Barcode requirements and implementation using GS1 standards are provided below at various levels of product packaging including at primary, secondary and shipper/carton levels and need to be complied with while supplying medical devices & other medical supplies to MoHFW.

Note: Barcodes using GS1 identification standards are required to be marked on product packaging in addition to existing statutory labeling & marking requirements.

Section A) Primary Level Packaging

Primary Level Packaging: Is defined as the first level of packaging in direct contact with the product and marked with an AIDC (Automatic Identification and Data Capture) data carrier either on the packaging or on a label affixed to the packaging. It 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.

Barcodes using GS1 standards are required to be marked onto the primary level packaging encoding GS1 product identification code (called GTIN–Global Trade Item Number).

Due to the wide variety of primary level packaging configurations for medical devices, following is additional guidance on defining the primary level packaging. Many medical devices contain an inner package which holds the actual product, enclosed in an outer package (e.g., a shelf pack or sterile outer pouch). The definition of primary level packaging is intended to require AIDC markings on only one of these packaging components as determined by the manufacturing process. See examples below:

- Device packaged in one-level sterile pouch.
- Device packaged in sterile blister pack enclosed in a second sterile outer pouch
- Multiple, different Devices intended for one therapy packaged in a single tray, and that single tray contained in a single outer carton (may also be referred to as a Kit):
  - The single tray = primary level packaging
  - The outer carton = secondary level packaging (see below)

Note: If a medical device meets the criteria for the 'Minimum Level of AIDC Marking (non-retail)' then no barcode on the primary level packaging is recommended. This applies to low-value consumables that are not likely to be scanned in a clinical setting as part of a therapy (for example, disposable drapes, gowns, syringe filters, syringes, and similar medical devices).

Complex medical devices, Reusable medical devices and implants (e.g., pacemakers, heart valves, re-processed instruments, re-sterilized instruments, X-ray machines, MRI machines, surgical instruments, Infusion pumps, etc.) which are considered high
risk items and are required by regulation to be tracked using serial number or batch number, should be marked with GTIN+ Serial Number/Lot No./Batch No. (whichever is applicable)+ Expiry date on the primary level packaging.

**GTINs (Global Trade Item Numbers):** It is the GS1 identification key used to uniquely identify each product type/variant. It is created using a GS1 or U.P.C. Company Prefix number. GTIN can be of 14 digits (i.e. GTIN -14) or 13 digits (i.e. GTIN -13) or 12 digits (i.e. GTIN -12) or 8 digits (i.e. GTIN -8) depending on barcode symbology used.

**Steps for Generation of GTINs:**

**Please Note:** - The company prefix number in this manual is only an example. The supplying company has to use the company prefix number issued by GS1 India or any other GS1 member organizations in other countries.

**Generation of GTIN -13:**

**Data structure and format of GTIN-13**

<table>
<thead>
<tr>
<th>GS1 Company Prefix</th>
<th>&lt; Item Reference</th>
<th>Check Digit</th>
</tr>
</thead>
<tbody>
<tr>
<td>N₁ N₂ N₃ N₄ N₅ N₆ N₇ N₈ N₉ N₁₀ N₁₁ N₁₂ N₁₃</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Steps to generate, GTIN-13 (13 digits product identification code):-

1) Use company prefix number allocated by GS1 India to your company
2) Assign item reference number of your own choice
3) Calculate check digit using Check Digit Calculator ( available at http://www.gs1india.org/serv/checkdgt.htm )

**Example:**

<table>
<thead>
<tr>
<th>GS1 Company Prefix</th>
<th>&gt;</th>
<th>&lt;</th>
<th>Item Reference</th>
<th>Check Digit</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 9 0 1 1 0 7 0 0 0 0 1 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In this example, we have
- Used company prefix number “8901107”
- Assigned item reference number “ 00001”
- Calculated Check Digit 1

**Generation of GTIN -12:**

**Data structure and format (GTIN – 12):**

<table>
<thead>
<tr>
<th>GS1 Company Prefix</th>
<th>&gt;</th>
<th>&lt;</th>
<th>Item Reference</th>
<th>Check Digit</th>
</tr>
</thead>
<tbody>
<tr>
<td>N₁ N₂ N₃ N₄ N₅ N₆ N₇ N₈ N₉ N₁₀ N₁₁ N₁₂</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Steps to generate, GTIN-12 (12 digits product identification code):-

1) Use the company prefix number allocated by GS1 India on registration
2) Generate an item reference number of your own choice (Variable length dependent on length of company prefix number allocated)
3) Calculate check digit using check digit calculator ( available at http://www.gs1india.org/serv/checkdgt.htm )
**Example:** Using a company prefix “8901107”

<table>
<thead>
<tr>
<th>GS1 Company Prefix</th>
<th>&gt; &lt; Item Reference</th>
<th>Check Digit</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>9</td>
<td>0</td>
</tr>
</tbody>
</table>

In this example,
- GS1 company prefix number is "8901107"
- Item reference number "0001" (Is generated by user at random)
- Calculated check digit “9”.

**The structure of GTIN – 8**

<table>
<thead>
<tr>
<th>N₁</th>
<th>N₂</th>
<th>N₃</th>
<th>N₄</th>
<th>N₅</th>
<th>N₆</th>
<th>N₇</th>
<th>N₈</th>
</tr>
</thead>
</table>

All GTIN 8 product codes are always allocated by GS1 India.

**Example:**

<table>
<thead>
<tr>
<th>GS1 Item Reference</th>
<th>Check Digit</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>9</td>
</tr>
</tbody>
</table>

**Generation of GTIN-14:**

**Data structure and format (GTIN – 14):**

<table>
<thead>
<tr>
<th>Indicator Digit</th>
<th>GS1 Company Prefix</th>
<th>&gt; &lt; Item Reference</th>
<th>Check Digit</th>
</tr>
</thead>
<tbody>
<tr>
<td>N₁</td>
<td>N₂</td>
<td>N₃</td>
<td>N₄</td>
</tr>
</tbody>
</table>

Steps to generate, GTIN-14 (14 digits product identification code):-

1) In this example we have generated GTIN-14 from GTIN-13. GTIN-14 can also be generated from GTIN-13,GTIN-12 & GTIN-8.

   Please refer to GS1 General Specifications on the use of indicator digit in healthcare.

2) Use the company prefix number allocated by GS1 India.

3) Generate an item reference number of your own choice (Variable length, dependent on length of company prefix number allocated)

4) Calculate check digit using Check Digit Calculator (available at [http://www.gs1india.org/serv/checkdgt.htm](http://www.gs1india.org/serv/checkdgt.htm))

**Example:** Using the company prefix “8901107”

<table>
<thead>
<tr>
<th>Indicator Digit</th>
<th>Company Prefix Code</th>
<th>&gt; &lt; Item Reference</th>
<th>Check Digit</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>8</td>
<td>9</td>
<td>0</td>
</tr>
</tbody>
</table>

In this example
- Use "0" as Indicator Digit*to generate GTIN-14 from a GTIN - 13.
- GS1 company prefix number is “8901107”
- Item reference number " 00001" (To be generated by the user at random)
- Check digit is calculated using check digit calculator available at [http://gs1india.org/serv/checkdgt.htm](http://gs1india.org/serv/checkdgt.htm). This uses the previous 13 digits as per pre-defined algorithm, to calculate the fourteenth digit i.e. the check digit. In this example, it works out to “1”.

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*Indicator Digit 0 is used for unique identification code.
**Barcode Symbology:** GS1 DataMatrix (two dimensional) symbology is the preferred option.

GS1 DataMatrix symbology can encode product data in much smaller space than is possible with one dimensional barcode symbology. This is an important consideration in healthcare sector due to very limited availability of printing space on product packaging, after complying with other statutory labeling & marking requirements. GS1 DataMatrix is thus the preferred option for marking in the healthcare sector.

**Examples:**

1) **GS1 DataMatrix barcode symbology**
   
a) encoding GTIN only, is represented schematically as below:-
   
   ![GS1 DataMatrix](image)

   (01)08901107000011
   
   b) encoding GTIN + Expiry Date + Serial Number (in case of complex medical devices, reusable medical devices and implants) is represented schematically as below:-
   
   ![GS1 DataMatrix](image)

   (01)08901107000011(17)110900
   (21)122347842305

   c) encoding GTIN + Expiry Date + Batch/Lot No (in case of complex medical devices, reusable medical devices and implants) is represented schematically as below:-
   
   ![GS1 DataMatrix](image)

   (01)08901107000011(17)110900
   (10)ABC123XY

Other barcode symbologies (EAN/UPC, GS1–128 and GS1 Databar) on primary level packaging shall also be acceptable.
2) Other Barcode Symbologies

Note: The following are examples of different barcode symbologies. The specific rules for the selection and creation of particular barcode symbol are available in GS1 General Specifications.

a) EAN - 13 barcode symbology, encoding GTIN-13 is represented schematically as below:

![EAN-13 Barcode](image1)

b) UPC - A barcode symbology, encoding GTIN-12 is represented schematically as below:

![UPC Barcode](image2)

c) EAN -8 barcode symbology, encoding GTIN-8 is represented schematically as below:

![EAN-8 Barcode](image3)

d) GS1 Databar barcode symbology, encoding GTIN-14 is represented schematically as below:

![GS1 Databar Barcode](image4)

Note: The above example shows one of the variants (GS1 Databar stacked omnidirectional) of GS1 Databar barcode symbology. The details on other variants of GS1 Databar symbology are available in GS1 General Specifications.
e) GS1 – 128 barcode symbology, encoding GTIN-14 is represented schematically as below:

![GS1-128 Barcode]

Section B) Secondary Level Packaging:

Secondary Level Packaging: Is defined as a level of packaging that may contain one or more primary packages or a group of primary packages containing a single item.

Due to the wide variety of secondary level packaging configurations for medical devices, following is additional guidance. In the following examples, the outer carton is the secondary level packaging.

- One device packaged in primary level packaging contained in a single outer carton.
- A collection of more than one of the same medical device, each packaged in primary level packaging, contained in a single outer carton (includes shelf packs).
- Multiple, different medical devices intended for one therapy packaged in a single tray, and that single tray contained in a single outer carton (may also be referred to as a Kit).
- Multiple, different medical devices intended for one therapy packaged in a single tray, and several of those trays are contained in a single outer carton (may also be referred to as a Kit).

**NOTE:** There may be additional intermediate packaging levels above the secondary level packaging, but below the Shipper / Carton level packaging. These intermediate packaging levels are not required to be barcoded at this time. Examples of these exclusions include:

- Inner packs (bundles)
- Intermediate packs (inner case)

At Secondary level packaging, the barcode should encode the following information:

1) Product identification code (Unique GTIN-14 of secondary pack)* using application identifier (01)
2) Expiry date in YYMMDD format using application identifier (17)
3) Batch/Lot Number using application identifier (10) or Serial No using application identifier (21).

*Note: GTIN-14 of secondary level packaging should be different from GTIN-14 of primary and shipper pack. For details on generation of same, refer to GS1 General Specifications.

The above barcoding requirements shall be **in addition** to existing statutory labeling & marking requirements.
Steps for Generation of Product Identification Code (GTIN-14) at Secondary Level Packaging:

Please refer to the steps for generation of GTINs in the earlier section.

Barcode Symbology: Any of the following GS1 barcode symbologies can be used to encode above stated data in barcodes at Secondary level packaging:-

GS1-128, GS1 DataMatrix, GS1 DataBar.

Examples:

1) Using GS1-128 symbology, encoding GTIN + Expiry Date + Batch/Lot No is represented schematically as below:-

![GS1-128 Example]

In the above example (01) Is the application identifier which indicates that the data field (element string) following it is GTIN 14 or 14 digit product code

08901107000028 14 digit product code (GTIN 14)

(17) Is the application identifier which indicates that the data field (element string) following it is an expiration date of the product in YYMMDD format

090400 Indicates the expiration date of the product in YYMMDD format (April 09 in this case)

(10) Is the application identifier which indicates that the data field following it is batch or lot number of product.

ab12345 Indicates the batch / lot number of product.

2) Using GS1 DataMatrix symbology, encoding GTIN + Expiry Date + Batch/Lot No is represented schematically as below:-

![GS1 DataMatrix Example]

3) Using GS1 Databar symbology, encoding GTIN + Expiry Date + Batch/Lot No is represented schematically as below:-

![GS1 Databar Example]
**Section C) Shipper/Carton Level Packaging**

Shipper/Carton Level Packaging: Is defined as a level of packaging that may contain one or more primary/secondary levels of packaging.

Shippers/cartons can be considered orderable trade items (requires homogeneous pack) AND may also be considered logistics units (heterogeneous packs). The following rules apply to each variation:

1) The requirements for the orderable trade item (homogeneous pack):

   **The first barcode:**
   1) Product Identification (Unique GTIN-14 of Shipper pack)* using application identifier (01)
   2) Expiry Date in YYMMDD format using application identifier (17)
   3) Batch/Lot Number using application identifier (10)

   **The second barcode:**
   a. SSCC (Serial Shipping Container Code) to identify individual carton uniquely using application identifier (00)

*Note*: GTIN-14 of shipper level packaging should be different from GTIN-14 of primary and secondary pack. For details on generation of same, refer to GS1 General Specifications.

**Barcode Symbology:** GS1-128 and GS1 DataMatrix symbologies can be used to generate the first barcode. The second barcode (SSCC) requires GS1-128.

*Human readable information on the label will be as per existing statutory labeling & marking requirements.*
The requirements for the logistics unit (heterogeneous pack):

If multiple items are packed in a carton / shipper (heterogeneous pack), and / or the shipper / carton level packaging is not an orderable unit, only second barcode should be present (i.e. SSCC).

Human readable information on the label will be as per existing statutory labeling & marking requirements.

Schematic example of GS1-128 symbology for the logistics unit (heterogeneous pack) encoding above stated data at Shipper/ Carton Level Packaging is as below:

SSCC (Serial Shipping Container Code) to identify individual carton uniquely using application identifier (00)

(Single Label for each carton)

General Notes:

1. While barcoding has been chosen as the automatic identification data capture (AIDC) technology currently, future requirements may demand use of any other data capture technology.

2. Data requirements as stipulated above, take into account minimum level of AIDC marking. MoHFW however reserves the right to modify the same and direct implementation of higher level of AIDC marking (additional data requirements) in future, in the event of higher perceived risks in line with GS1 General Specifications.

3. Complete details on GS1 standards along with technical guidelines can be downloaded from www.gs1india.org or www.gs1.org

4. For any assistance, you can contact Shri. Gopal Valecha at 011-26168720/721/725, email – gopal@gs1india.org

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