

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

PROCUREMENT AND SUPPLY MANAGEMENT

GLOBAL STANDARDS AND TRACEABILITY GLOSSARY OF TERMS

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Term	Definition
automatic identification and data capture (AIDC)*	A technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics, and radio frequency identification devices.
barcode*	A symbol that encodes data into a machine-readable pattern of adjacent, varying width, parallel, rectangular dark bars and pale spaces.
barcode verification*	The assessment of the printed quality of a barcode based on International Organization for Standardisation (ISO)/International Electrotechnical Commission (IEC) standards using ISO/IEC-compliant bar code verifiers.
batch/lot*	The batch or lot number associates an item with production information that the manufacturer considers relevant for traceability of the trade item. The data may refer to the trade item itself or to items contained in it.
brand owner*	The Organization that owns the specifications of a trade item, regardless of where and by whom it is manufactured. The brand owner is normally responsible for the management of the GTIN. <small>DRAFT</small>
classification	A form of cataloguing, or identifying, products that can be defined as a process for grouping products into categories based on an understanding of the essential properties and relationships between them. A classification system is used to group like products such as medical devices versus pharmaceutical drugs. Example classification systems are UNSPSC, GPC, eClass, and ATC.
check digit*	A final digit calculated from the other digits of some GS1 identification keys. This digit is used to check that the data has been correctly composed. (See GS1 check digit calculation.)
concatenation*	The representation of several element strings in one barcode.
data architecture	Data architecture is composed of models, policies, rules, or standards that govern how data is stored, managed, and utilized in an information system.
data governance	The development, execution, and supervision of policies, programs, and practices that standardize, collect, control, protect, deliver, and enhance the value of data and information assets.
data synchronization	The process of maintaining the consistency and uniformity of data instances across all consuming applications and storing devices.
Data Matrix*	A standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern.
Global Location Number (GLN)*	The GS1 identification key used to identify physical locations or parties. The key comprises a GS1 Company Prefix, location reference, and check digit.
Global Trade Item Number® (GTIN®)*	The GS1 identification key used to identify trade items. The key comprises a GS1 Company Prefix, an item reference, and check digit.
GS1	A neutral, not-for-profit, global Organization that develops and maintains the most widely used supply chain standards in the world.

*GS1 AISBL. GS1 General Specifications. Release 18, Ratified January 2019.

GS1-128 linear barcode	A barcode symbology using bars and spaces in one dimension that leverages a subset of Code 128 that is used exclusively for GS1 system data structures.
GS1 Application Identifier*	The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.
GS1 Company Prefix*	A globally unique string of four to twelve digits assigned to an entity and used to issue GS1 identification keys. The first digits are a valid GS1 prefix and the length must be at least one longer than the length of the GS1 prefix. The GS1 Company Prefix is issued by a GS1 Member Organization. As the GS1 Company Prefix varies in length, the issuance of a GS1 Company Prefix excludes all longer strings that start with the same digits from being issued as GS1 Company Prefixes.
GS1 DataMatrix*	GS1 implementation specification for use of the DataMatrix.
GS1 Healthcare	A global, voluntary user group that develops standards to advance global harmonization. GS1 Healthcare consists of manufacturers, wholesalers, distributors, hospitals, and pharmacy retailers and maintains close contacts with regulatory agencies and trade Organizations worldwide. It drives the development of GS1 standards and solutions to meet the needs of the global healthcare industry and promotes the effective use and implementation of global standards for the industry.
GS1 identification key*	A unique identifier for a class of objects (e.g., a trade item) or an instance of an object (e.g., a logistic unit).
GS1 Member Organization*	A member of GS1 that is responsible for administering the GS1 system in its country (or assigned area). This task includes, but is not restricted to, ensuring user companies make correct use of the GS1 system; have access to education, training, promotion, and implementation support; and have opportunity to play an active role in the Global Standards Management Process.
healthcare primary packaging*	The first level of packaging for the product marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system and may consist of a single item or group of items for a single therapy such as a kit. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item.
healthcare secondary packaging*	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.
human readable interpretation*	Characters, such as letters and numbers, which can be read by persons and are encoded in GS1 AIDC data carriers confined to a GS1 standard structure and format. The human readable interpretation is a one-to-one illustration of the encoded data. However, start, stop, shift, and function characters, as well as the symbol check character, are not shown in the human readable interpretation.
kit*	A collection of different regulated healthcare items assembled for use in a single therapy.

* GS1 AISBL. GS1 General Specifications. Release 18, Ratified January 2019.

* GS1 AISBL. GS1 General Specifications. Release 18, Ratified January 2019.

logistic unit*	An item of any composition established for transport and/or storage that needs to be managed through the supply chain. It is identified with an SSCC.
manufacturer	An entity that makes or produces drugs, pharmaceuticals, or medical devices through a process involving raw materials, components, or assemblies, usually on a large scale.
medical device*	Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for any medical purpose.
product	An object with a defined set of attributes or characteristics.
serial number*	A code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime. Example: microscope model AC-2 with serial number 1234568 and microscope model AC-2 with serial number 1234569. A unique individual item may be identified with the combined GTIN and serial number.
Serial Shipping Container Code (SSCC)*	The GS1 identification key used to identify logistic units. The key comprises an extension digit, GS1 Company Prefix, serial reference, and check digit.
solution provider	A vendor that provides products and/or technical or service support to a company. It offers companies hardware, software, guidance, resources, and tools in a variety of areas. Examples are barcode services, including labels, printing, designing, and verifying; barcode hardware, including printers, readers, and scanners; and barcode software.
supplier	An entity with which a procurement agent has a contractual relationship for providing one or more trade items. The supplier is involved or plays a role in the buying, selling, or production of the pharmaceutical or medical device and can be a manufacturer, brand owner, wholesaler, or distributor.
tertiary homogenous pack	A tertiary pack that consists entirely of the same trade item with the same batch number and expiration date.
tertiary mixed pack	A tertiary pack that contains either more than one unique trade item or entirely the same trade item with different batch numbers or expiration dates.
tertiary packaging	The highest level of packaging that may include a pallet that contains (one or usually) several cases or a case that contains (one or usually) several items in its primary or secondary packaging. Tertiary packaging may refer to either a logistic unit or a trade item.
tertiary partial pack	A homogenous pack of products that is not to be considered a trade item because it is less than full.
trade item*	Any item (product or service) upon which there is a need to retrieve predefined information and that may be priced, ordered, or invoiced at any point in any supply chain.

*GS1 AISBL. GS1 General Specifications. Release 18, Ratified January 2019.