## Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDI Requirements Overview</td>
<td>03</td>
</tr>
<tr>
<td>Which Instructions to Use in this Guide</td>
<td>05</td>
</tr>
<tr>
<td>Create a Primary Device, Count of One</td>
<td>06</td>
</tr>
<tr>
<td>How to Create the Primary Device</td>
<td>07</td>
</tr>
<tr>
<td>Generate a Barcode</td>
<td>08</td>
</tr>
<tr>
<td>Create a Primary Device, Non-Retail, Count Greater than One</td>
<td>09</td>
</tr>
<tr>
<td>How to Create the Unit of Use DI</td>
<td>10</td>
</tr>
<tr>
<td>Unit of Use DI: Generate a Barcode</td>
<td>11</td>
</tr>
<tr>
<td>How to Create the Primary Device DI</td>
<td>12</td>
</tr>
<tr>
<td>Primary Device DI: Generate a Barcode</td>
<td>13</td>
</tr>
<tr>
<td>Create a Primary Device, Retail, Count Greater than One</td>
<td>14</td>
</tr>
<tr>
<td>How to Create the Unit of Use DI</td>
<td>15</td>
</tr>
<tr>
<td>Retail – Unit of Use DI: Generate a Barcode</td>
<td>16</td>
</tr>
<tr>
<td>Retail - How to Create the Primary Device</td>
<td>17</td>
</tr>
<tr>
<td>Retail - Generate a Barcode</td>
<td>18</td>
</tr>
<tr>
<td>Create a Higher Level Packaging Item</td>
<td>19</td>
</tr>
<tr>
<td>How to Create the Higher Level Packaging Item</td>
<td>20</td>
</tr>
<tr>
<td>Generate a Barcode</td>
<td>21</td>
</tr>
</tbody>
</table>
GS1 US DATA HUB | PRODUCT
UDI Requirements Overview

This guide is designed to provide only the basic steps needed to create the two segments of the UDI: the “Device Identifier” (DI) and the “Production Identifier” (PI) using GS1 US Data Hub® | Product.

Please refer to our GS1 US Healthcare page and click the “Unique Identification of Medical Devices” links for more complete resources to determine how you are going to structure your GTIN hierarchy. Resources on this page include links to the UDI System Final Rule and to the Implementation Guideline: Using the GS1 System for U.S. FDA UDI Requirements.

GS1 US Data Hub | Product enables you to assign Device Identifiers (DI) using Global Trade Item Numbers (GTINs) for your Primary Device and Higher Levels of Packaging. UDI Production Identifiers (PI) are represented by GS1 Application Identifiers (AIs). When the barcode is generated, you can then apply GS1 AIs to certain types of barcodes.

What if Your Device Count is Greater than One?
GS1 US Data Hub can be used to create the Unit of Use DI if it is different from the Primary Device DI.

The Unit of Use DI is created when the Primary Device has a device count greater than one. One method is to assign the “Each” Packaging Level to the Unit of Use DI in GS1 US Data Hub | Product.

You will then need to determine whether the barcode will be read in a retail environment. Use the decision tree on Page 5 to determine which set of instructions can best align with your business needs.

This guide presents just two options for assigning GTINs to hierarchies for regulated healthcare products that contain a Unit of Use DI. Several other options are available. If you have questions after reviewing the Healthcare resources noted above, please contact GS1 Member Support with questions at info@gs1us.org
The illustration on the right shows a packaging hierarchy that includes both the Primary Device DI and Unit of Use DI, and are both entered as “Each” in GS1 US Data Hub | Product. Two additional DIs are shown for higher levels of packaging.

This method represents one option for creating GTINs for both the Primary Device and Unit of Use via GS1 US Data Hub | Product, and included in this guide, starting on Page 14 of this guide. Use the decision tree on Page 5 to determine which set of instructions can best align with your business needs.

When you create DIs using GS1 US Data Hub | Product, you should select Regulated Healthcare from the Product Industry pull-down menu.

The GS1 General Specifications defines Regulated Healthcare Trade Items as:

<table>
<thead>
<tr>
<th>Trade Item Type</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulated healthcare retail consumer trade item</td>
<td>A regulated healthcare trade item to be sold to the end consumer at a regulated healthcare retail point-of-sale (pharmacy). They are identified with a GTIN-13, GTIN-12 or GTIN-8 utilizing linear or 2D matrix barcodes that can be scanned by image-based scanners.</td>
</tr>
<tr>
<td>Regulated healthcare non-retail consumer trade item</td>
<td>A consumer trade item not intended for scanning at POS and identified with a GTIN-14, GTIN-13, GTIN-12 or GTIN-8 utilizing linear or 2D matrix barcodes that can be scanned by image-based scanners.</td>
</tr>
<tr>
<td>Regulated healthcare trade item</td>
<td>Pharmaceuticals or medical devices that are sold or dispensed in a controlled environment (e.g. retail pharmacy, hospital pharmacy).</td>
</tr>
</tbody>
</table>

Contact your regulatory department if you are unsure if your items are Regulated Healthcare Trade Items.
Use the decision tree below to determine which set of instructions to use in this guide. Please read the Implementation Guideline: Using the GS1 System for U.S. FDA UDI Requirements.

The decision tree below represents several methods for creating a DI for a Primary Device, and if necessary, a DI for a Unit of Use.

For alternative methods, please contact our Member Support team. Please note that the barcode options provided by GS1 US Data Hub may vary if other methods are applied.

### Are You Creating a DI for a Primary Device or Higher Level of Package?

<table>
<thead>
<tr>
<th>DI for Primary Device</th>
<th>Go to these instructions in this guide:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the Primary Device Count Greater than 1?</td>
<td>If no, go to page 6 – Primary Device, Count of 1</td>
</tr>
<tr>
<td></td>
<td>If yes, answer this question:</td>
</tr>
<tr>
<td></td>
<td>Is the Primary Device scanned in retail?</td>
</tr>
<tr>
<td></td>
<td>If no, go to Page 10 – Primary Device, Non-Retail, Count Is Greater than 1</td>
</tr>
<tr>
<td></td>
<td>If yes, go to Page 14, Primary Device, Retail, Count Is Greater than 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DI for Higher Level Packaging</th>
<th>Go to these instructions in this guide:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the DI for Higher Level Packaging?</td>
<td>Go to Page 19 – Higher Level Packaging</td>
</tr>
<tr>
<td><strong>Note:</strong> These instructions explain how to create a “trade item grouping,” as described in more detail in the GS1 US Healthcare, Implementation Guideline, Applying the GS1 System of Standards for U.S. FDA Unique Device Identification (UDI).</td>
<td></td>
</tr>
</tbody>
</table>
Complete the steps on the next two pages to assign a DI using a GTIN to your **Primary Device** with a count of 1. In these instructions, you will indicate that the item is purchasable by a consumer (retail point-of-sale).

If the item is NOT purchased by the consumer, you can uncheck the box, as noted in Step 7 on the next page. This will impact the barcode options you have.
Complete these steps to assign a DI using a GTIN to your **Primary Device** with a count of 1. In these instructions, you will indicate that the item is purchasable by a consumer (retail point-of-sale). If the item is NOT purchased by the consumer, uncheck the box, as noted in Step 7.

**How to Create a New Primary Device DI**

1. From the menu bar, click **Product**
2. Click **Create**
3. Fill in the required fields: **Product Description** and **Brand Name**
4. For Product Industry, select **Regulated Healthcare**
5. Leave **Each** for the **Packaging Level**
6. Leave the box **unchecked** for "Is this item variable measure?"
7. Leave the box **checked** for “Can this item be purchased by the consumer?”
8. Scroll to the bottom and click **Save**. The three “Assign GTIN” buttons are now enabled.

   ![GTIN Assignment Options](image)

9. Click the **Auto Assign GTIN** button. If your company has more than one prefix, you will be prompted to choose which prefix you want to use. Click the **Assign GTIN** button. A GTIN-12 is assigned to this item.

10. The product is now in the **PreMarket** status. If the product is ready to share with the marketplace, scroll to the bottom of the screen to the **Status** field and select **In Use** from the drop-down menu, then click **Save**. The GTIN is now subject to the GS1 **GTIN Management Standard**.

11. Click **Continue**. The device has been created and you can generate a barcode (see steps on the next page)

For more details on the steps needed to create a product in GS1 US Data Hub, refer to the **Product Create/Manage User Guide**.
Complete these steps to assign a DI using a GTIN to your Primary Device with a count of 1. In these instructions, because you indicate the item is purchasable by a consumer (retail point-of-sale), the default barcode image is UPC-A.

### Primary Device DI: Generate a Barcode

1. Click the Barcode tab for the newly created product. **Note:** To create a scannable barcode, a GTIN needs to be assigned and the product needs to be in the In Use status.

2. Application Area defaults to the Retail Pharmacy (Over-The-Counter Medication). **Note:** If you unchecked the box for “Can this item be purchased by the consumer,” then three options are available. Change if necessary.

3. The Barcode Type defaults to UPC-A.

4. The Size defaults to the “Target” barcode size. You can choose a Minimum or Maximum size to better fit your packaging.

5. If you select a barcode type other than UPC-A or ITF-14, you can add Production Information. Scroll down the page and Type ** to view most common Application Identifiers. Enter the appropriate data for the device.

6. Click Preview Barcode to view the barcode or to download the barcode image. If you want to share barcode definitions with a print vendor, click the Export Definitions to save a barcode definitions file.

7. When finished, click Product from the menu bar to return to the main page.
In this section are instructions for assigning a DI using a GTIN to your Primary Device with a count greater than one. For this set of instructions, the Primary Device cannot be purchased by the consumer, meaning it cannot be scanned at retail.

Also, these instructions suggest that you first create the Unit of Use DI, and then create the Primary Device DI.

This set of instructions represent one option for assigning GTINs to hierarchies for regulated healthcare products that contain a Unit of Use DI. Several other options are available. If you have questions after reviewing the Healthcare resources noted above, please contact GS1 Member Support with questions at info@gs1us.org
GS1 US DATA HUB | PRODUCT
Primary Device, Non-Retail, Count Is Greater than One (Continued)

Complete these steps to assign a DI using a GTIN to your Primary Device with a count greater than one. In these instructions, you will assign the Unit of Use DI using a GTIN, and then assign the Primary Device DI using a GTIN to contain quantities of the Unit of Use DI. The Primary Device is NOT purchased by the consumer, meaning it is not scanned at retail.

How to Create a Unit of Use Device Identifier

1. From the menu bar, click Product
2. Click Create
3. Fill in the required fields: Product Description and Brand Name
4. For Product Industry, select Regulated Healthcare
5. Leave Each for the Packaging Level
6. Leave the box unchecked for “Is this item variable measure?”
7. Uncheck the box for “Can this item be purchased by the consumer?”
8. Scroll to the bottom and click Save. The three “Assign GTIN” buttons are now enabled.
   ![Assign GTIN Buttons]
9. Click the Auto Assign GTIN button. If your company has more than one prefix, you will be prompted to choose which prefix you want to use. Click the Assign GTIN button. A GTIN is assigned to this item.
10. The product is now in the PreMarket status. If the product is ready to share with the marketplace, scroll to the bottom of the screen to the Status field and select In Use from the drop-down menu, then click Save. The GTIN is now subject to the GS1 GTIN Management Standard.
11. Click Continue. The device has been created and you can generate a barcode (see steps on the right)

For more details on the steps needed to create a product in GS1 US Data Hub, refer to the Product Create/Manage User Guide.
1. Click the **Barcode** tab for the newly created product. **Note:** To create a scannable barcode, a **GTIN** needs to be assigned and the product needs to be in the **In Use** status.

2. **Application Area** defaults to the Retail Pharmacy (Over-The-Counter Medication). Change if necessary.

3. Several **Barcode Type** options exist, including GS1-128 and GS1 DataMatrix. You cannot download an image file of GS1 DataMatrix but you can click the “Export Definition” button to download details to share with your printer.

4. The **Size** defaults to the “Target” barcode size. Select a different size to better fit your packaging.

5. If you select a barcode type other than UPC-A or ITF-14, you can add Production Information. Scroll down the page and **Type ** to view most common Application Identifiers. Enter the appropriate Production Information for the device.

6. Click **Preview Barcode** to view the barcode or to download the barcode image. If you want to share barcode definitions with a print vendor, click the **Export Definitions** to save a barcode definitions file.

7. When finished, click **Product** from the menu bar to return to the main page.
After you created the Unit of Use DI on the previous pages, you can create the Primary Device as an item that is NOT scanned at retail (point of sale). When you click “Add Contents,” you can add the Unit of Use and quantities into this Primary Device. GS1 US Data Hub will generate a GTIN-14 for the Primary Device DI.

How to Create a New Primary Device Identifier

1. From the menu bar, click **Product**
2. Click **Create**
3. Fill in the required fields: **Product Description** and **Brand Name**
4. For Product Industry, select **Regulated Healthcare**
5. Select a **Packaging Level** (for example, Inner Pack or Case).
6. Leave the box unchecked for “Is this item variable measure?”
7. Leave the box unchecked for “Can this item be purchased by the consumer?”
8. Scroll to the bottom and click **Save**. Then click the **Add Contents** button. The **Add GTIN to Container** dialog box opens. Click the row for the Unit of Use item you added previously. The item is highlighted in gray. Click **Add to Container**.
9. In the **Qty** field, enter how many “eaches” will go into this item. Click the check mark to accept the quantity. The “Quantity Change Successful” message will display in a green box.
10. Scroll to the bottom and click **Save**. The three “Assign GTIN” buttons are now enabled.
11. Click the **Auto Assign GTIN** button. If your company has more than one prefix, you should select the same prefix as the one assigned to the Unit of Use DI. Click the **Assign GTIN** button. A GTIN-14 is assigned to the Primary DI:

   ![Primary DI](image)

12. The product is now in the **PreMarket** status. If the product is ready to share with the marketplace, scroll to the bottom of the screen to the **Status** field and select **In Use** from the drop-down menu, then click **Save**. The GTIN is now subject to the GS1 **GTIN Management Standard**.
13. Click **Continue**. The device has been created and you can generate a barcode (see steps on the right).
After you created the Unit of Use DI on the previous pages, you can create the Primary Device as an item that is NOT scanned at retail (point of sale). When you click "Add Contents," you can add the Unit of Use and quantities into this Primary Device. GS1 US Data Hub will generate a GTIN-14 for the Primary Device DI.

### Primary Device DI: Generate a Barcode

1. Click the **Barcode** tab for the newly created product.  
   **Note:** To create a scannable barcode, a **GTIN** needs to be assigned and the product needs to be in the **In Use** status.

2. **Application Area** defaults to Regulated Healthcare: Point of Care or Point of Service. Choices will vary based on barcode type selection. Change if necessary.

3. The **Barcode Type** defaults to ITF-14, which does NOT carry Production Information. To add Production Information, change the barcode type to GS1-128 or GS1 DataMatrix. Then scroll down the page and **Type ** ** to view most common Application Identifiers. Enter the appropriate data for the device.

4. The **Size** defaults to the "Target" barcode size. You can select "Minimum" to better fit your packaging.

5. Click **Preview Barcode** to view the barcode or to download the barcode image. If you want to share barcode definitions with a print vendor, click the **Export Definitions** to save a barcode definitions file.

6. When finished, click **Product** from the menu bar to return to the main page.
In this section are instructions for assigning a DI using a GTIN to your Primary Device with a count greater than one. For this set of instructions, the Primary Device can be purchased by the consumer, meaning it can be scanned at retail.

Also, these instructions suggest that you first create the Unit of Use DI, and then create the Primary Device DI.

This set of instructions represent one option for assigning GTINs to hierarchies for regulated healthcare products that contain a Unit of Use DI. Several other options are available. If you have questions after reviewing the Healthcare resources noted above, please contact GS1 Member Support with questions at info@gs1us.org
Complete these steps if your Primary Device has a count greater than one, and is also sold at retail (point-of-sale). You’ll first assign the Unit of Use DI using a GTIN, and then assign the Primary Device DI using a GTIN (next page). For this method, both the Unit of Use DI and Primary DI are entered as an “Each” packaging level. You can then click the Barcode tab to generate a UPC-A barcode for the Primary Device DI.

### How to Create a Unit of Use Device Identifier

1. From the menu bar, click **Product**
2. Click **Create**
3. Fill in the required fields: **Product Description** and **Brand Name**
4. For Product Industry, select **Regulated Healthcare**
5. Leave **Each** for the **Packaging Level**
6. Leave the box **unchecked** for “Is this item variable measure?”
7. Uncheck the box for “Can this item be purchased by the consumer?”
8. Scroll to the bottom and click **Save**. The three “Assign GTIN” buttons are now enabled.

   - [Auto Assign GTIN](#)
   - [Assign GTIN From Reserved](#)
   - [Assign GTIN Manually](#)

9. Click the **Auto Assign GTIN** button. If your company has more than one prefix, you will be prompted to choose which prefix you want to use. Click the **Assign GTIN** button. A GTIN is assigned to this item.

10. The product is now in the **PreMarket** status. If the product is ready to share with the marketplace, scroll to the bottom of the screen to the **Status** field and select **In Use** from the drop-down menu, then click **Save**. The GTIN is now subject to the GS1 **GTIN Management Standard**.

11. Click **Continue**. The device has been created and you can generate a barcode (see steps on the right)

For more details on the steps needed to create a product in GS1 US Data Hub, refer to the **Product Create/Manage User Guide**.
GS1 US DATA HUB | PRODUCT
Primary Device - Retail, Count Is Greater than One (Continued)

Complete these steps if your Primary Device has a count greater than one, and is also sold at retail (point-of-sale). You’ll first assign the Unit of Use DI using a GTIN, and then assign the Primary Device DI using a GTIN (next page). For this method, both the Unit of Use DI and Primary DI are entered as an "Each" packaging level. You can then click the Barcode tab to generate a UPC-A barcode for the Primary Device DI.

Unit of Use DI: Generate a Barcode

1. Click the Barcode tab for the newly created product. **Note:** To create a scannable barcode, a GTIN needs to be assigned and the product needs to be in the In Use status

2. Application Area defaults to the Retail Pharmacy (Over-The-Counter Medication). Change if necessary

3. Several Barcode Type options exist, including GS1-128 and GS1 DataMatrix. You cannot download an image file of GS1 DataMatrix but you can click the “Export Definition” button to download details to share with your printer.

4. The Size defaults to the “Target” barcode size. Select a different size to better fit your packaging

5. If you select a barcode type other than UPC-A or ITF-14, you can add Production Information. Scroll down the page and **Type ** to view most common Application Identifiers. Enter the appropriate Production Information for the device

6. Click Preview Barcode to view the barcode or to download the barcode image. If you want to share barcode definitions with a print vendor, click the Export Definitions to save a barcode definitions file

7. When finished, click Product from the menu bar to return to the main page
GS1 US DATA HUB | PRODUCT
Primary Device - Retail, Count Is Greater than One (Continued)

After you enter the Unit of Use DI on the previous page, enter the Primary Device DI. In these instructions, you specify that the Primary Device is an “Each” packaging level that can be purchased by a consumer (at retail or point-of-sale), so you can generate a UPC-A barcode.

How to Create a New Primary Device Identifier

1. From the menu bar, click Product
2. Click Create
3. Fill in the required fields: Product Description and Brand Name
4. For Product Industry, select Regulated Healthcare
5. Leave Each for the Packaging Level
6. Leave the box unchecked for “Is this item variable measure?”
7. Keep the box checked for “Can this item be purchased by the consumer?”
8. Scroll to the bottom and click Save. The three “Assign GTIN” buttons are now enabled.
9. Click the Auto Assign GTIN button. A GTIN-12 is assigned to the item.
10. If your company has more than one prefix, you should select the same prefix as the one assigned to the Unit of Use DI. Otherwise, skip to the next step.
11. The product is now in the PreMarket status. If the product is ready to share with the marketplace, scroll to the bottom of the screen to the Status field and select In Use from the drop-down menu, then click Save. The GTIN is now subject to the GS1 GTIN Management Standard.
12. Click Continue. The device has been created and you can generate a barcode (see steps on the right)

For more details on the steps needed to create a product in GS1 US Data Hub, refer to the Product Create/Manage User Guide.
After you enter the Unit of Use DI on the previous page, enter the Primary Device DI. In these instructions, you specify that the Primary Device is an “Each” packaging level that can be purchased by a consumer (at retail or point-of-sale), so you can generate a UPC-A barcode.

1. Click the **Barcode** tab for the newly created product. **Note:** To create a scannable barcode, a **GTIN** needs to be assigned and the product needs to be in the **In Use** status.

2. **Application Area** defaults to the Retail Pharmacy (Over-The-Counter Medication). Other Regulated Healthcare Trade Items beyond pharmacy items can use this option. Choices will vary based on barcode type selection.

3. The **Barcode Type** defaults to UPC-A. Other options are available.

4. The **Size** defaults to the “Target” barcode size. You can choose a Minimum or Maximum size to better fit your packaging.

5. Click **Preview Barcode** to view the barcode or to download the UPC-A barcode image. If you want to share barcode definitions with a print vendor, click the **Export Definitions** to save a barcode definitions file.

6. When finished, click **Product** from the menu bar to return to the main page.
Complete the steps on the next page after you have created your Primary Device DI, to create **Higher Level Packaging**, such as a case.

The steps provided on the next page are for illustrative purposes only. You may need to determine another hierarchy level, based on your business needs.
How to Create a Higher Level Packaging Item

1. From the menu bar, click **Product**
2. Click **Create**
3. Fill in the required fields: **Product Description** and **Brand Name**
4. For Product Industry, select **Regulated Healthcare**
5. Choose the desired **Packaging Level**. For definitions, view the Packaging Level Definitions article in the GS1 US Data Hub Help Center
6. Leave the box unchecked for "Is this item variable measure?"
7. Leave the box unchecked for "Can this item be purchased by the consumer?"
8. Scroll to the bottom and click **Save**. Then click the **Add Contents** button. The **Add GTIN to Container** dialog box opens. Click the row for the desired item you want to add to this packaging. The item is highlighted in gray. Click **Add to Container**.
9. In the **Qty** field enter how many items will go into this item. Click the check mark to accept the quantity. The "Quantity Change Successful" message will display in a green box.
10. Click the **Auto Assign GTIN** button. A GTIN-14 will be assigned to this item:
    
11. If your company has more than one prefix, you should select the same prefix as the one assigned to the Primary Device DI. Otherwise, skip to the next step
12. The product is now in the **PreMarket** status. If the product is ready to share with the marketplace, scroll to the bottom of the screen to the **Status** field and select **In Use** from the drop-down menu, then click **Save**. The GTIN is now subject to the GS1 GTIN Management Standard.
13. Click **Continue**. The device has been created and you can generate a barcode (see steps on the right)
Complete these steps after you have created your Primary Device DI, to create Higher Level Packaging, such as a case.

Higher Level Packaging: Generate a Barcode

1. Click the Barcode tab for the newly created product. **Note:** To create a scannable barcode, a GTIN needs to be assigned and the product needs to be in the In Use status.

2. Application Area defaults to Regulated Healthcare: Point of Care or Point of Service. Change if necessary.

3. The Barcode Type defaults to ITF-14. Select GS1-128 or GS1 DataMatrix to enter Production Information (see step 5). You cannot download an image file of GS1 DataMatrix but you can click the Export Definition button to save barcode definitions and share with your print vendor.

4. The Size defaults to the “Target” barcode size. Select a different size to better fit your packaging.

5. Scroll down the page and Type ** to view most common Application Identifiers. Enter the appropriate Production Information for the device.

6. Click Preview Barcode to view the barcode or to download the barcode image. If you want to share barcode definitions with a print vendor, click the Export Definitions to save a barcode definitions file.

7. When finished, click Product from the menu bar to return to the main page.