



## 4.1 Introduction

A Regulated Healthcare Trade Item (RHTI) is a special type of trade item namely a pharmaceutical or medical device that is sold or dispensed in a controlled environment (e.g. retail pharmacy, hospital pharmacy).

The Global Trade Item Number (GTIN) is the GS1 Identification Key used to identify trade items including Regulated Healthcare Trade Items. Each trade item that is different from another in design and/or content is allocated a unique GTIN, which remains the same as long as it is traded. As well as the GTIN, Regulated Healthcare Trade Items are often assigned additional identification in the form of attributes such as Batch Number and Use-By Date. Refer to chapter 2 Introduction and Basic Rules on page 16 for detailed information on basic rules for numbering of trade items and to chapter 8 GS1 Application Identifiers (AIs) on page 120 for the details of GS1 Application Identifiers for attributes.

Scanning of all trade items can be broken into three groups based on the application and sector.

- **General Retail Consumer Trade Items** use omnidirectional linear bar codes that are read by high-volume omnidirectional retail Point-of-Sale (POS) scanners or linear hand held scanners. This scanning environment cannot read GS1 DataMatrix Symbols.
- **Regulated Healthcare Retail Consumer Trade Items** require GS1 DataMatrix Symbols but these cannot be deployed for high-volume omnidirectional retail POS. Regulated Healthcare Retail Consumer Trade Items marked with GS1 DataMatrix Symbols are intended to be read in lower-volume retail scenarios or hospital pharmacies or in high volume applications such as distribution centres.
- **Non-Retail Trade Items** are trade items that do not cross retail POS. Commonly, these trade items will appear in mixed scanning environments (laser, image based, etc.) depending on the application and industry sector. Typical examples include standard trade item groupings, direct part marked items, etc.

The application and sector for a particular trade item are most important as the particular rules governing identification and bar coding of trade items depend on them. For example, some items may be scanned in both General Retail and Regulated Healthcare Retail environments while others may be scanned in both retail and non-retail environments and there are specific rules governing these situations described in the sections that follow.



## 4.2 Identification

### 4.2.1 Levels of AIDC Marking

A Regulated Healthcare Trade Item can be identified with a GTIN-8, GTIN-12, GTIN-13 or GTIN-14 data structure. In addition, attribute information (e.g Batch Number, Use-By Date) is often required in particular circumstances.

For Regulated Healthcare Trade Items (RHTIs) three levels of identification have been developed:

- Minimum Level of AIDC Marking - GTIN with no attribute information.
- Enhanced Level of AIDC Marking - GTIN plus attribute information.
- Highest Level of AIDC Marking - GTIN, serialization, and potentially other attribute information

The identification solution for each of these levels may differ between the category of “pharmaceuticals” (which includes biologics, vaccines, controlled substances, clinical trial pharmaceuticals, and therapeutic nutritional products) versus the category of “medical devices” (which includes all classes of medical devices). Identification may also differ by configuration or packaging level (trade items direct marked, Primary Packaging, Secondary Packaging, case/shipper, pallet, logistic unit).

For purposes of identification, bar coding and RFID marking, the brand owner is responsible for determining the proper assignment of each particular Regulated Healthcare Trade Item to either the pharmaceutical or medical device category in accordance with local regulatory requirements.

### 4.2.2 GTIN Allocation Rules

Refer to Chapter 2 on page 17 for basic numbering rules. Specific rules that apply to healthcare trade items can be found in the Healthcare GTIN Allocation Rules publication found at [www.gs1.org/gtinrules/](http://www.gs1.org/gtinrules/).

### 4.2.3 GTIN-8, GTIN-12 and GTIN-13

Strict rules govern the allocation of GTIN-8s and these can be found in chapter 2 GTIN-8 on page 28

See chapter 2 GTIN-12 on page 52 for details on how to construct a GTIN-12

See chapter 2 GTIN-13 on page 27 for details on how to construct a GTIN-13



## 4.2.4 Rules for GTIN-14s

For trade items in general, a GTIN-14 can only be allocated to a uniform grouping (a standard and stable grouping of identical trade items). The brand owner has the option of either assigning a unique GTIN-13 or GTIN-12 to each uniform grouping or assigning a unique GTIN-14.

The GTIN-14 comprises an Indicator digit and the GTIN of the trade item (less its Check Digit) contained in each grouping. The Check Digit for each GTIN-14 is then recalculated. In the case of a GTIN-12 and a GTIN-8, one and five filler zeros respectively must be added after the Indicator digit.

The Indicator is a digit with a value of 1 to 9; Indicator 9 is reserved for variable measure trade items. Indicators have no meaning and are assigned as required by brand owner thereby creating extra numbering capacity.

	Format of the Element String			
	Global Trade Item Number (GTIN)			
	Indicator	GTIN of Contained Trade Items (Without Check Digit)		
GTIN-8 based	N <sub>1</sub>	0 0 0 0 0	N <sub>7</sub> N <sub>8</sub> N <sub>9</sub> N <sub>10</sub> N <sub>11</sub> N <sub>12</sub> N <sub>13</sub>	N <sub>14</sub>
GTIN-12 based	N <sub>1</sub>	0	N <sub>3</sub> N <sub>4</sub> N <sub>5</sub> N <sub>6</sub> N <sub>7</sub> N <sub>8</sub> N <sub>9</sub> N <sub>10</sub> N <sub>11</sub> N <sub>12</sub> N <sub>13</sub>	N <sub>14</sub>
GTIN-13 based	N <sub>1</sub>	N <sub>2</sub>	N <sub>3</sub> N <sub>4</sub> N <sub>5</sub> N <sub>6</sub> N <sub>7</sub> N <sub>8</sub> N <sub>9</sub> N <sub>10</sub> N <sub>11</sub> N <sub>12</sub> N <sub>13</sub>	N <sub>14</sub>

**TABLE 41** Formation of a GTIN-14

For packaging configuration hierarchies which include a Retail Consumer Trade Item identified with a GTIN-13, GTIN-12, or GTIN -8, this GTIN must always be one of the relevant levels of packaging contained, usually the lowest level (see bullet points under ‘Special rules for Regulated Healthcare Trade Items’). Restricted Circulation Numbers must not be used in this Element String.

### Special Rules for Regulated Healthcare Trade Items

- For Regulated Healthcare Trade Items on the Primary Packaging, the phrase “usually the lowest level” shall be interpreted as allowing for the use of GTIN-14 on packaging configurations below the Retail Consumer Trade Item level, if one exists. This interpretation **may not** be applied to other trade item categories.
- Any trade item which will encounter scanning or product listing for sale at retail POS shall be identified according to retail POS specifications. Refer to chapter 2 Retail POS - Fixed Measure on page 26.
- When a GTIN change at the Retail Consumer Trade Item level is required:
  - the GTIN change must be made at all configuration levels **above** the Retail Consumer Trade Item level.
  - for GTIN-14s on packaging configurations **below** the Retail Consumer Trade Item level (where the GTIN-14 is based on the retail level GTIN), there are three scenarios to consider:
    - If changes to the Primary Packaging drive the change of the GTIN assigned to the Retail Consumer Trade Item level, the GTIN of the Primary Packaging will change.



- If changes to Retail Consumer Trade Item level GTIN are not caused by a change in Primary Packaging, the GTIN at the Primary Packaging level may or may not change per the discretion of the brand owner.
- If additional retail level package(s) are introduced beyond the original retail package or replace the original retail package, the GTIN-14 on the Primary Packaging may remain tied to the original retail level GTIN.

## 4.2.5 Attribute Information

As mentioned previously, Regulated Healthcare Trade Items often require Application Identifiers (AIs) to provide additional information. Full details on AIs are found in chapter 8 GS1 Application Identifiers (AIs) on page 120.

## 4.2.6 Trade Item Extended Packaging

For information on Extended Packaging see Trade Item Extended Packaging on page 24.

For the specifications for GS1 DataMatrix encoding AI(8200) see Table 43 on page 92, Table 45 on page 96 and Table 47 on page 99.



## 4.3 Bar Coding

For information on all symbologies apart from GS1 DataMatrix and GS1 Composite, refer to chapter 9 Bar Code Printing and Dimensions on page 192 in this manual. For GS1 DataMatrix and GS1 Composite, refer to the GS1 Australia User Manual Bar Code Technical Details.

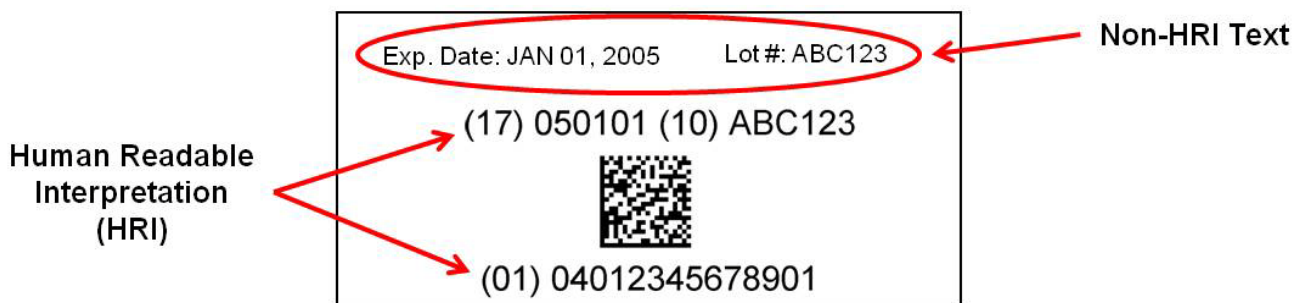
The particular bar coding options and symbol specifications for different types of Regulated Healthcare Trade Items are described separately in the sections that follow.

### 4.3.1 Human Readable Interpretation (HRI)

For the purposes of interpreting this standard, there are two types of text that appear on a label, package, or item: Human-Readable Interpretation (HRI) and non-HRI Text. See example in Figure 19 on page 85.

Human Readable Interpretation (HRI) is the information below or beside a barcode or tag which is encoded in the bar code or tag and represents the same characters as carried in the bar code or tag (See Glossary of Terms on page 257. for full definition).

Non-HRI Text is all other text on package, label or item (See Glossary of Terms on page 257. for full definition)



**Figure 19 HRI and Non-HRI Text**

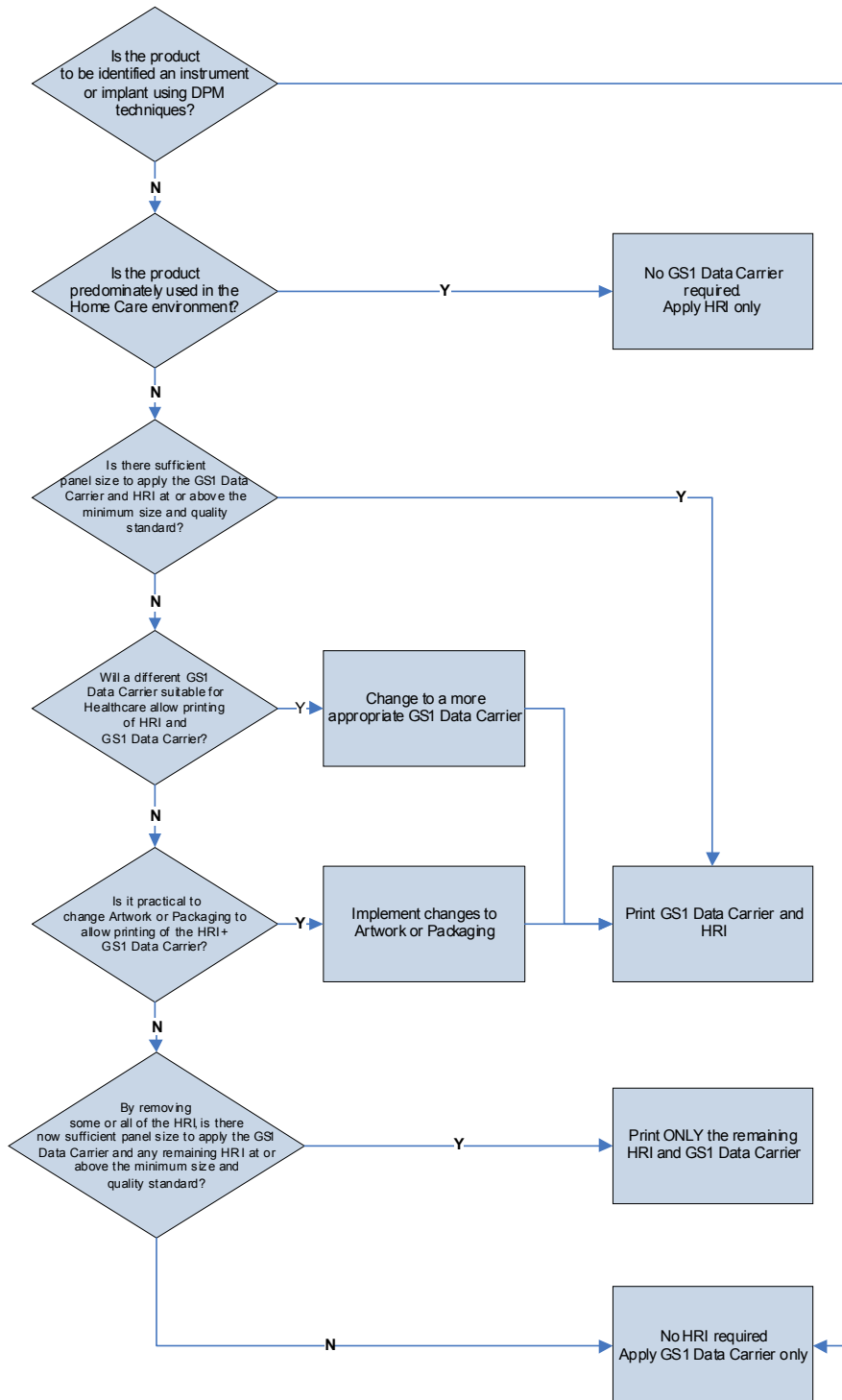
The GS1 System requires printing of both the GS1 Data Carrier and the HRI that represents all the information encoded within that GS1 Data Carrier. However, printing of both the GS1 Data Carrier and the associated HRI may not be possible due to many factors such as the type of item being labelled or marked, intended use of the item, available space for marking, etc.

If the GS1 Data Carrier cannot be read or scanned, usually the HRI should be used as backup information. If the HRI is not printed then the Non-HRI Text could be used as a backup.

Whenever it is not possible to print both the GS1 Data Carrier and HRI, Figure 20 on page 86 should be used to determine the most appropriate course of action to be taken in deciding how HRI will be implemented. When it is not possible to print all of the HRI, preference for printing shall be given to the GS1 Key.



**Figure 20 Healthcare Human Readable Interpretation (HRI) Decision Tree**





## Active Potency AI(7004) Rule

Printing of the Active Potency on the item is controlled by regulation. Human Readable Interpretation of the Active Potency is not required on the trade item.

## 4.3.2 Bar Code Location

Refer to chapter 10 Bar Code Location on page 229 for details on preferred location of bar codes. In addition to the general rules in this section the following placement rules should be added for Regulated Healthcare Trade Items:

### Blister Cells

Blister cells are pre-formed clear plastic bubbles, or blisters, containing a product.

#### Perforated Blister Cells

- Placement:
  - At the primary packaging level for pharmaceutical products packaged with perforated blister cells, a bar code shall be placed on each blister cell.

#### Non-Perforated Blister Cells

- Placement:
  - At the primary packaging level for pharmaceutical products packaged with non-perforated blister cells, a bar code shall be placed once on the grouping of blister cells (e.g. blister card). The bar code may be placed anywhere on the blister card.
  - If random printing (e.g. no one to one correlation between printing impression and blister cell position) is used, the symbol may be placed multiple times to ensure that the symbol remains scannable until each blister has been used.

## Products Requiring Variable Data On Primary and Secondary Packaging

Where such marking is feasible from a production and marking standpoint, the bar code carrying variable data (e.g. batch/lot number or expiry date) shall be marked on the primary and secondary packaging.

- Placement:
  - The bar code shall be placed only on one side of the packaging, which may be either the face, side or end panel.



## 4.4 Types of Regulated Healthcare Trade Items

In the following sections, numbering and bar coding of these Regulated Healthcare Trade items are considered:

- Healthcare Primary Packaging (Non-Retail Trade Items)
- Healthcare Secondary Packaging (Regulated Healthcare Retail Consumer Trade Items)
- Healthcare Items Scanned in General Distribution
- Small Medical/Surgical Instruments - Direct Part Marked

### 4.4.1 Healthcare Primary Packaging (Non-Retail Trade Items)

Healthcare Primary Packaging trade items are pharmaceutical and medical products or their packages presented to support the Point-of-Care (direct consumption based on right product, dose, and route of administration). Because the product is never scanned at retail POS the use of symbologies beyond EAN/UPC and the use of GTIN-14 data structure is permitted. These products, which may be packaged in a sterile packaging system or in a non-sterile packaging system, are only marked when the package is intended for dispensing to the consumer in a hospital or equivalent facility (e.g. field hospital, nursing home, home healthcare).

- GTIN-8, GTIN-12, GTIN-13 or GTIN -14 data structures
- GTIN attributes such as Batch/Lot Number, Expiration Dates, or Serial Numbers
- Marking with GS1 DataMatrix Bar Codes that require imaging-based scanners or linear symbologies such as GS1 DataBar or GS1-128.

See Multiple Bar Code Rules for Healthcare on page 102 if the product is intended for scanning at general retail and **also must** meet regulatory requirements for this application section based on multiple market use.

**Note:** If an item is a Regulated Healthcare Retail Consumer Trade Item and also a Non-Retail Trade Item, then the bar code marking for Regulated Healthcare Retail Consumer Trade Items is required at a minimum.

#### 4.4.1.1 Rules

- If the Regulated Healthcare Retail Consumer Trade Item to be marked on the Primary Packaging does not also have Secondary Packaging, then the Primary Packaging markings in this section do not apply and are replaced by the required markings in the Secondary Packaging section. Refer to Healthcare Secondary Packaging (Regulated Healthcare Retail Consumer Trade Items) on page 93

Example: a bottle of 50 pharmaceutical tablets (the Primary Package) is not enclosed into a carton (which would represent the Secondary Packaging). In this instance, the Secondary Packaging markings are required on the Primary Packaging level.



- If the required AIDC marks are placed directly on the part, then those AIDC marks (e.g., bar code, Human Readable Interpretation) satisfy the requirements for Primary Package marking and those marks are functional (scannable) through the Primary Packaging, then no additional AIDC marks are required on the Primary Package.
- If the product to be marked has Primary Packaging that is a blister pack containing several individual Pharmaceutical items, for instance a blister pack of 12 pills or tablets, then the GTIN is the only required mark.

Table 42 on page 89 describes the GTIN and attribute data required for Minimum, Enhanced and Highest Levels of AIDC marking. For bar coding refer to Data Carrier Choices on page 90.

AIDC Marking level	Key	Batch/Lot Number AI (10)	Expiration Date AI (17)	Serial Number AI (21)	Other
Minimum-pharmaceutical	GTIN-8, GTIN-12, GTIN-13, or GTIN-14	No	No	No	None
Enhanced-medical device	GTIN-8, GTIN-12, GTIN-13, or GTIN-14	Yes	Yes	No	None
Highest – pharmaceutical brand owner AIDC marking	GTIN-8, GTIN-12, GTIN-13, or GTIN-14	No	No	No	No
Highest – medical device - brand owner AIDC marking	GTIN-8, GTIN-12, GTIN-13, or GTIN-14	Yes	Yes	Yes	Active Potency AI (7004) for Kits with Pharmaceuticals
Highest – Hospital* AIDC marking of pharmaceutical	GTIN-8, GTIN-12, GTIN-13, or GTIN-14	No	Yes, AI (7003) if needed for short life items	Yes	None
Highest –Hospital* AIDC marking of certain medical devices (see page 100)	GRAI, AI (8003), or GIAI, AI (8004), is optional if GTIN, AI (01), + Serial Number, AI (21), is not marked on the product.	No	No	GRAI, AI (8003), or GIAI, AI (8004), is optional if GTIN, AI (01), + Serial Number, AI (21), is not marked on the product.	

\* Hospital AIDC marking refers to the process of numbering and bar coding by the hospital

**Note:** GS1 Application Identifiers may be used in GS1 endorsed Bar Codes as outlined under Data Carrier Choices on page 90 and may also be used in RFID tags as defined in the latest version of the EPC Tag Data Standards that can be found on at: <http://www.epcglobalinc.org/standards/tds/>

**TABLE 42** AIDC Marking for Regulated Healthcare Non-Retail Trade Items



#### 4.4.1.2 Data Carrier Choices

The preferred options long term are GS1 DataMatrix, GS1-128 and GS1 DataBar Symbologies. If a product package serves multiple markets then the appropriate rules must be followed together with the rules for use of multiple symbols outlined in Multiple Bar Code Rules for Healthcare on page 102.

**Note:** A Regulated Healthcare Non-Retail Trade Item can be marked with an EPC RFID tag in addition to the bar code.

Other acceptable bar code options include the EAN/UPC Symbology family and the ITF-14 Bar Code. If attribute information is required, a GS1 Composite Bar Code can be used but GS1 DataMatrix is preferred as it encodes GTIN and AIs in the one symbol and does so efficiently in terms of print speed and panel size.



### 4.4.1.3 Symbol Specifications of Regulated Healthcare Non-Retail Trade Items (not scanned in General Distribution)

For each symbol type, particular X-dimension, minimum symbol height and minimum symbol quality apply. Table 43 on page 92 summarise these specifications for Regulated Healthcare Non-Retail Consumer Trade Items. Note that this table contains several symbol options all of which are permitted to promote backward compatibility. .

Symbol(s) Specified	X-Dimension mm			Minimum Symbol Height for Given X (mm)			Quiet Zone		Minimum Quality Specification
	Min	Target	Max	For Min. X-dim.	For Target X-dim	For Max. X-dim	Left	Right	
GS1-128	0.170	0.495	0.495	12.70	12.70	12.70	10X	10X	1.5/10/670
GS1 DataMatrix (ECC 200) **	0.255	0.380	0.495	Height is determined by X-Dimension for Data that is encoded			1X *	1X *	1.5/***/670
GS1 DataBar Omnidirectional ****	0.170	0.200	0.410	5.61	6.60	13.53	Not Applic.	Not Applic.	1.5/06/670
GS1 DataBar Truncated***	0.170	0.200	0.410	2.21	2.60	5.33	Not Applic.	Not Applic.	1.5/06/670
GS1 DataBar Stacked***	0.170	0.200	0.410	2.21	2.60	5.33	Not Applic.	Not Applic.	1.5/06/670
GS1 DataBar Stacked Omnidirectional ****	0.170	0.200	0.410	11.73	13.80	28.29	Not Applic.	Not Applic.	1.5/06/670
GS1 DataBar Limited***	0.170	0.200	0.410	1.70	2.00	4.10	Not Applic.	Not Applic.	1.5/06/670
GS1 DataBar Expanded****	0.170	0.200	0.410	5.78	6.80	13.94	Not Applic.	Not Applic.	1.5/06/670
GS1 DataBar Expanded Stacked****	0.170	0.200	0.410	12.07	14.20	29.11	Not Applic.	Not Applic.	1.5/06/670
EAN-13	0.170	0.330	0.660	20.73	25.91	51.82	11X	7X	1.5/06/670
EAN-8	0.170	0.330	0.660	17.03	21.29	42.58	7X	7X	1.5/06/670
UPC-A	0.170	0.330	0.660	20.73	25.91	51.82	9X	9X	1.5/06/670
UPC-E	0.170	0.330	0.660	20.73	25.91	51.82	9X	7X	1.5/06/670
ITF-14	0.170	0.495	0.495	12.70	12.70	12.70	10X	10X	1.5/10/670



CC-A	All CCs need to be printed at the same printing densities as their linear components, therefore consult the appropriate row and column for the linear symbol to be used.	Height is determined by X-Dimension for data that is encoded	1X	1X	1.5/06/670
CC-B			1X	1X	1.5/06/670
CC-C			2X	2X	1.5/06/670

\* 2D Quiet Zones - Quiet Zones for GS1 DataMatrix are 1X on all four sides.

\*\* 2D X-dimension - Because of the physics of optics, GS1 DataMatrix needs to be printed at 1.5 times the equivalent printing density allowed for linear or Composite Symbols.

\*\*\* 2D Quality Measurement - The effective aperture for GS1 DataMatrix quality measurements should be taken at 80% of the printing density. An aperture of 8 is used for Regulated Healthcare Non-Retail Consumer Trade Items in this application.

\*\*\*\* The GS1 DataBar Symbology has symbol characters in which spaces can be 9X in width and for omnidirectional scanners in autodiscrimination mode, performance loss can occur in large symbols due to the 9X space appearing as a Quiet Zone. Maximum X-dimension for GS1 DataBar Symbols is therefore set at 0.41 mm until further tests are performed.

**TABLE 43** Symbol Specifications for Regulated Healthcare Non-Retail Consumer Trade Items



## 4.4.2 Healthcare Secondary Packaging (Regulated Healthcare Retail Consumer Trade Items)

A Regulated Healthcare Retail Consumer Trade Item is not intended to be scanned in high volumes per consumer transaction at retail but does require additional data beyond GTIN to support regulatory requirements. This means, these trade items support:

- GTIN-8, GTIN-12 or GTIN-13 data structures
- GTIN attributes such as Batch/Lot Number, Expiration Dates, or Serial Numbers
- Marking with GS1 DataMatrix Bar Codes that require imaging-based scanners or linear symbologies such as GS1 DataBar or GS1-128.

**Note:** If an item is both a General Retail Consumer Trade Item and Regulated Healthcare Retail Consumer Trade Item then the bar code marking for general retail is required at a minimum. For General Retail Consumer Trade Item bar code marking, refer to the table on page 193 then follow the appropriate page reference for the bar code required.

Table 44 on page 94 describes the GTIN and attribute data required for Minimum, Enhanced and Highest Levels of AIDC marking.

For bar coding refer to Data Carrier Choices on page 90.



#### 4.4.2.1 Rules

AIDC Marking level	Key	Batch/ Lot Number - AI (10)	Expiration Date – AI (17)	Serial Number – AI (21)	Other
Minimum – pharmaceutical & medical device	GTIN-8, GTIN-12, GTIN-13	Yes	Yes	No	None
Enhanced – pharmaceutical & medical device	GTIN-8, GTIN-12, GTIN-13	Yes	Yes	No	None
Highest – brand owner AIDC marking pharmaceutical and medical devices	GTIN-8,GTIN-12, GTIN-13	Yes	Yes	Yes	Potency AI (7004) (for Pharmaceutical, and for medical device Kits with Pharmaceuticals)
Highest – hospital* AIDC marking of pharmaceuticals	GTIN-8,GTIN-12, GTIN-13	No	Yes, AI (7003) if needed for short life items	Yes	None
Highest - hospital* AIDC marking of certain medical devices	GRAI, AI (8003), or GIAI, AI (8004), is optional if GTIN, AI (01), + Serial Number, AI (21), is not marked on the product.	No	No	GRAI, AI (8003), or GIAI, AI (8004), is optional if GTIN, AI (01), + Serial Number, AI (21), is not marked on the product.	
* Hospital AIDC marking refers to the process of numbering and bar coding by the hospital GS1 Application Identifiers may be used in GS1 endorsed Bar Codes as outlined under Data Carrier Choices on page 90 and may also be used in RFID tags as defined in the latest version of the EPC Tag Data Standards that can be found on at: <a href="http://www.epcglobalinc.org/standards/tds/">http://www.epcglobalinc.org/standards/tds/</a>					

**TABLE 44** Regulated Healthcare Retail Consumer Trade Item Identification





## 4.4.2.2 Symbol Specifications for Regulated Healthcare Retail Consumer Trade Items

For each symbol type, particular X-dimensions, minimum symbol height and minimum symbol quality apply. Table 45 on page 96 summarises these specifications for Regulated Healthcare Retail Consumer Trade Items. Note that this table contains several symbol options all of which are permitted to promote backward compatibility; for more details refer to the note following this table.

Symbol(s) Specified	X-Dimension mm			Minimum Symbol Height for Given X mm			Quiet Zone		Min Quality Specification
	Min	Target	Max	For Min X-dim	For Target X-dim	For Max X-dim	Left	Right	
GS1-128	0.264	0.330	0.660	12.70	12.70	12.70	10X	10X	1.5/10/670
GS1 DataMatrix (ECC 200)**	0.396	0.495	0.990	Height is determined by X-Dimension for Data that is encoded			1X*	1X*	1.5/***/670
GS1 DataBar Omnidirectional	0.264	0.330	0.660	8.71	10.89	13.53	Not Applic.	Not Applic.	1.5/06/670
GS1 DataBar Truncated	0.264	0.330	0.660	3.43	4.29	5.33	Not Applic.	Not Applic.	1.5/06/670
GS1 DataBar Stacked	0.264	0.330	0.660	3.43	4.29	5.33	Not Applic.	Not Applic.	1.5/06/670
GS1 DataBar Stacked Omnidirectional	0.264	0.330	0.660	18.22	27.77	28.29	Not Applic.	Not Applic.	1.5/06/670
GS1 DataBar Limited	0.264	0.330	0.660	2.64	3.30	4.10	Not Applic.	Not Applic.	1.5/06/670
GS1 DataBar Expanded	0.264	0.330	0.660	8.98	11.22	13.94	Not Applic.	Not Applic.	1.5/06/670
GS1 DataBar Expanded Stacked	0.264	0.330	0.660	18.74	23.43	29.11	Not Applic.	Not Applic.	1.5/06/670
EAN-13	0.264	0.330	0.660	20.73	25.91	51.82	11X	7X	1.5/06/670
EAN-8	0.264	0.330	0.660	17.03	21.29	42.58	7X	7X	1.5/06/670
UPC-A	0.264	0.330	0.660	20.73	25.91	51.82	9X	9X	1.5/06/670
UPC-E	0.264	0.330	0.660	20.73	25.91	51.82	9X	7X	1.5/06/670





ITF-14	0.264	0.330	0.660	12.70	12.70	12.70	10X	10X	1.5/10/670
<p>* 2D Quiet Zones - Quiet Zones for GS1 DataMatrix are 1X on all four sides.</p> <p>** 2D X-dimension - Because of the physics of optics, GS1 DataMatrix needs to be printed at 1.5 times the equivalent printing density allowed for linear or Composite Symbols.</p> <p>*** 2D Quality Measurement - The effective aperture for GS1 DataMatrix quality measurements should be taken at 80% of the printing density. An aperture of 8 is used for Regulated Healthcare Non-Retail Consumer Trade Items in this application.</p>									

**TABLE 45** Symbol Specifications for Regulated Healthcare Retail Consumer Trade Items

**Note:** Since June 2007 GS1 has recommended all trading partners in the healthcare sector invest exclusively in imaging-based scanners. Now that GS1 DataMatrix has been approved within the standard, it is important to inform all trading partners of a process within GS1 to establish target deployment dates. Without these dates, brand owners do not have a way of knowing when to deploy GS1 DataMatrix on their packaging and those needing to invest in scanning equipment may inadvertently purchase equipment that will not support the standards. In GS1, strategic AIDC “Sunrise” or target implementation dates are approved by the GS1 Board and GS1 General Assembly after a recommendation is provided by a Task Force. In this situation, the GS1 Healthcare Leadership Team will support the Task Force being established to consider all options and has proposed a target deployment date for use of GS1 DataMatrix in open trade on all Regulated Healthcare Trade Items (no barriers). Once this date is approved, GS1 DataMatrix, GS1 DataBar versions, GS1-128, and ITF-14 will be added to the list of permitted symbols for use in retail pharmacies. GS1 DataMatrix will also be added to the list of symbols permitted for use in automated scanning environments.



## 4.4.3 Healthcare Items Scanned in General Distribution

If the item is a single product, it may be identified with a GTIN-8, GTIN-12, GTIN-13 or, under the conditions described in Rules for GTIN-14s on page 83, a GTIN-14.

If the item is a uniform grouping of trade items it may be identified with a GTIN-12, GTIN-13 or GTIN-14 (See Identification on page 82)

In addition to the GTIN, attribute data may be needed. The specific requirements for identification are outlined in Table 46 on page 98 and for bar coding in Data Carrier Choices on page 98.



### 4.4.3.1 Rules

AIDC Marking level	Key	Batch/Lot Number AI (10)	Expiration Date AI (17)	Serial Number AI (21)	Other
Minimum-pharmaceutical and medical	GTIN-8, GTIN-12, GTIN-13, GTIN -14	Yes	Yes	No	None
Enhanced-pharmaceutical and medical	GTIN-8, GTIN-12, GTIN-13, GTIN -14	Yes	Yes	No	None
Highest – brand owner AIDC marking	GTIN-8, GTIN-12, GTIN-13, GTIN -14	Yes	Yes	Yes	Potency AI (7004) for pharmaceutical and for medical device Kits with pharmaceutical (cases only for both situations)
Highest – Hospital* AIDC marking of pharmaceutical	GTIN-8, GTIN-12, GTIN-13, GTIN -14	No	Yes, AI (7003) for short life items	Yes	None
Highest – AIDC marking of medical devices	No	No	No	No	None

\* Hospital AIDC marking refers to the process of numbering and bar coding by the hospital

GS1 Application Identifiers may be used in GS1 endorsed Bar Codes as outlined under Data Carrier Choices on page 90 and may also be used in RFID tags as defined in the latest version of the EPC Tag Data Standards that can be found at: <http://www.epcglobalinc.org/standards/tds/>

**TABLE 46** Identification of Regulated Healthcare Trade Items Scanned in General Distribution

### 4.4.3.2 Data Carrier Choices

The preferred option is GS1-128 Symbology and if one symbol cannot accommodate the data (i.e. data exceeds 48 characters) two symbols should be used. Where the package or label size does not permit the use of GS1-128 Symbology, GS1 DataMatrix is permitted but should be avoided wherever possible if the package could be scanned by a mounted conveyerised scanner.

A Regulated Healthcare Non-Retail Trade Item can be marked with an EPC RFID tag in addition to the bar code.

Other acceptable bar code options include the EAN/UPC Symbology family and the ITF-14 Bar Code. If attribute information is required, a GS1 Composite Bar Code can be used but GS1 DataMatrix is preferred as it encodes GTIN and AIs in the one symbol and does so efficiently in terms of print speed and panel size.



### 4.4.3.3 Symbol Specifications for Regulated Healthcare Trade Items Scanned in General Distribution

For each symbol type, particular X-dimensions, minimum symbol height and minimum symbol quality apply. Table on page 99 summarises these specifications for Regulated Healthcare Trade Items scanned in General Distribution. Please refer to the note that follows this table also.

Symbol(s) Specified	X-dimension mm			Minimum Symbol Height for Given X (mm)			Quiet Zone		Minimum Quality Specification
	Min	Target	Max	For Min X-dim	For Target X-dim	For Max X-dim	Left	Right	
GS1-128	0.495	0.495	1.016	32.00	32.00	32.00	10X	10X	1.5/10/670
GS1 DataMatrix (ECC 200)**	0.750	0.750	1.520	Height is determined by X-Dimension for Data that is encoded			1X*	1X*	1.5/***/670
EAN-13	0.495	0.660	0.660	38.87	51.82	51.82	11X	7X	1.5/06/670
EAN-8	0.495	0.660	0.660	31.94	42.58	42.58	7X	7X	1.5/06/670
UPC-A	0.495	0.660	0.660	38.87	51.82	51.82	9X	9X	1.5/06/670
UPC-E	0.495	0.660	0.660	38.87	51.82	51.82	9X	7X	1.5/06/670
ITF-14	0.495	0.495	1.016	32.00	32.00	32.00	10X	10X	1.5/10/670

\* 2D Quiet Zones - Quiet Zones for GS1 DataMatrix are 1X on all four sides.

\*\* 2D X-dimension - Because of the physics of optics, GS1 DataMatrix needs to be printed at 1.5 times the equivalent printing density allowed for linear or Composite Symbols.

\*\*\* 2D Quality Measurement - The effective aperture for GS1 DataMatrix quality measurements should be taken at 80% of the printing density. An aperture of 8 is used for Regulated Healthcare Non-Retail Consumer Trade Items in this application.

**TABLE 47** Symbol Specifications for Trade Items Scanned in Retail Pharmacy and General Distribution or Non-Retail Pharmacy and General Distribution

**Note:** Since June 2007 GS1 has recommended all trading partners in the healthcare sector invest exclusively in imaging-based scanners. Now that GS1 DataMatrix has been approved within the standard, it is important to inform all trading partners of a process within GS1 to establish target deployment dates. Without these dates, brand owners do not have a way of knowing when to deploy GS1 DataMatrix on their packaging and those needing to invest in scanning equipment may inadvertently purchase equipment that will not support the standards. In GS1, strategic AIDC "Sunrise" or target implementation dates are approved by the GS1 Board and GS1 General Assembly after a recommendation is provided by a Task Force. In this situation, the GS1 Healthcare Leadership Team will support the Task Force being established to consider all options and has proposed a target deployment date for use of GS1 DataMatrix in open trade on all Regulated Healthcare Trade Items (no barriers). Once this date is approved, GS1 DataMatrix, GS1-128, and ITF-14 will be added to the list of permitted symbols for use in retail pharmacies. GS1 DataMatrix will also be added to the list of symbols permitted for use in automated scanning environments.



## 4.4.4 Small Medical/Surgical Instruments - Direct Part Marked

Direct part marking (DPM) refers to the process of marking a symbol directly onto an item using an intrusive or non-intrusive method instead of applying a label or using another indirect marking process. Within this application are the rules and recommendations for the direct part marking of small medical/surgical instruments for the Automatic Identification and Data Capture (AIDC) management of instruments within the micro-logistics cycle of use, cleaning and sterilization.

Small medical/surgical instruments shall be identified with GTIN and AI (21) Serial Number in all future brand owner/source marking cases. The use of GTIN and AI (21) Serial Number is also preferred for all hospital/instrument owner marking. However, recognizing that some existing in-house legacy systems use GS1 asset identifiers (GIAI or GRAI), hospital/instrument owners may use GIAI or GRAI for marking. For more information on Assets Identification refer to chapter 4 Numbering Assets on page 79.

**Note:** At no time should two different identification numbers be marked on a single instrument

There are two basic types of non ink based Direct Part Marks:

- GS1 DataMatrix Direct Part Marking – A  
Symbols produced with these types of methods have “connected modules” in the “L” shaped finder pattern created by DPM marking technologies such as laser or chemical etching
- GS1 DataMatrix Direct Part Marking – B  
Symbols produced with these types of methods have “non connected modules” in the “L” shaped finder pattern created by DPM marking technologies such as dot peen.

Due to the marking technologies and characteristics of reading the two methods each have varied ranges of X-Dimensions and different quality criteria recommended and may require different reading equipment.

GS1 DataMatrix – A is suggested for marking of small medical / surgical instruments. The Minimum X-Dimension of 0.100mm shown in Table 48 on page 101 is based upon the specific need for permanence in direct marking of small medical instruments which have limited marking area available on the instrument with a target useable area of 2.5mm x 2.5mm and a data content of GTIN (AI 01) plus Serial Number (AI 21).





#### 4.4.4.1 Symbol Specifications for Direct Part Marking of small Medical/Surgical Instruments

For each symbol type that is permitted for Direct Part Marking of small medical/surgical instruments, particular X-dimensions, minimum symbol height and minimum symbol quality apply. These specifications are summarised in Table 48 on page 101

Symbol(s) Specified	X-Dimension mm ****			Minimum Symbol Height for Given X-dimension mm			Quiet Zone	Minimum Quality Specification
	Min	Target	Max	For Min X-dim	For Target X-dim	For Max X-dim		
GS1 DataMatrix Ink Based Direct Part Marking	0.255	0.300	0.615	Height is determined by X-Dimension for data that is encoded			1X on all four sides	1.5/08/670 ***
GS1 DataMatrix Direct Part Marking - A	0.100	0.200	0.300	Height is determined by X-Dimension for data that is encoded			1X on all four sides	1.5/03/* ** ***
GS1 DataMatrix Direct Part Marking - B	0.200	0.300	0.495	Height is determined by X-Dimension for data that is encoded			1X on all four sides	1.5/06/* ** ***

\* The wavelength for Direct Part Marked GS1 DataMatrix is based upon the practical scanning environment and thus must in the grade be matched to the scanner / imagers being used. See ISO/IEC 15415 and AIM DPM-1-2006.

\*\* The angle is an additional parameter defining the angle of incidence (relative to the plane of the symbol) of the illumination for Direct Part Marking verification. It shall be included in the overall symbol grade when the angle of incidence is other than 45 degrees. Its absence indicates that the angle of incidence is 45 degrees. See ISO/IEC 15415 and AIM DPM-1-2006.

\*\*\* The effective aperture for GS1 DataMatrix quality measurements should be taken at 80 percent of the minimum X-dimension allowed for the application. For Direct Part Marking - A this would equate to an aperture of 3; for Direct Park Marking – B this would equate to an aperture of 6 and for general healthcare label printing, an aperture of 8. See ISO/IEC 15415 and AIM DPM-1-2006

\*\*\*\* The largest X-dimension in a given range that will allow a symbol with the needed data content to fit within the available marking area should be used to maximise marking and reading performance (depth of field, tolerance to curvature, etc.).

**TABLE 48** Symbol Specifications for Direct Part Marking of Small Medical/Surgical Instruments

**Note:** In small instrument marking, mixed marking technologies used within the same scanning environment should be avoided to ensure highest reading performance. Laser etching is recommended for small instrument marking.



## 4.5 Multiple Bar Code Rules for Healthcare

A product package that serves multiple markets may have the need for application of multiple bar codes. When this occurrence is unavoidable, the rules for use of multiple symbols found in Table 49 on page 104 apply. This table separates solutions based on combinations of scanner environments encountered for each scenario:

- Scanners Encountered Combination #1: Package scanned in retail pharmacies AND NOT in general distribution
- Scanners Encountered Combination #2: Package NOT scanned in retail pharmacies BUT in general distribution

Combinations of Scanners Encountered	Bar Code		Data Scenario		Scanner Environment	Symbol Arrangement	Bar Code Options	Gen Spec	Proposal
	Symbol 1	Symbol 2	Retail Pharmacy or Non-Retail Pharmacy /Bedside	Automated Conveyor					
#1	GTIN A	Only Attributes for GTIN A	Y	N	NA	GS1 DataMatrix GS1-128 GS1 DataBar * EAN/UPC or * ITF-14 plus GS1 DataMatrix, GS1 DataBar Expanded, GS1-128, or * EAN/UPC, GS1 DataBar, or GS1-128 plus ** Composite Component	2.1.2.3 2.1.2.4	Note 1 Note 10 * Note, 2 ** Note 3	
#2	GTIN A	Only Attributes for GTIN A	Y	Y	Horizontal	GS1 DataMatrix GS1-128 *EAN/UPC or * ITF-14 plus GS1 DataMatrix or GS1-128	2.1.2.6 2.1.2.7	Note 1 Note 10 * Note 2	



#1	GTIN A	*GTIN A + GTIN A Attributes	Y	N	Depends upon packaging limitations	GS1 DataMatrix GS1-128 GS1 DataBar ** EAN/UPC or ** ITF-14 plus GS1 DataMatrix, GS1 DataBar Expanded, GS1-128,  or ** EAN/UPC, GS1 DataBar, or GS1-128 plus *** Composite Component	2.1.2.3 2.1.2.4	Note 1 Note 4 Note 10 * Note 5 ** Note 6 *** Note 3
#2	GTIN A	*GTIN A + GTIN A Attributes	Y	Y	Depends upon packaging limitations	GS1 DataMatrix GS1-128 **EAN/UPC or **ITF-14 plus GS1 DataMatrix or GS1-128	2.1.2.6 2.1.2.7	Note 1 Note 2 Note 4 Note 10 * Note 5
#1	GTIN A + Attribute Set 1	GTIN A + Attribute Set 1	Y	N	Duplicate symbols on bulky packages	GS1 DataMatrix GS1-128 GS1 DataBar Expanded EAN/UPC plus Composite Component	Duplicate of first symbol 2.1.2.3 2.1.2.4	Note 1 Note 5 Note 7 Note 10
#2	GTIN A + Attribute Set 1	GTIN A + Attribute Set 1	Y	Y	Duplicate symbols on bulky packages	GS1 DataMatrix GS1-128 EAN/UPC plus Composite Component	Duplicate of first symbol 2.1.2.6 2.1.2.7	Note 1 Note 5 Note 7 Note 10
#1	GTIN A + Attribute Set 1	GTIN A + Attribute Set 2	Y	N	Depends upon packaging limitations	GS1 DataMatrix GS1-128 GS1 DataBar Expanded EAN/UPC plus Composite Component	GS1 DataMatrix GS1-128 GS1 DataBar Expanded EAN/UPC plus Composite Component	2.1.2.3 2.1.2.4 Note 1 Note 5 Note 8 Note 10



#2	GTIN A + Attribute Set 1	GTIN A + Attribute Set 2	Y	Y	Horizontal	GS1 DataMatrix GS1-128	GS1 DataMatrix GS1-128	2.1.2.6 2.1.2.7	Note 1 Note 5 Note 8 Note 10
#1	GTIN with Serial Number	GTIN A or GRAI	Not Permitted in Regulated Healthcare on Small Surgical Instruments where only one mark can be made based on the available marking surface and SGTIN is source-marked by brand owner on that surface See Note 10 below						
#1 or #2	GTIN A	GTIN B	Not Permitted						
#2	GTIN A	SSCC	Permitted. Symbol placement per Section 6. (All clauses contained in sections 6.2,6.4, 6.6, 6.7 and 6.8) See Note 10 below						
#1	SSCC	AI (02) + AI (37)	Y	N	Vertical	GS1-128	GS1-128	2.2.1	Note 9
#2	SSCC	AI (02) + AI (37)	Y	Y	Vertical	GS1-128	GS1-128	2.2.1	Note 9
#1 and #2	GS1 Data carried by 1 or 2 symbols	Non-GS1 Data	Symbols containing internal or proprietary data should not be placed in a location where they could be scanned in the open supply chain (e.g. retail POS, by an automated conveyor line scanner per GS1 specifications) See Note 10						

**TABLE 49** Multiple Bar Code Management Rules

**Note 1:** Concatenation into one symbol is the preferred option for Regulated Healthcare Retail Consumer Trade Items to validate connectivity between GTIN and attributes

**Note 2:** Symbols which are not preferred for Regulated Healthcare Retail Consumer Trade Items because they do not allow for concatenation but remain permissible options.

**Note 3:** GS1 Composite Component does not stand alone as a complete symbol; it is necessary to associate the composite component with a linear symbol such as EAN/UPC, ITF-14, GS1-128 or GS1 DataBar. GS1 Composite Component therefore remains a legitimate option however **but only in non-retail applications**, GS1 DataMatrix is preferred for Regulated Healthcare Retail Consumer Trade Items based on its ability to encode all information in one symbol and do so efficiently in terms of print speed and panel size.

**Note 4:** It is recommended to use only one symbol that contains the GTIN and attributes

**Note 5:** Using Two Symbol Types with GTIN Is Not Recommended

**Note 6:** Symbols which are not preferred for Regulated Healthcare Retail Consumer Trade Items because they do not allow for concatenation but remain permissible options. Where these symbols carry GTIN no other symbol type carrying GTIN is recommended

**Note 7:** Recommended for bulky or large trade items or pallets

**Note 8:** Wherever possible use of one symbol to carry GTIN plus all attributes is preferred to carrying attributes in two symbols

**Note 9:** AI (02) + AI (37) not recommended in regulated healthcare supply chain



**Note 10:** Since June 2007 GS1 has recommended all trading partners in the healthcare sector invest exclusively in imaging-based scanners. Now that GS1 DataMatrix has been approved within the standard, it is important to inform all trading partners of a process within GS1 to establish target deployment dates. Without these dates, brand owners do not have a way of knowing when to deploy GS1 DataMatrix on their packaging and those needing to invest in scanning equipment may inadvertently purchase equipment that will not support the standards. In GS1, strategic AIDC “Sunrise” or target implementation dates are approved by the GS1 Board and GS1 General Assembly after a recommendation is provided by a Task Force. In this situation, the GS1 Healthcare Leadership Team will support the Task Force being established to consider all options and has proposed a target deployment date for use of GS1 DataMatrix in open trade on all Regulated Healthcare Trade Items (no barriers). Once this date is approved, GS1 DataMatrix, GS1-128, and ITF-14 will be added to the list of permitted symbols for use in retail pharmacies. GS1 DataMatrix will also be added to the list of symbols permitted for use in automated scanning environments.

## 4.6 Logistic Units

For information on Logistic Units refer to Chapter 3 on page 65 but note the following requirements for Regulated Healthcare:

- Use of AI (02) and AI (37) with SSCC AI (00) is not the preferred option for Regulated Healthcare Trade Items. For Regulated Healthcare Trade Items, AI (02) + AI (37) is limited to bilateral use between trading partners for exception handling during a migration period to eCom (EDI) implementation or if the product is sold as a non-regulated trade item within a retail distribution channel for certain markets. SSCC is the approach selected by healthcare and provides the appropriate level of identification when associated with eCom messaging to provide traceability inclusive of count for trade items contained. SSCC when associated with eCom is required for identification purposes to reach our extended goals for traceability.
- The mandatory data carrier used to represent GS1 System individual logistic units is the GS1-128 Bar Code Symbology. For healthcare, an EPC RFID tag can be present in addition to the bar code.

