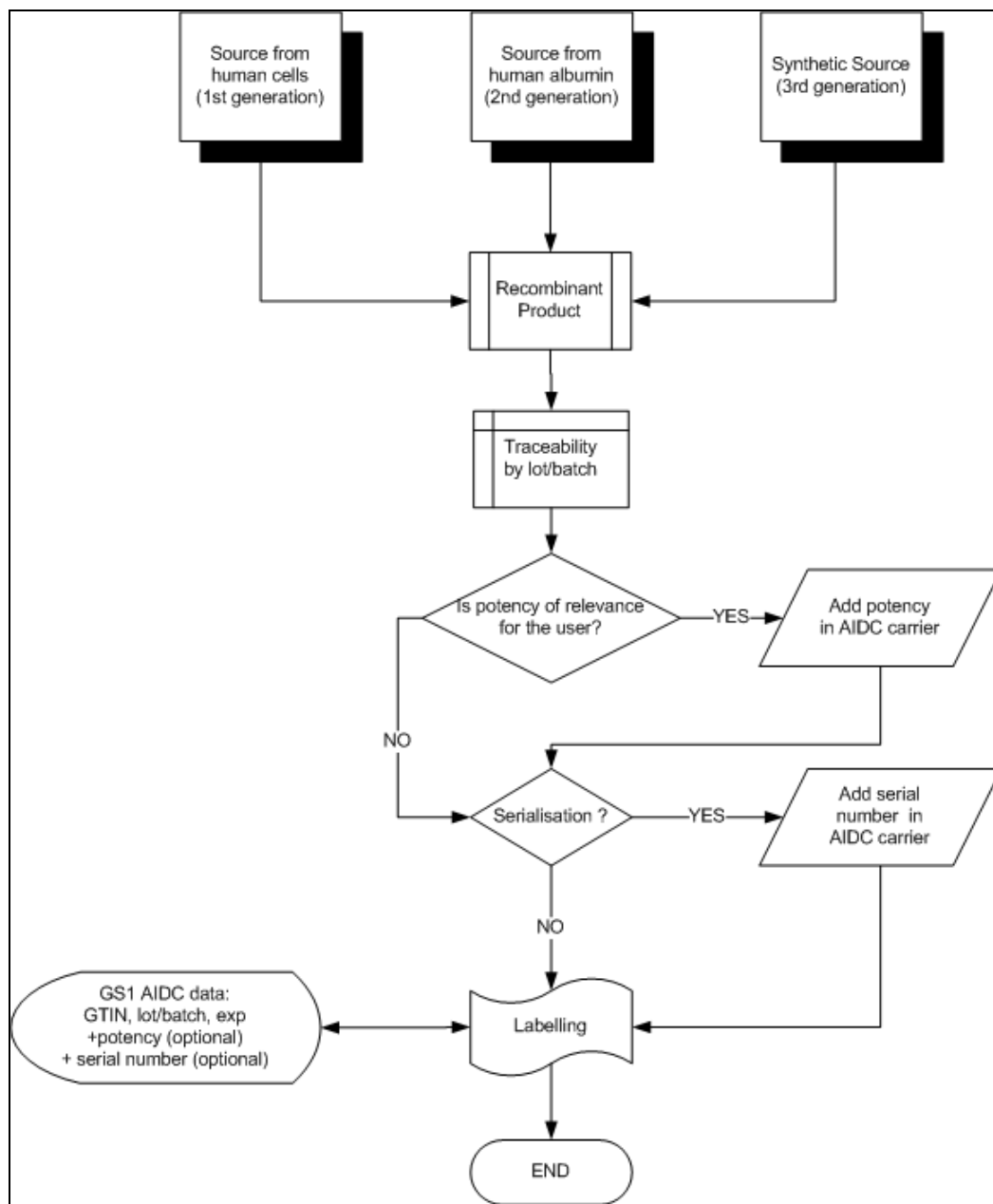



Figure 2.2-1 Plasma Recombinant Products

3. Implementation Procedures

Implementation procedures refer to both ISBT 128 and GS1 standards. The business scenarios are driving the user to proceed with the appropriate standard for the selected product. Implementation guidelines concentrate on the AIDC applications for product labelling. Regulatory requirements may supersede AIDC labelling specification.

This guideline is built on the assumption that the user has access to the appropriate documentation from both standards organisations. As a consequence, the guideline is limited to essentials for users and implementers, who are invited to consult ISBT 128 Standard Technical Specification and GS1 General Specifications in their latest versions.

The GS1 General Specification lists preferred data carrier options as a long term direction for AIDC marking of primary packages in Healthcare. These options include GS1 DataMatrix, GS1-128 and GS1 DataBar. GS1 DataMatrix may be used to meet the space labelling requirements for plasma derivatives.

 **Note:** For assistance with the GS1 General Specification please contact your local GS1 Member Organisation. In addition they will be able to provide you with further information on all of GS1 standards. Full details can be found on: <http://www.gs1.org/contact/worldwide.php>

 **Note:** For assistance with ISBT 128 standard, consult or contact www.iccbba.org.

3.1. Traceability, data synchronisation and electronic commerce

Both ISBT 128 and GS1 provide keys and processes for the purposes of traceability. The GS1 System of Standards uses additional keys within their system for AIDC, Data Synchronisation and Electronic Commerce.

Described below are GS1 Keys and examples of applications when used in the extended healthcare supply chain as shown in Figure 3.1-1. The examples of the GS1 Keys are not intended to be an exhaustive list but rather an illustration of potential opportunities.

- **GTIN (Global Trade Item Number)** used to identify trade items. Trade items are product or service upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any supply chain. This key can be combined with other information on data carriers to uniquely identify a healthcare product along with a serial number, lot or batch number and expiry date and can be used for pharmaceutical products and medical devices. The GTIN is also used with the GDSN and for electronic commerce.
- **SSCC (Serial Shipping Container Code)** used to identify logistic units. A logistic unit is an item of any composition established for transport and/or storage that needs to be managed through the supply chain. The SSCC is used in the supply chain to easily identify logistics shipping units consisting of multiple products, enabling quick and easy identification, tracking of deliveries and receipt of goods. This key is used with a data carrier for AIDC and in electronic commerce (eCom).
- **GRAI (Global Returnable Asset Identifier)** used to identify returnable assets such as roll cages, tote boxes and parcels used to ship products into and among hospitals. This key enables AIDC to be used for tracking the movement of assets.
- **GIAI (Global Individual Asset Identifier)** used to identify an individual asset such as patient monitoring devices, infusion pumps and x-ray machines. This key enables AIDC to be used for inventory control and management.
- **GDTI (Global Document Type Identifier)** used to identify a document type and could be used to identify medical documents such as patient records, prescriptions and discharge notices. This key enables AIDC of records.

- **GSRN (Global Service Relation Number)** used to identify the relationship between a service provider and service recipient. For example it could be used for the relationship between a hospital and services provided to a patient such as room charges, treatments, and medical tests. This key enables AIDC to be used for billing purposes.

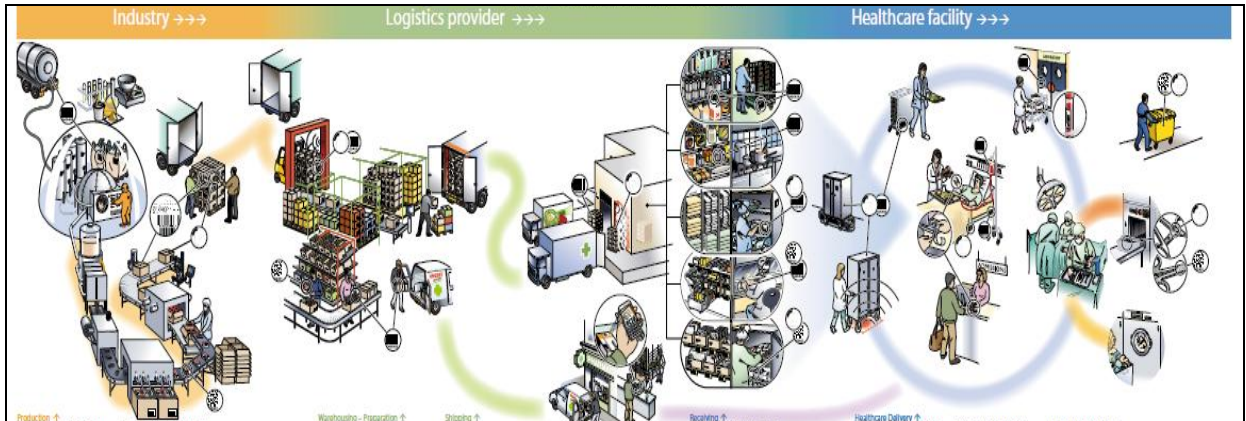


Figure 3.1-1 Extended Healthcare Supply Chain

✓ **Note:** More information on GS1 Keys is available at www.gs1.org and by contacting your local GS1 Member Organisation.

3.1.1. Traceability

Traceability requires the trading partner to base their processes on common product identification and other keys, which are used in their processes for internal and external traceability.

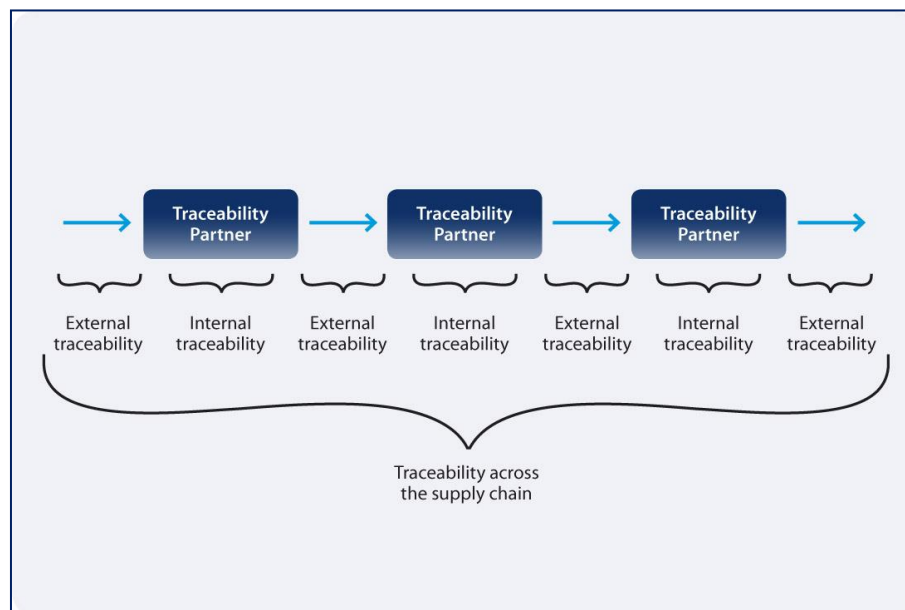


Fig. 3.1.1.-1 GS1 Traceability

Note: For more information, consult GS1 Traceability documentation (see § 1.3).

3.1.2. Data Synchronisation

The GS1 Global Data Synchronisation Network (GDSN) allows the managing and updating of standardised product information to be shared with its trading partners. Trading partners synchronise their product information master data within the GDSN via a GDSN solution provider (Certified Data Pool) of their choice, so that they can integrate their product identification for each level of packaging of the products they are supplying or purchasing.

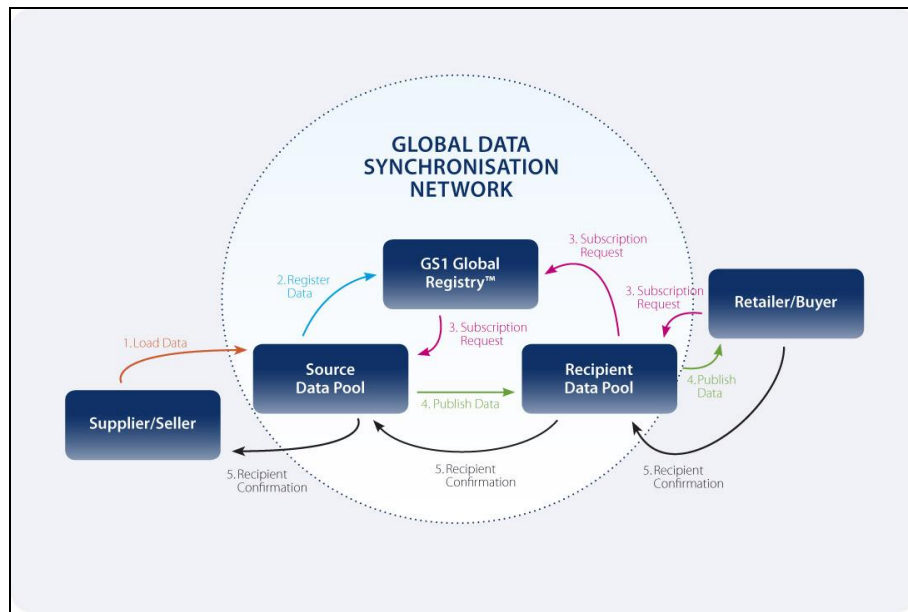


Figure 3.1.2-1 GS1 Global Data Synchronisation Network

Note: For more information, consult GS1 GDSN documentation (see § 1.3).

3.1.3. Electronic commerce

eCom provides a set of standardised messages in GS1 EANCOM and GS1 XML. This allows the trading partner to exchange information about orders, deliveries and invoices as shown in Figure 3.1.3-1 eCom Messages.

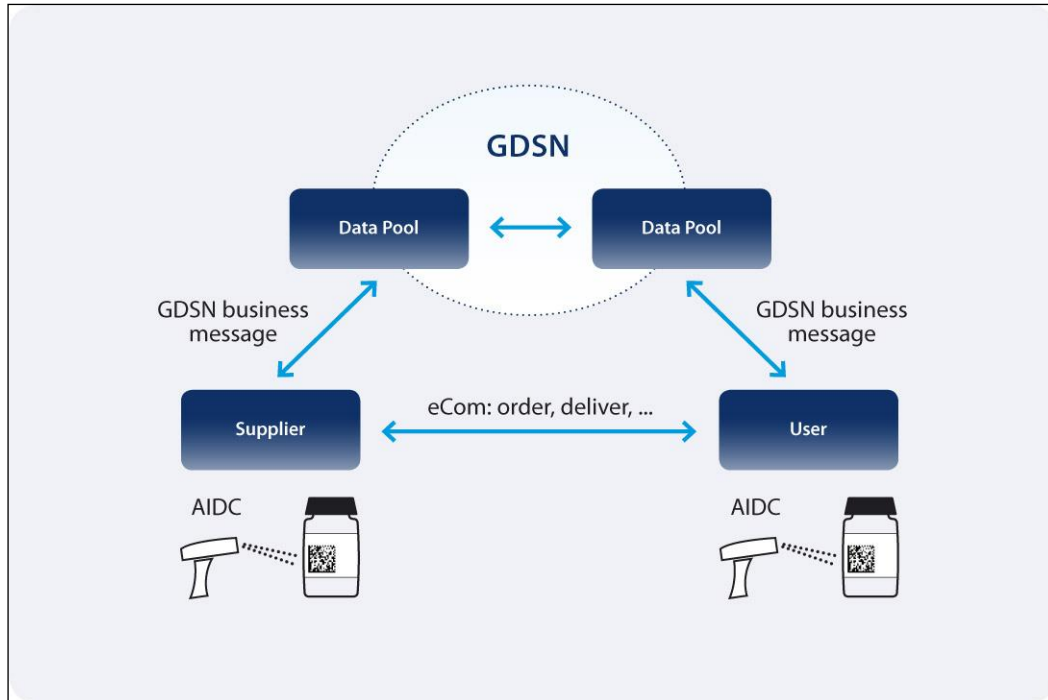


Figure 3.1.3 eCom Messages

The combination of AIDC, eCom and GDSN is enabled by the use of the GS1 Keys and The GS1 System.

3.2. Software implementations

Software vendors should adopt processes consistent with managing GS1 traceability data, as well as master data from GDSN sources.

This will in particular allow users to manage the link between primary and secondary package level, which is part of Master Data Synchronisation (Global Data Synchronisation); the concept used for this is “Parent GTIN”, respectively “Child GTIN”.



Note: For additional information on Parent GTIN – Child GTIN refer to Appendix 5.2.

3.3. Labelling blood product

ISBT 128 is a global standard for labelling of blood and blood components, as well as human tissue and cells. ISBT 128 allows each product from a blood donation to be identified uniquely by assignment of:

- a globally unique donation identification number to each donation
- a product code to each blood component from a donation.

The donation identification number comprises (1) a five-character facility identification number assigned by ICCBBA, the not-for-profit organization that manages the ISBT 128 standard, (2) a two-character year of collection, and (3) a six-character serial number assigned by the blood collection facility.

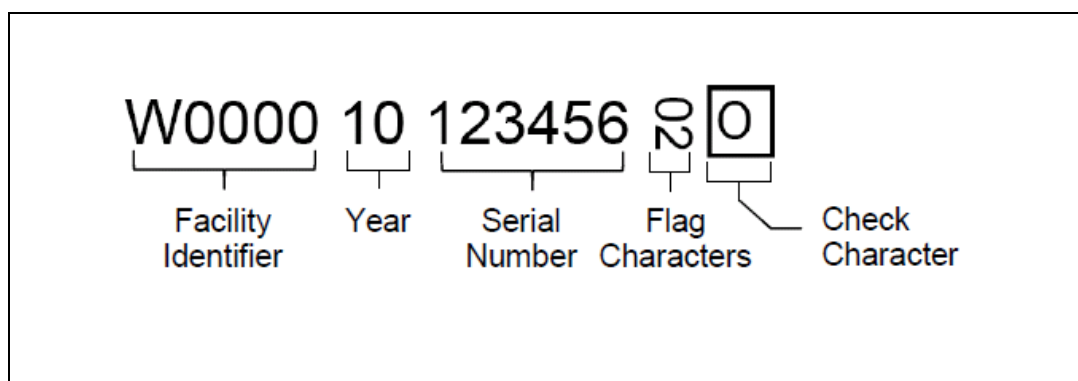


Figure 3.3 ISBT 128 Donation Identification Number

Product codes are defined based on global consensus for terminology and definitions. An appropriate product code is selected by the collecting or processing facility from an ICCBBA-maintained database and assigned to the product.

The symbology is Code 128. To improve efficiency, an additional data matrix symbol may also be present on the label.



Note: For more information, consult ISBT 128 documentation (see § 1.3).

3.4. Labelling plasma derivatives – primary package

First level of packaging is to be labelled to meet user requirements at the point of care.

3.4.1. Pre-Requisite

The identity of a primary package and associated data need to be captured at the point of care. The packaging levels have to be differentiated and therefore each must have a different GTIN.

If the plasma derivative is provided as a kit (because the secondary package contains, for example, the active ingredient in one vial, and the dilution substance in a second vial), each component should be labelled with its own GTIN.

The product database (catalogue) of the users has to link the GTINs so that the relation between items can be retrieved.

GTINs are non-significant, not necessarily sequential, and function as a pointer to database information.

3.4.2. Traceability

The primary pack level is identified with a different GTIN to the higher levels of the hierarchy (“Parent GTIN”). When primary and secondary pack levels are a 1:1 relationship, each has a different GTIN and both have the same lot or batch number.

When the secondary pack is a kit which contains more than one primary package, the lot or batch number of each of the items is different. When the secondary pack contains one or more identical primary pack their lot or batch number should be identical. The assumption of the standard is that product recalls should be made on the base of the secondary packaging level identification (the combination GTIN and lot or batch number).

For traceability purposes, the user must be able to manage product identification (GTIN and lot or batch number) at each packaging level.

3.4.3. How to label

Labels with variable information (GTIN followed by lot or batch number, expiry date, etc.) have to be printed along / at the end of the production chain.

The GS1 General Specification lists preferred data carrier options as a long term direction for AIDC marking of primary packages in Healthcare. These options include GS1 DataMatrix, GS1-128 and GS1 DataBar. GS1 DataMatrix may be used to meet the space labelling requirements for plasma derivatives.

It is good practice to let the symbology and its selection be checked, especially in the first stages of implementation. GS1 local Member Organisations provide such a service for their members.



Note: For additional information on how to label refer to Appendix 5.1.

3.4.4. Software implication

GTIN identifies an item with a pre-defined quantity. If administration differs from the predefined quantity, the Electronic Patient Record should be documented accordingly (GTIN & attribute plus exact quantity which is captured manually).

In a supply chain vision, the item identified with a GTIN is “consumed” even if only a fraction of it has been administered to the patient.

When a primary package comes back to the Hospital –because of no-use- the Hospital IT system must be able to recognise it as part of a secondary package (which had been shipped to the ward or operating theatre).

3.5. Labelling plasma derivatives – secondary package

Second level of packaging is to be labelled to meet regulatory and users requirements

3.5.1. Pre-Requisite

Identification of secondary package level is part of the wider project to identify products at company / organisation level: each package level of each product has to be allocated a different GTIN. GTINs are non-significant, not necessarily sequential, and function as pointer to database information.

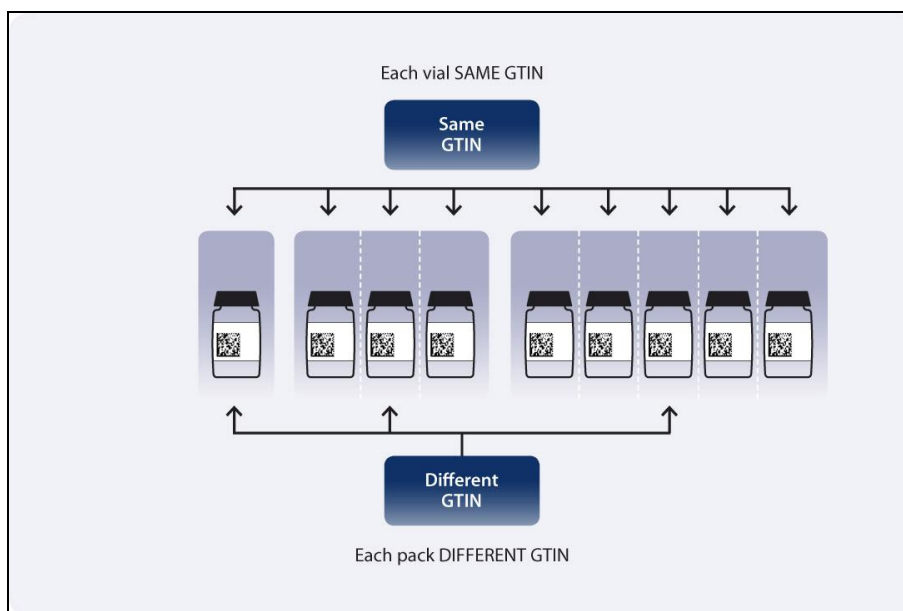


Figure 3.5.1-1 Secondary Packaging

3.5.2. Traceability

AIDC component of traceability is the combination GTIN plus lot or batch number (and eventually expiry date). Traceability requires that each step of the supply chain –or physical flow- corresponds with an information flow –generally processed by electronic messaging (GS1 eCom).

This means that each step in the supply chain records the combination GTIN and lot or batch number of the incoming and outgoing items, with identification of their origin (incoming items) or destination (outgoing items).

In the plasma derivative industry, traceability is heavily based on secondary package. For example, product recalls should be issued by referring to the secondary package.

3.5.3. How to label

Labels with variable information (GTIN followed by lot or batch number, expiry date, etc.) have to be printed along / at the end of the production chain.

The GS1 General Specification lists preferred data carrier options as a long term direction for AIDC marking of primary packages in Healthcare. These options include GS1 DataMatrix, GS1-128 and GS1 DataBar. GS1 DataMatrix may be used to meet the space labelling requirements for plasma derivatives.

It is good practice to let the symbology and its selection be checked, especially in the first stages of implementation. GS1 local organisations provide such a service for their members.

Note: For additional information on how to label refer to Appendix 5.1.

3.5.4. Software implication

Software must be able to record the item identity (GTIN) at secondary package level as well as the relation “Child GTIN” to the next lower level of packaging (primary package level).

Software must be able to manage lot or batch numbers and expiry date for the secondary package level, as recalls are usually announced by referring to that packaging level.

Stocks are managed at secondary package level. If an item may be shipped back from the ward / OR, the software must be able to retrieve to which delivery it belonged by using the “parent – child GTIN” relation as well as the respective lot or batch number(s).



Note: For additional information on Parent GTIN – Child GTIN refer to Appendix 5.2.

3.6. Labelling plasma recombinant products

Labelling of plasma recombinant products follows the same rules as plasma derivatives (primary and secondary package levels).

3.7. Serialisation of plasma derivatives – secondary package

Some regulators and users require plasma derivatives to be serialised. This is for traceability to individual items (secondary packaging level) rather than by lot or batch number only. Serialisation requirements focus on secondary package level.

3.7.1. Pre-Requisite

Serialisation at secondary package level is built on GTIN identification, the serial number being an attribute to the GTIN. Product serialisation comes in addition to the AIDC marking of lot or batch number and expiry date.

3.7.2. When is product serialisation required?

Regulators require product serialisation mostly to fight against counterfeiting. This will require the supply chain actors to capture information at item level at each step (pedigree model) or at manufacturing and dispensing points (authentication model).

Some users would also like serialisation to allow identification of different units so that individual pathways could be tracked. For example, serialisation would allow users to differentiate between units that were shipped under appropriate conditions from those that were not.

Some users would also like serialisation on secondary packaging to allow traceability to the patient.

Manufacturers must provide the combination GTIN plus serial number in an appropriate way to their supply chain partner. Usually, suppliers provide their customers the detailed product information (including GTIN and serial number) in an electronic despatch advice.

3.7.3. How To

The user community considers it a good practice to generate the serial numbers in a pseudo randomised way, serial numbers being unique by GTIN.

As the manufacturer is responsible for issuing the serial numbers, they will have to decide to use numeric only data (less impact on symbology size), or to use alpha-numeric data (symbology will increase in size).

3.7.4. Software implication


Software must be able to manage serialised items, by also storing their lot or batch number and expiry date. Traceability efforts or recalls are usually made by lot or batch number. When secondary

packages are serialised, the hospital must be able to retrieve the origin and the destination of items which are stored or have been shipped to a patient care unit.

If a primary package is shipped back from the patient care unit, the Hospital software must be able to retrieve to which delivery it belonged by using the “parent – child GTIN” relation as well as the respective lot or batch number(s). It may not be possible at this time to retrieve to which serialised secondary package the item belonged to.

 **Note:** For additional information on Parent GTIN – Child GTIN refer to Appendix 5.2.

4. Glossary

 **Note:** Refer to the GS1 General Specification and Global Data Dictionary for the current approved definitions.

Term	Description
ABO (group)	Refers to blood groups (A, B, AB, O)
Active potency	Represents the measured actual ("Active") potency of a biologic such as haemophilia products.
(Authorised) Distributor	Negotiates Distributor Price Point with manufacturer; distributes product to end-users; manages finished goods inventory (based on contract agreements)
Blood collection centre	Selects and tests suitable donors, collects and processes whole blood to blood components, as well as collecting blood components by apheresis, tests and prepares blood components for distribution. May receive, store and distribute plasma derivatives to hospital blood banks/pharmacies. Many BCC act as reference labs for hospitals.
Blood component	Blood that is used whole or is separated into constituent parts as cellular and liquid fractions, based on the relative density of the constituents (e.g., separated by centrifugation), but is not separated using chemical or other fractionation processes. It is traced by a single donor or a small group of donors.
Donor	A person from whom blood is collected for processing into blood components.
Dose	The quantity of something that may be eaten by or administered to an organism, or that an organism may be exposed to. Quantities of nutrients, drugs, and toxins are referred to as doses.
GPO (Group Purchasing Organisation)	Negotiates discounts with manufacturers to gain the best price and secure value for members (i.e., hospitals); GPOs involve non-possession contracts - do not "handle" product (which is role of distributor)

Term	Description
Hospital (Transfusion Services)	<p>The hospital transfusion service performs pre-transfusion testing and maintains patients' transfusion records; receives, stores, prepares and distributes blood components and where applicable, plasma derivatives, to clinical care units for transfusion; maintains traceability to final disposition and carries out recalls/withdrawals, look backs and trace backs as required.</p> <p>Some hospital transfusion services select donors and collect blood and/or blood components.</p>
Infusion/Administration	The introduction of a solution containing fractionated plasma proteins or recombinant proteins into the body for therapeutic purposes.
Kit	A collection of different regulated healthcare items assembled for use in a single therapy.
Patient Care Unit	Patient care units where products (blood components and/or plasma derivatives) are prescribed, requested, received (from the Hospital blood bank or pharmacy) and transfused and patients are monitored during transfusion with appropriate reporting and follow up in the event of a transfusion reaction. Some CCU store products temporarily for trauma and/or surgery.
Plasma derivative	A product that contains concentrated fractions of plasma proteins that have been separated using physico-chemical or other fractionation processes. It is made from pooling plasma from large numbers of donors and is traced based on the lot or batch number of the pooled product. The pooling performed is not based on the ABO group of the individual components.
Plasma protein product	<p>Purified, manufactured proteins used to replace or supplement proteins in circulating human blood.</p> <p>A "plasma-derived" product is manufactured from human plasma. A "recombinant" product is manufactured by genetically manipulated cells in in-vitro culture</p>
Primary package	The first level of packaging in direct contact with the product and marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. May consist of a single item or group of items for a single therapy such as a Kit.
Recombinant product	Clotting factors or other proteins created by inserting the DNA encoding the relevant factor into mammalian cells and growing the cells in culture
Secondary package	A level of packaging marked with an AIDC carrier that may contain one or more primary packages or a group of primary packages containing a single item.

Term	Description
Solvent detergent plasma	Plasma that has been prepared by pooling large numbers of plasma components from single donors and pathogen-inactivating using a solvent detergent process. Product is divided into individual dose containers and frozen by a process and to a temperature that will maintain the activity of labile protein fractions. Pools of SD plasma are made only within same ABO group and the product must be ABO blood group labeled
Transfusion	The transfer of whole blood or blood components from one person (the donor) into the bloodstream of another person (the recipient). Blood components may include red cells, platelets, and plasma (unfractionated).

5. Appendices

5.1. Data structure in GS1 Data Carriers

A range of GS1 Data Carriers carry data structured in Element Strings. An Element String is the combination of a GS1 Application Identifier and a GS1 Application Identifier Data Field (see GS1 General Specifications, Section 3).

This can be illustrated with the following example of a GS1 DataMatrix symbol:




(01)03453120000011(17)091125(10)ABCD1234

The human readable information includes GS1 Application Identifiers in brackets () to facilitate readability; these brackets are not encoded in the GS1 DataMatrix (nor are they in any GS1 Data Carrier).

Here is the detailed information carried in this single symbol. For trade items, please note that the sequence of the GS1 Application Identifiers must always start with a GTIN; the further GS1 Application Identifiers may not follow a specified order:

GS1 Application Identifier	GS1 Application Identifier Data Field	Comment
01	GTIN	GTIN (14 digits, numeric, fix length) is always the first Data Field on a Trade Item
17	Expiry date	Expiry date as YYMMDD
10	Lot (Batch) Number	Variable length, alpha-numeric, maximum 20 digits.

Here is a second example to illustrate the use of GS1 DataMatrix:

Manufacturer XYZ	
Fantasybulin s/D 10 000 mg Product description, 1ml solution contains Protein xxmg, etc... 1 vial contains powder, 1 vial contains solvent	
Market authorisation Number 1234 Holder of Market Authorisation : Distributor Ltd	Exp 31 December 2010 Lot / Batch 12345A  (01)07612345000435(17)101231 (7004)123(10)12345A

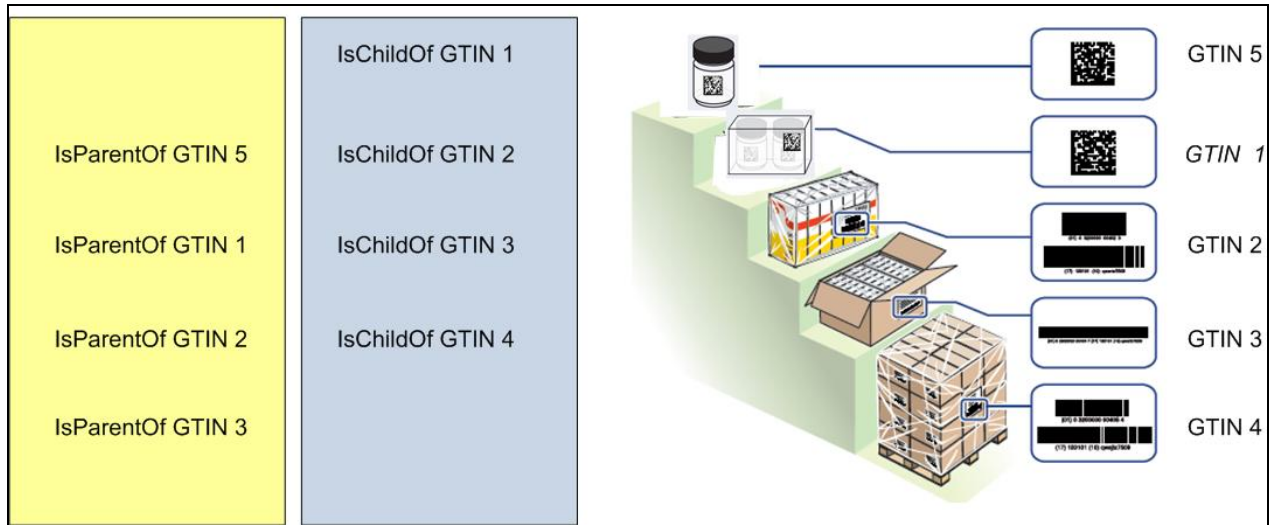
In this case, the human readable information is immediately below the symbol; expiry date and Lot/Batch are also provided in human readable form.

Here is the detailed information carried in this single symbol:

GS1 Application Identifier	GS1 Application Identifier Data Field	Comment
01	GTIN	GTIN (14 digits, numeric, fix length) is always the first Data Field on a Trade Item
17	Expiry date	Expiry date as YYMMDD
7004	Active Potency	Numeric field with max 4 digits; Value here is fantasy
10	Lot or Batch Number	Variable length, alpha-numeric, maximum 20 digits.

5.2. Product hierarchy: Parent / Child GTIN

Here a first illustration of the Parent/Child relationship:



Here another example, with a pallet that contains a child GTIN of CASE that contains a child GTIN of BASE_UNIT_OR_EACH (assumption: A unit load that is not “display ready” and contains a single instance of case). The case contains a single instance of an each.

tradeItemUnitDescriptor	Description	GTIN	TradeItemIdentificationOfNextLowerLevelTradeItem (GTIN)	quantityOfNextLowerLevelTradeItem	quantityOfChildren (different GTIN)
PL	240 cases	23041090004821	13041090004824	240	1
CA	12 retail packs	13041090004824	03041090004827	12	1
EA	2 vials in a box	03041090004827	03041090009556	2	1
EA	1 vial	03041090009556	X	X	X

X= not applicable

5.3. GS1 Data Carriers

With the increased capabilities of camera based scanners that read both linear and two-dimensional bar codes, GS1 Healthcare strongly recommends organizations invest in such scanners when introducing bar code scanners or when replacing existing laser bar code scanners. This will facilitate the future adoption of global standards for AIDC in the Healthcare supply chain.

Global standards for AIDC provide the opportunity to make the healthcare supply chain more efficient and accurate, and thus safer.

Biologics, such as plasma derivatives, pharmaceuticals, etc. and medical devices coding have very specific requirements, including:

- a large amount of data (product ID, lot or batch number, expiry date, active potency, etc.) to be stored on a small space
- variable information (such as unique identification number at secondary package level) to be marked at high production rates

The GS1 General Specification lists preferred data carrier options as a long term direction for AIDC marking of primary packages in Healthcare. These options include GS1 DataMatrix, GS1-128 and GS1 DataBar. GS1 DataMatrix may be used to meet the space labelling requirements for plasma derivatives.