Global Standards Labeling and Barcode Requirements for pharmaceuticals, medical devices, sterile kits and laboratory reagents

LOGISTIC UNIT
A logistic unit is an item of any composition established for transport and/or storage that needs to be managed through the supply chain. GS1-128 barcode symbology encoded with and printed as HRI: (00) SSCC

HELPFUL TERMS
HRI: Human Readable Interpretation; the printed characters that accompany a barcode or other data carrier
GTIN: Global Trade Item Number, the GS1 key that uniquely identifies a product
Trade Item: Trade items are products and services that may be priced, ordered, or invoiced at any point in the supply chain
SSCC: Serial Shipping Container Code; a unique identification key used to identify logistic units

PRIMARY PACK
Primary packaging is the first level of packaging that is in direct contact with the item. Data carrier required only when the item is supplied in cartonless packaging. GS1 DataMatrix symbology encoded with and printed as HRI:
(01) GTIN
(10) Batch/lot
(17) Expiration date
(21) Serial number

SECONDARY PACK
Secondary packaging is a level of packaging that may contain one or more primary packages, or a group of primary packages containing a single item. GS1 DataMatrix symbology encoded with and printed as HRI:
(01) GTIN
(10) Batch/lot
(17) Expiration date
(21) Serial number

HOMOGENOUS TERTIARY PACK
Tertiary packaging refers to upper levels of the packaging hierarchy. Homogenous tertiary packaging may be:
- A pallet that contains (one or usually) several cases
- A case that contains (one or usually) several items in the items’ primary or secondary packaging GS1 DataMatrix or GS1-128 barcode symbology encoded with and printed as HRI:
(01) GTIN
(10) Batch/lot
(17) Expiration date
(21) Serial number

MIXED OR PARTIAL TERTIARY PACK
Tertiary packaging refers to upper levels of the packaging hierarchy. Mixed or partial tertiary packaging may be:
- Partial – consisting of a homogenous pack of items that is not to be considered a trade item because it is less than full
- Mixed – either more than one unique trade item or entirely the same trade item with different batch numbers or expiration dates GS1-128 barcode symbology encoded with and printed as HRI: (00) SSCC

*mandatory as of June 30, 2022  **mandatory for pharmaceuticals only
Global Standards Labeling and Barcode Requirements for long-lasting insecticide-treated nets (LLINs)

**GS1-128 LINEAR BARCODE**

GTIN of contained items  Production Date  Batch Number  Count of contained items

GTIN of contained items  Production Date  Batch Number  Count of contained items

GTIN: Global Trade Item Number, the GS1 key that uniquely identifies a product

**TERIARY PACK LOGISTICS UNIT (BALE)**

GS1-128 barcode symbology encoded with and printed as HRI:

- (00) SSCC
- (02) GTIN of contained items
- (37) Count of contained items
- (10) Batch/lot number
- (11) Production date

**HELPFUL TERMS**

HRI: Human Readable Interpretation; the printed characters that accompany a barcode or other data carrier

GTIN: Global Trade Item Number, the GS1 key that uniquely identifies a product

Trade Item: Trade items are products and services that may be priced, ordered, or invoiced at any point in the supply chain

SSCC: Serial Shipping Container Code; a unique identification key used to identify logistic units

**GS1 DATAMATRIX**

GTIN-14  Production Date  Batch Number  Serial No.

**PRIMARY PACK (BAG WITH LLIN)**

GS1 DataMatrix symbology encoded with and printed as HRI:

- (01) GTIN
- (10) Batch/lot number
- (11) Production date

**INDIVIDUAL LLIN**

GS1 DataMatrix symbology encoded with and printed as HRI:

- (01) GTIN
- (10) Batch/lot number
- (11) Production date
- (21) Serial number

*mandatory as of June 30th 2022*