



GS1 US Data Hub® | Product

Unique Device Identification (UDI) Creation

User Guide

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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.

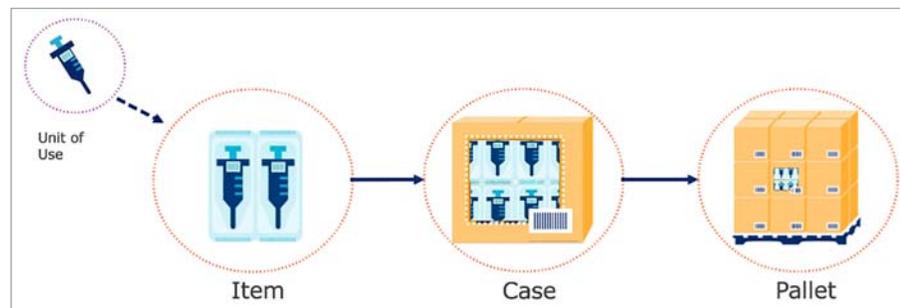
Please refer to our [GS1 US Healthcare page](#) and click the “Unique Identification of Medical Devices” links for more complete resources to determine how you are going to structure your GTIN hierarchy. Resources on this page include links to the **UDI System Final Rule** and to the **Implementation 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.



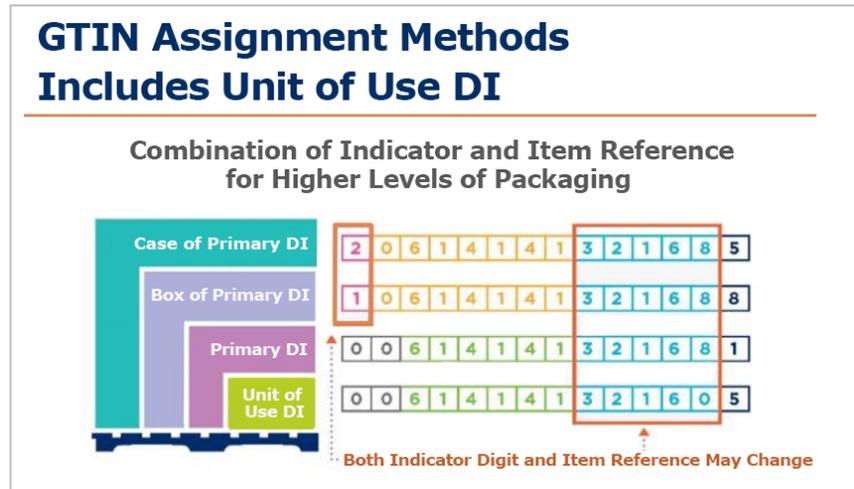
This guide presents just **two options** for assigning GTINs to hierarchies for regulated healthcare products that contain a Unit of Use DI. Several other options are available. If you have questions after reviewing the Healthcare resources noted above, please contact GS1 Member Support with questions at info@gs1us.org

GS1 US DATA HUB | PRODUCT UDI Requirements Overview (Continued)

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.



Product Industry

General

General

CPG

Regulated Healthcare

Foodservice

Apparel

The GS1 General Specifications defines **Regulated Healthcare Trade Items** as:

Trade Item Type	Definition
Regulated healthcare retail consumer trade item	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.
Regulated healthcare non-retail consumer trade item	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.
Regulated healthcare trade item	Pharmaceuticals or medical devices that are sold or dispensed in a controlled environment (e.g. retail pharmacy, hospital pharmacy).

Contact your regulatory department if you are unsure if your items are Regulated Healthcare Trade Items.

GS1 US DATA HUB | PRODUCT

Which Instructions to Use in this Guide

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?	
DI for Primary Device	Go to these instructions in this guide:
Is the Primary Device Count Greater than 1?	If no , go to page 6 – Primary Device, Count of 1
	If yes , answer this question:
	Is the Primary Device scanned in retail?
	<p>If no, go to Page 10 – Primary Device, Non-Retail, Count Is Greater than 1</p> <p>If yes, go to Page 14, Primary Device, Retail, Count Is Greater than 1</p>
DI for Higher Level Packaging	Go to these instructions in this guide:
Is the DI for Higher Level Packaging?	<p>Go to Page 19 – Higher Level Packaging</p> <p>Note: 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).</p>

GS1 US DATA HUB | PRODUCT Primary Device, Count of 1

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.



*Example of a Primary Device
with a count of 1*

GS1 US DATA HUB | PRODUCT Primary Device, Count of 1 (Continued)

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

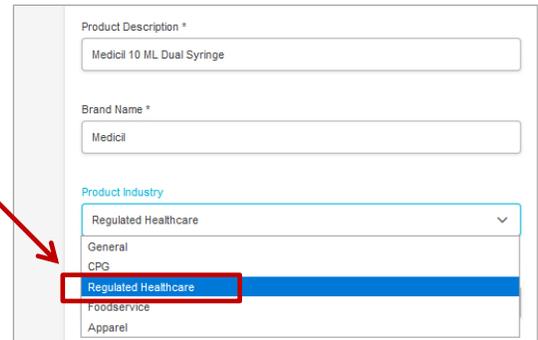
1. From the menu bar, click **Product**
2. Click **Create**
3. Fill in the required fields: **Product Description** and **Brand Name**
4. For Product Industry, select **Regulated Healthcare**
5. Leave **Each** for the **Packaging Level**
6. Leave the box *unchecked* for "Is this item variable measure?"
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.

Auto Assign GTIN

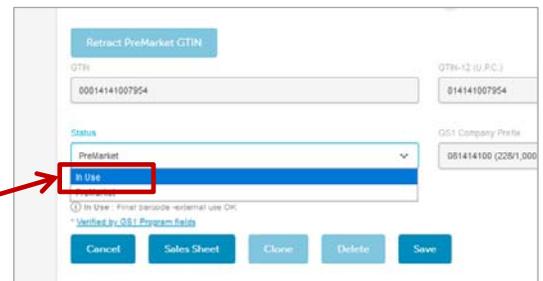
Assign GTIN From Reserved

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-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)



A screenshot of a web form showing the 'Product Industry' dropdown menu. The menu is open, displaying several options: 'Regulated Healthcare', 'General', 'CPG', 'Foodservice', and 'Apparel'. The 'Regulated Healthcare' option is highlighted in blue and has a red rectangular box around it. A red arrow points from the text 'Regulated Healthcare' in the instructions to this option in the dropdown.



A screenshot of a web form showing the 'Status' dropdown menu. The menu is open, displaying two options: 'PreMarket' and 'In Use'. The 'In Use' option is highlighted in blue and has a red rectangular box around it. A red arrow points from the text 'In Use' in the instructions to this option in the dropdown. Other fields visible include 'GTIN' (00014141007954), 'GTIN-12 (U.P.C.)' (014141007954), and 'GS1 Company Prefix' (001414100 (228/1,000)).

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, Count of 1 (Continued)

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



GS1 US DATA HUB | PRODUCT Primary Device, Non-Retail, Count Is Greater than One

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



Example of a Primary Device with a count greater than 1

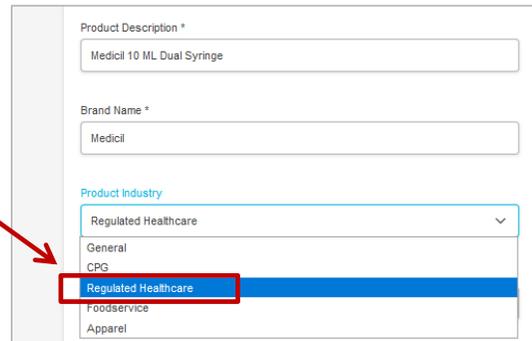


GS1 US DATA HUB | PRODUCT Primary Device, Non-Retail, Count Is Greater than One (Continued)

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.



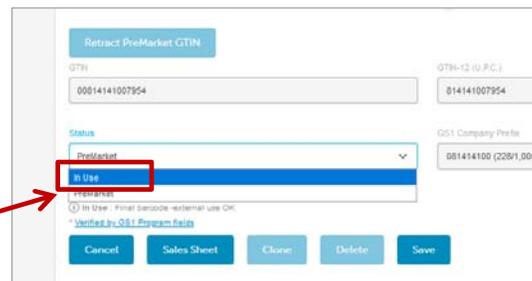
The screenshot shows a dropdown menu for 'Product Industry'. The options are: Regulated Healthcare (selected and highlighted in blue), General, CPG, Foodservice, and Apparel. A red box highlights the 'Regulated Healthcare' option, and a red arrow points from step 4 of the instructions to this box.

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)



The screenshot shows the 'Status' dropdown menu. The options are: PreMarket and In Use (selected and highlighted in blue). A red box highlights the 'In Use' option, and a red arrow points from step 10 of the instructions to this box. Other fields visible include GTIN (00014141007954), GS1 Company Prefix (001414100), and buttons for Cancel, Sales Sheet, Close, Delete, and Save.

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, 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.

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

Product Detail	Additional Information	Hierarchy	Sharing	History	Barcode
Application Area					
Retail Pharmacy (Over-The-Counter Medication)					
Barcode Type					
UPC-A					
Size					
Target - 0.33000 mm X 22.85000 mm					

Application Identifiers	
A0011 GTIN	00816471020115
Additional Application Identifiers	
Type in ** to select from the most common Application Identifiers	
Application Identifier Code	Application Identifier Value
**10 - Batch or Lot Number	65503
Application Identifier Code	Application Identifier Value
**11 - Production Date (YYMMDD)	200112



GS1 US DATA HUB | PRODUCT Primary Device, Non-Retail, Count Is Greater than One (Continued)

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.

Auto Assign GTIN

Assign GTIN From Reserved

Assign GTIN Manually

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

1 0 6 1 4 1 4 1 3 2 1 6 8 8

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)



GS1 US DATA HUB | PRODUCT Primary Device, Non-Retail, Count Is Greater than One (Continued)

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

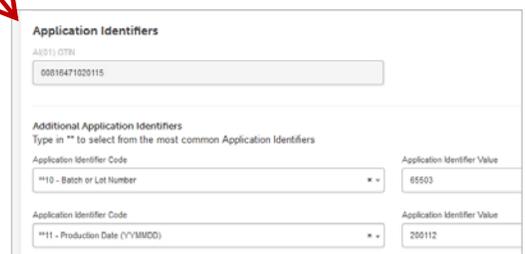


Product Detail Additional Information Hierarchy Sharing History Barcode

Application Area
Retail Pharmacy (Over-The-Counter Medication)

Barcode Type
UPC-A

Size
Target - 0.33000 mm X 22.85000 mm



Application Identifiers

AI(01) GTIN
00816471020115

Additional Application Identifiers
Type in ** to select from the most common Application Identifiers

Application Identifier Code **10 - Batch or Lot Number	Application Identifier Value 65503
Application Identifier Code **11 - Production Date (YYMMDD)	Application Identifier Value 200112

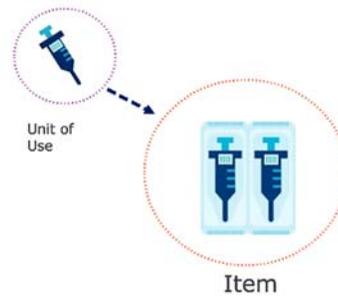


GS1 US DATA HUB | PRODUCT Primary Device, Retail, Count Is Greater than One

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



*Example of a Primary Device,
Retail, with a count greater
than 1*



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.

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

Product Detail	Additional Information	Hierarchy	Sharing	History	Barcode
Application Area					
Retail Pharmacy (Over-The-Counter Medication)					
Barcode Type					
UPC-A					
Size					
Target - 0.33000 mm X 22.85000 mm					

Application Identifiers	
GS1 GTIN	
00816471020115	
Additional Application Identifiers	
Type in ** to select from the most common Application Identifiers	
Application Identifier Code	Application Identifier Value
**10 - Batch or Lot Number	65503
Application Identifier Code	Application Identifier Value
**11 - Production Date (YYMMDD)	200112

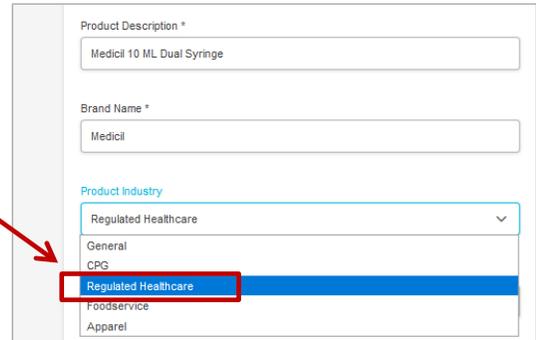


GS1 US DATA HUB | PRODUCT Primary Device - Retail, Count Is Greater than One (Continued)

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.



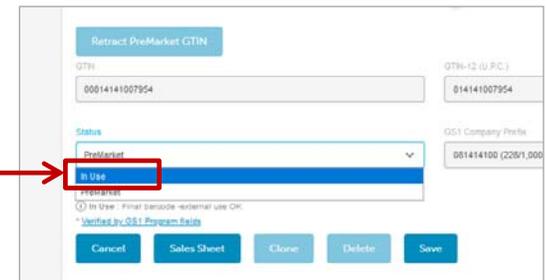
A screenshot of a web form showing a dropdown menu for 'Product Industry'. The dropdown is open, showing several options: 'Regulated Healthcare', 'General', 'CPG', 'Regulated Healthcare', 'Foodservice', and 'Apparel'. The 'Regulated Healthcare' option is highlighted in blue. A red box is drawn around this option, and a red arrow points from the text 'Regulated Healthcare' in the instructions to this box.

Auto Assign GTIN

Assign GTIN From Reserved

Assign GTIN Manually

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)



A screenshot of a web form showing a dropdown menu for 'Status'. The dropdown is open, showing several options: 'PreMarket', 'In Use', and 'In Use'. The 'In Use' option is highlighted in blue. A red box is drawn around this option, and a red arrow points from the text 'select In Use' in the instructions to this box.

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)

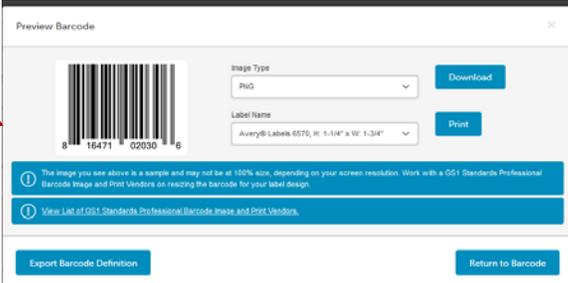
After you enter the Unit of Use DI on the previous page, enter the Primary Device DI. In these instructions, you specify that the Primary Device is an “Each” packaging level that can be purchased by a consumer (at retail or point-of-sale), so you can generate a UPC-A barcode.

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). 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



The screenshot shows the 'Barcode' tab in a web application. It contains three dropdown menus: 'Application Area' set to 'Retail Pharmacy (Over-The-Counter Medication)', 'Barcode Type' set to 'UPC-A', and 'Size' set to 'Target - 0.33000 mm X 22.85000 mm'. A red arrow points from the second step of the instructions to the 'Application Area' dropdown.



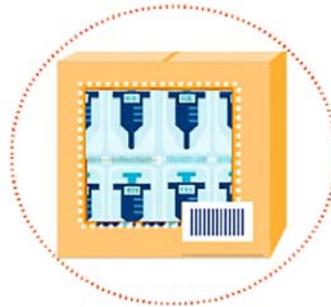
The screenshot shows the 'Preview Barcode' dialog box. It displays a barcode with the numbers '8 16471 02030 8' below it. To the right, there are dropdown menus for 'Image Type' (set to 'PNG') and 'Label Name' (set to 'Avery® Labels 6570, W: 1.14" x H: 1.314"'). There are 'Download' and 'Print' buttons. At the bottom, there are 'Export Barcode Definition' and 'Return to Barcode' buttons. A red arrow points from the fifth step of the instructions to the 'Preview Barcode' dialog.



GS1 US DATA HUB | PRODUCT Higher Level Packaging

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.



Case

Example of higher level packaging



GS1 US DATA HUB | PRODUCT Higher Level Packaging (Continued)

Complete these steps after you have created your Primary Device DI, to create **Higher Level Packaging**, such as a case.

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.

GTIN	Description	Status	Level	Qty
00816471020115	Medicinal Syringe, 10 ml	In Use	Each	20 <input checked="" type="checkbox"/>

10. Click the **Auto Assign GTIN** button. A GTIN-14 will be assigned to this item:

Case of Primary DI 2 0 6 1 4 1 4 1 3 2 1 6 8 5
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)



GS1 US DATA HUB | PRODUCT Higher Level Packaging (Continued)

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

Application Area
Regulated Healthcare: Point of Care or Point of Service

Barcode Type
ITF-14

Size
Target - 0.49500 mm X 12.70000 mm

Preview Barcode Export Definition

Application Identifiers

AKD1) GTIN
00818471020115

Additional Application Identifiers
Type in "*" to select from the most common Application Identifiers

Application Identifier Code	Application Identifier Value
**10 - Batch or Lot Number	85503
**11 - Production Date (YYMMDD)	200112

