



# **GS1 US Data Hub® | Product**

## Unique Device Identification (UDI) Creation User Guide

**September 9<sup>th</sup>, 2024**

## Table of Contents

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<b>UDI Requirements Overview .....</b>	<b>03</b>
<b>Select Regulated Healthcare Industry .....</b>	<b>03</b>
<b>Which Instructions to Use in this Guide .....</b>	<b>04</b>
<b>Create a Primary Device, Count of One .....</b>	<b>05</b>
<b>How to Create the Primary Device .....</b>	<b>06</b>
<b>Generate a Barcode .....</b>	<b>07</b>
<b>What If Your Primary Device Count is Greater than One? .....</b>	<b>08</b>
<b>Option #1 - "Unit of Use" Packaging Level .....</b>	<b>09</b>
<b>Option #2 - "Each" Packaging Level for Unit of Use Item .....</b>	<b>17</b>
<b>Create a Higher Level Packaging Item .....</b>	<b>22</b>
<b>How to Create the Higher Level Packaging Item .....</b>	<b>23</b>
<b>Generate a Barcode .....</b>	<b>24</b>
<b>Appendix A - Import Products .....</b>	<b>25</b>

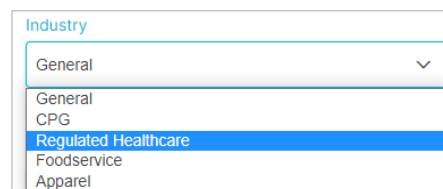
## UDI Requirements Overview

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 resources provided 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.

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



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 healthcare retail point-of-sale (POS) (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.

## 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 Unique Device Identification \(UDI\) Requirements](#).

This decision tree represents just a few options available for creating a DI for a Primary Device, and if necessary, a DI for a Unit of Use. For alternative options, please contact GS1 US Member Support team. Please note that the barcode option provided by GS1 US Data Hub may vary if other options 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:		
<b>Is the Primary Device Count Greater than One?</b>	<p><b>If no</b>, go to <b>Page 5 – Primary Device, Count of One</b></p> <p><b>If yes</b>, you need to identify the lowest item (Unit of Use) – refer to <b>Page 8</b> for an introduction to Unit of Use.</p>		
	<table border="1"> <tr> <td> <p><b>Option #1:</b> Assign the <b>Unit of Use</b> packaging level to the Unit of Use item.</p> <p><b>Note:</b> You must first enable the Unit of Use Packaging Level.</p> </td> <td> <p><b>Go to Page 9:</b></p> <p><b>Option #1 – “Unit of Use” Packaging Level</b></p> </td> </tr> </table>	<p><b>Option #1:</b> Assign the <b>Unit of Use</b> packaging level to the Unit of Use item.</p> <p><b>Note:</b> You must first enable the Unit of Use Packaging Level.</p>	<p><b>Go to Page 9:</b></p> <p><b>Option #1 – “Unit of Use” Packaging Level</b></p>
<p><b>Option #1:</b> Assign the <b>Unit of Use</b> packaging level to the Unit of Use item.</p> <p><b>Note:</b> You must first enable the Unit of Use Packaging Level.</p>	<p><b>Go to Page 9:</b></p> <p><b>Option #1 – “Unit of Use” Packaging Level</b></p>		
	<table border="1"> <tr> <td> <p><b>Option #2:</b> Assign the <b>Each</b> packaging level to the Unit of Use item.</p> </td> <td> <p><b>Go to Page 17:</b></p> <p><b>Option #2 – “Each” Packaging Level for Unit of Use</b></p> </td> </tr> </table>	<p><b>Option #2:</b> Assign the <b>Each</b> packaging level to the Unit of Use item.</p>	<p><b>Go to Page 17:</b></p> <p><b>Option #2 – “Each” Packaging Level for Unit of Use</b></p>
<p><b>Option #2:</b> Assign the <b>Each</b> packaging level to the Unit of Use item.</p>	<p><b>Go to Page 17:</b></p> <p><b>Option #2 – “Each” Packaging Level for Unit of Use</b></p>		
DI for Higher Level Packaging	Go to these instructions in this guide:		
<b>Is the DI for Higher Level Packaging?</b>	<p><b>If yes</b>, go to <b>Page 22 – Higher Level Packaging</b></p> <p><b>Note:</b> 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 One

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In all cases the first step is to assign a GTIN to the Primary Device. Complete the steps on the next two pages to assign a DI using a GTIN to your **Primary Device** with a count of one.

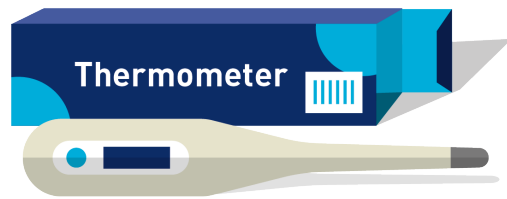
The Primary Device identifier is the identifier assigned to the lowest level of a product that is marked with the identifier and any relevant application identifiers. This lowest packaging level is often referred to as the “base package”.

In these instructions, the default is “Yes” for “Purchasable By Consumer?”, meaning the item is the lowest saleable unit.

If the product is NOT sold in a retail point-of-sale setting, then you may select “No.” The product is still considered the lowest saleable unit, but will not be shared with the GS1 Registry Platform. This centralized global repository enables brand owners to upload point-of-sale product data, so retailers can access and use that data.

At this time, only **In Use** retail point-of-sale products in which “Yes” has been selected for **Purchasable by Consumer?** are being shared with the GS1 Registry Platform.

This enables any individual globally to view this data. For more information, please refer to the [GS1 US Data Hub Product Share User Guide](#).



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



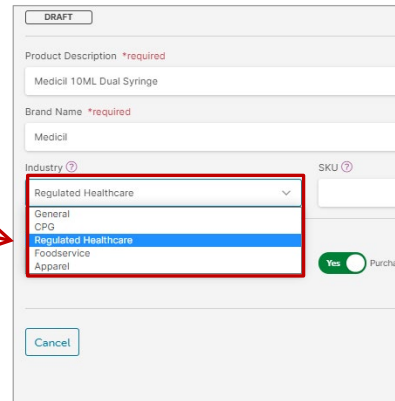
# GS1 US DATA HUB | PRODUCT

## Primary Device, Count of One *(Continued)*

Complete these steps to assign a DI using a GTIN to your **Primary Device** with a count of one.

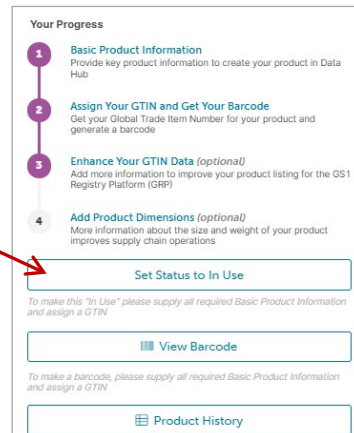
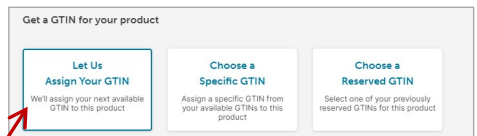
### How to Create a New Primary Device DI

1. From the menu bar, click **Product**
2. Click **Add New Product**
3. Fill in the required fields: **Product Description** and **Brand Name**
4. For Industry, select **Regulated Healthcare**
5. Leave **Each** for the **Packaging Level**
6. If this product is the lowest saleable unit and can be sold at retail point-of-sale, leave "Yes" selected for **Purchasable by Consumer?**



If this item is NOT sold at retail point-of-sale, then select "No".

7. Scroll to the bottom and click **Save and Continue**. The three "Get a GTIN for your Product" buttons are displayed.
8. Click the **Let Us Assign Your GTIN** button. If your company has more than one GS1 Company Prefix, you will be prompted to select the desired prefix. Click **Save and Continue**. Confirm the GTIN Assignment by clicking "Yes". A GTIN-12 is assigned to this item.
9. The product is now in the **PreMarket** status. If the product is ready to share with the marketplace, click the **Set Status to In Use** button. The **Status Change to In Use** dialog box displays. Click **Continue**. The GTIN is now subject to the [GS1 GTIN Management Standard](#).
10. The device has been created and you can now 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](#).



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

Complete these steps to assign a DI using a GTIN to your **Primary Device** with a count of one.

### Primary Device DI: Generate a Barcode

1. Click the **View Barcode** button 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.

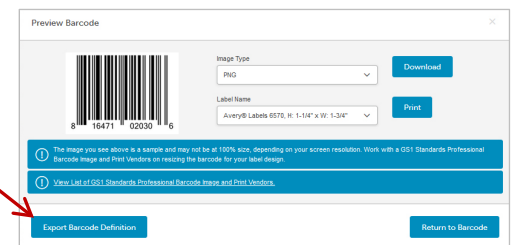
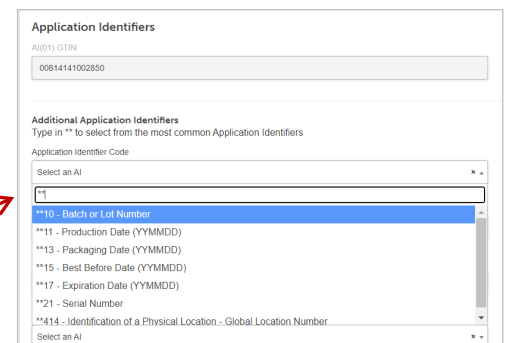
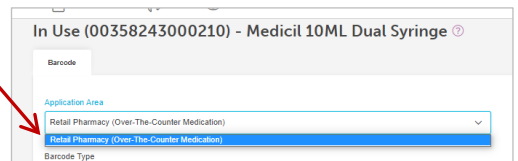
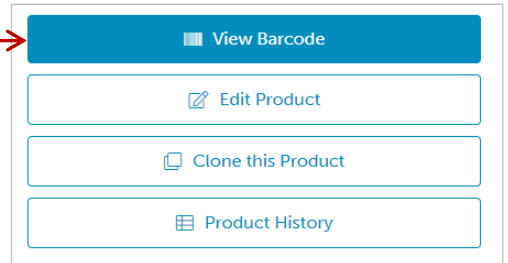
2. **Application Area** defaults to the Retail Pharmacy (Over-The-Counter Medication).

**Note:** If “Yes” was selected for **Purchasable by 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 for the GS1-128 only (the GS1 DataMatrix image file cannot be downloaded). If you want to share barcode definitions with a print vendor, click the **Export Barcode 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 UDI Requirements Overview – Count Greater than One

## 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 defined as an identifier assigned to an individual medical device when the Primary DI has a "count of devices" greater than 1. The Unit of Use DI is assigned to the single device below the lowest saleable unit marked with a DI. This allows for unique identification of the actual device used in patient care.

## Two Options to Assign the Unit of Use DI

You have two options when creating the Unit of Use DI in GS1 US Data Hub | Product:

**Option #1: Select "Unit of Use" Packaging Level for the Unit of Use DI (See Page 9)**

**Option #2: Select "Each" Packaging Level for the Unit of Use DI (see Page 17)**

Here's an example of the two Unit of Use DI options:

Assignment Method	Level below the Each	Lowest marked or Saleable unit	Next Higher packaging level	Second higher packaging level
Unit of Use and Each Packaging Levels	GTIN-14 with Packaging Level = <b>Unit of Use</b> 10614141 <b>321688</b>	GTIN-12 with Packaging Level = <b>Each</b> 00614141 <b>321681</b>	GTIN-14 with Packaging Level = Case 20614141 <b>321685</b>	GTIN-14 with Packaging Level = Pallet 30614141 <b>321682</b>
Each and Each Packaging Levels	GTIN-12 with Packaging Level = <b>Each</b> 00614141 <b>321605</b>	GTIN-12 with Packaging Level = <b>Each</b> 00614141 <b>321681</b>	GTIN-14 with Packaging Level = Case 10614141 <b>321688</b>	GTIN-14 with Packaging Level = Pallet 20614141 <b>321685</b>



This user guide presents two options for assigning GTINs to hierarchies for regulated healthcare products that contain a Unit of Use DI.

If you have questions after reviewing the Healthcare resources noted in this user guide, please contact GS1 US Member Support with questions at [info@gs1us.org](mailto:info@gs1us.org)





# GS1 US DATA HUB | PRODUCT

## Option #1 – “Unit of Use” Packaging Level

The **Unit of Use DI** is created when the **Primary Device** has a device count greater than one. Option #1 is presented below. If you apply this option, you must enable the Unit of Use Packaging Level, and these steps are provided on the next page.

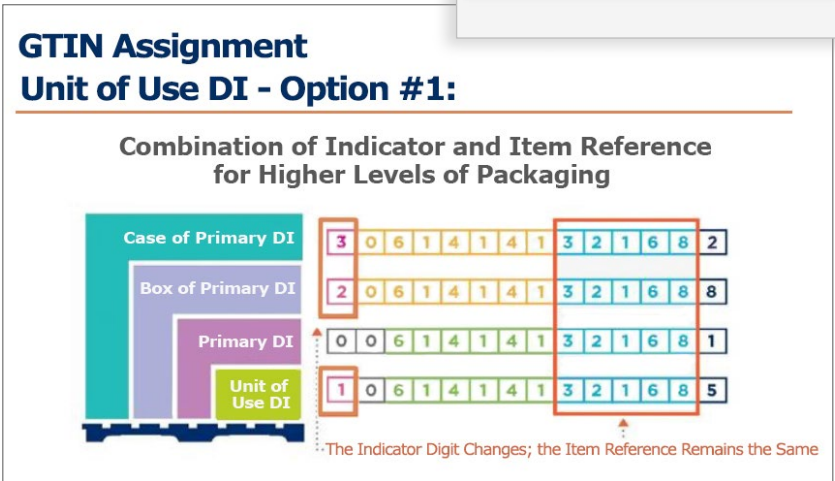
### Option #1: Select the "Unit of Use" Packaging Level for the Unit of Use DI

#### Why Use this Option:

- Conserves the GS1 Company Prefix GTIN capacity. The Unit of Use DI may be assigned a GTIN-14, which has the same “Item Reference” as the GTIN of the Primary Device DI. The number of Item References determines GTIN capacity.
- Enables you to view the association of the “Unit of Use DI” with the Primary Device when viewing the Product Hierarchy of the Product Detail Record.

Packaging Level ?

Unit of Use

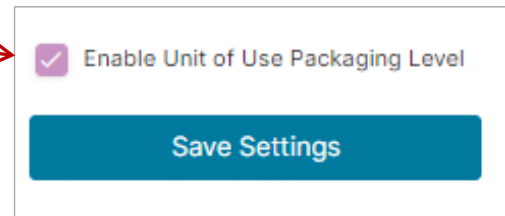
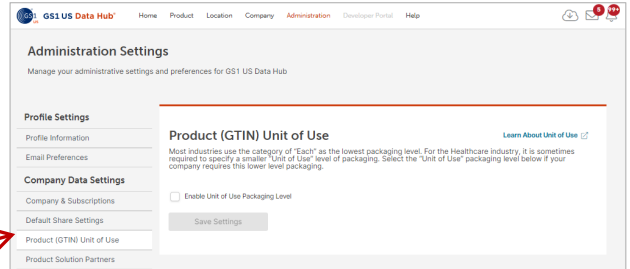


# GS1 US DATA HUB | PRODUCT

## Option #1 – “Unit of Use” Packaging Level *(Continued)*

To use Option #1, you must first enable the “Unit of Use” packaging level in GS1 US Data Hub. Follow these steps:

1. If you are assigned the GS1 US Data Hub General User Administrator role for your company, click the **Administration** link.
2. On the main Administration page, click the **Product (GTIN) Unit of Use** link.
3. Check the box for **Enable Unit of Use Packaging Level**.
4. Click **Save Settings**.
5. The “Unit of Use” packaging level is now available when you add products.



A user assigned the Product Create/Manage can now click the **Product** link and then click **Add New Product**. “Unit of Use” is now an option in the Packaging Level dropdown.

**Note:** After this Unit of Use packaging level is enabled, and a product is saved in GS1 US Data Hub with the **PreMarket** Status, you cannot disable this feature.

- Q Will I still be able to assign the “Each” packaging level to Unit of Use items after this feature is enabled?**
- A** Yes, even after the “Unit of Use” packaging level is enabled, you can still apply Option#2 (“Each” Packaging Level) to a Unit of Use item.



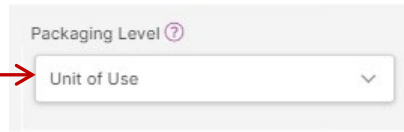
**Note:** You cannot use the import tool to import “Unit of Use” DIs if they contain the “Unit of Use” packaging levels. However, you can import all associated “Each” items (Primary Device DI) and higher levels of packaging, then add your “Unit of Use” items as instructed in this user guide. You can then associate these items with the Primary Device “Each” items that you had imported. See the “Appendix A - Import Products” in this user guide for more details.



## GS1 US DATA HUB | PRODUCT Option #1 – “Unit of Use” Packaging Level (Continued)

In this section are instructions to adding a Unit of Use GTIN to your Primary Device if it has a count that’s greater than one.

**Follow these instructions if you are using Option #1: selecting a “Unit of Use” packaging level to the Unit of Use item.**



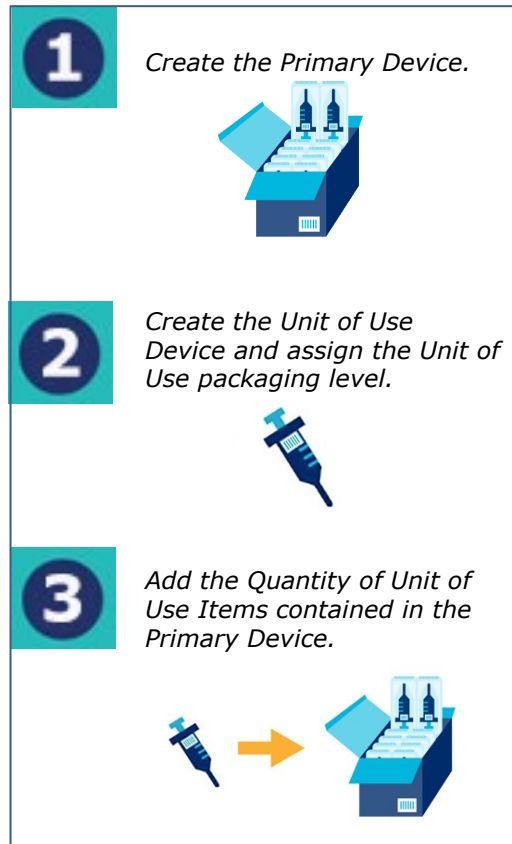
**Note:** Make sure you have reviewed the previous page to learn how to enable the “Unit of Use” Packaging Level feature in GS1 US Data Hub before using these steps.

In this section are instructions that explain these steps:

1. Create the Primary Device DI;
2. Create the Unit of Use DI and associate the Unit of Use DI to the Primary Device DI;
3. Add the Quantity of the Unit of Use items contained in the Primary Device DI.

These instructions represent one option for assigning GTINs to hierarchies for regulated healthcare products that contain a Unit of Use DI. Other options are available.

If you have questions, please contact GS1 US Member Support with questions at [info@gs1us.org](mailto:info@gs1us.org).



# GS1 US DATA HUB | PRODUCT

## Option #1 – “Unit of Use” Packaging Level (Continued)

The first step is to create the Primary Device DI. You will then continue to the next page to enter the Unit of Use DI and associate that item to this Primary Device DI.

### 1 Create the New Primary Device Identifier



1. From the menu bar, click **Product**
2. Click the **Add New Product** link
3. Fill in the required fields: **Product Description** and **Brand Name**
4. For Industry, select **Regulated Healthcare**
5. Leave **Each** for the **Packaging Level**
6. If this product is the lowest saleable unit and can be sold at retail point-of-sale, leave “Yes” selected for **Purchasable by Consumer?**

If this item is NOT sold at retail point-of-sale, then select “No”.

7. Do NOT click the **Add Contents** button at this time. You will associate the Primary Device DI to the Unit of Use DI at a later step. For now, click **Save and Continue**.
8. The three “Get a GTIN for your product” buttons are displayed. Click the **Let Us Assign Your GTIN** button. If your company has more than one GS1 Company Prefix, you will be prompted to select the desired prefix. You should select the same prefix as the one that will be assigned to the Unit of Use DI. Click **Save and Continue**. Confirm the GTIN Assignment by clicking “Yes.” A GTIN-12 is assigned to this item.
9. The product is now in the **PreMarket** status. If the product is ready to share with the marketplace, click the **Set Status to In Use** button. The **Status Change to In Use** dialog box displays. Click **Continue**. The GTIN is now subject to the GS1 [GTIN Management Standard](#).
10. Continue to the next page to create the Unit of Use DI and associate that item to this Primary Device DI.



## GS1 US DATA HUB | PRODUCT

### Option #1 – “Unit of Use” Packaging Level (Continued)

Now that you’ve entered your Primary Device, you can now add the Unit of Use DI and associate this Unit of Use DI to the Primary Device DI.

# 2

## Create a Unit of Use Device Identifier and Associate with the Primary Device



1. From the menu bar, click **Product**
2. Click **Add New Product**
3. Fill in the required fields: **Product Description** and **Brand Name**
4. For Industry, select **Regulated Healthcare**
5. Select **Unit of Use** for the **Packaging Level**. “No” is selected for both **Purchasable by Consumer?** and **For Shipping Purposes Only?**
6. Click **Choose Products** to associate the Unit of Use DI and the Primary Device DI.
7. Click **Save and Continue**. The GTIN-14 is automatically assigned to this item.
8. If the product is ready to share with the marketplace, click the **Set Status to In Use** button. Click **Save and Exit** to return to the My Products page.

Set Status to In Use

# 3

## Add the Quantity of the Unit of Use Device Contained in the Primary Device



1. From the My Products page, locate the Primary Device and click the Product Description. The product detail record displays.
2. Click the **Edit Product** button.
3. In the **Qty** field, enter the Quantity of the Unit of Use items that go into this Primary Device. You can change this quantity after the item is In Use.
4. Click the **Save and Exit** button. This Unit of Use quantity is now saved with this Primary Device.

Edit Product

You will see this quantity displayed when you view the Primary Device product hierarchy on the product detail record.



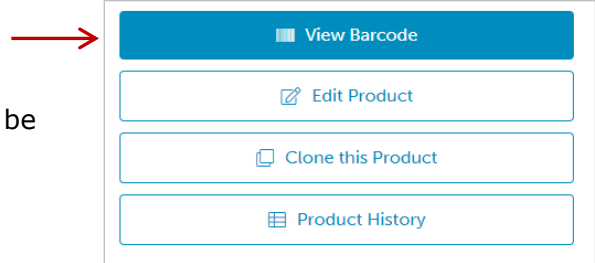
# GS1 US DATA HUB | PRODUCT

## Option #1 – “Unit of Use” Packaging Level (Continued)

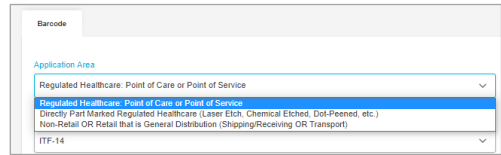
GS1 US Data Hub enables you to generate a GS1-128 or GS1 DataMatrix barcode for the **Primary Device DI**, so that it can contain production information.

### Primary Device DI: Generate a Barcode

1. Click the **View Barcode** button 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.

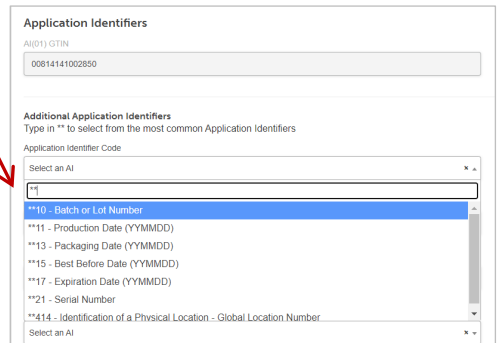


2. **Application Area** defaults to Regulated Healthcare: Point of Care or Point of Service. Choices will vary based on barcode type selection. Change if necessary.



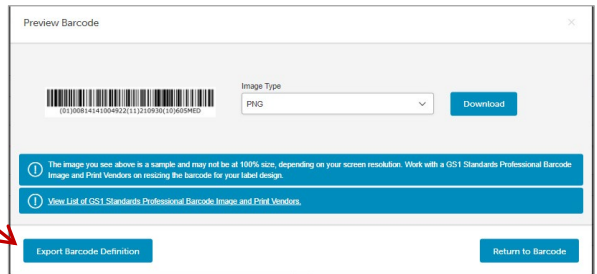
3. The **Barcode Type** defaults to ITF-14, which does NOT carry Production Information. To add Production Information, change the barcode type to GS1-128 or GS1 DataMatrix. Then scroll down the page and **Type \*\*** to view the most common Application Identifiers. Enter the appropriate data for the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

This enables you to generate a GTIN with production information to be embedded in a GS1-128 or GS1 DataMatrix for the Primary Device DI.



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 for the GS1-128 only (the GS1 DataMatrix image file cannot be downloaded). If you want to share barcode definitions with a print vendor, click the **Export Barcode Definitions** to save a barcode definitions file.



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



# GS1 US DATA HUB | PRODUCT

## Option #1 – “Unit of Use” Packaging Level (Continued)

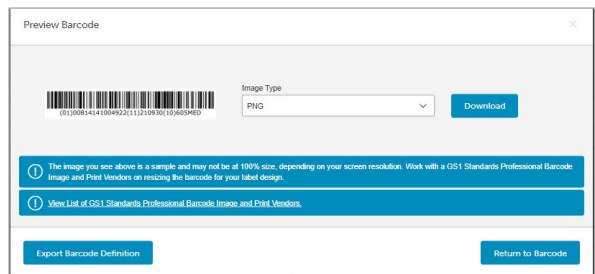
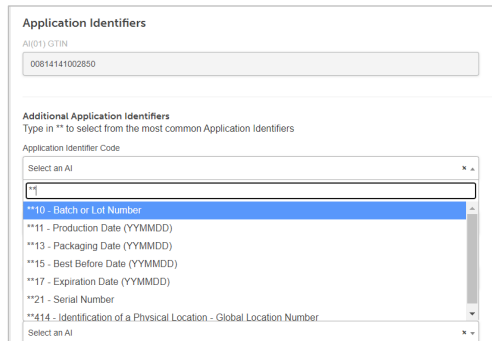
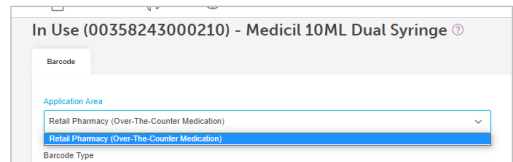
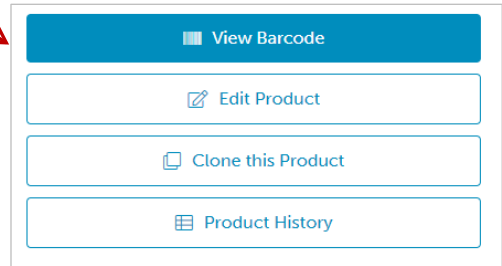
GS1 US Data Hub enables you to generate a GS1-128 or GS1 DataMatrix barcode for the **Unit of Use** DI, so that it can contain production information. Please note that most Unit of Use DIs are virtual identifiers so this step may not apply to your business needs.

### Unit of Use DI: Generate a Barcode

1. Click the **View Barcode** button 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). 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.
3. The **Size** defaults to the “Target” barcode size. Select a different size to better fit your packaging.
4. 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.
5. Click **Preview Barcode** to view the barcode or to download the barcode image for the GS1-128 only (the GS1 DataMatrix image file cannot be downloaded). 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.



## GS1 US DATA HUB | PRODUCT Option #1 – “Unit of Use” Packaging Level (Continued)

**Q How can I add an existing “Unit of Use” item to a new Primary Device (i.e., a box with a different count)?**

**A** First, enter the new Primary Device and assign the GTIN-12, then click **Save and Exit**. From My Products, click this item’s Product Description to view the Product Detail Record. Click the **Edit Product** button.

Click “Add Contents,” then check the box for the Unit of Use to associate with this Primary Device. Enter the quantity and click **Save and Continue**.

The association displays in the Product Hierarchy on the Unit of Use Product Detail Screen (see next question below).

Description	GTIN	Packaging Level	Status
Medical Syringe 20 ML	20830001480228	Unit of Use	PREMARKET
Medical Syringe	10830001480221	Unit of Use	IN USE

**Q How can I view the Packaging Hierarchy for an item?**

**A** Click the “Each” item (Primary Device) or the “Unit of Use” item from the My Products Page.

When the Product Detail Record displays, scroll down to the **Product Hierarchy** section.

For an “Each” item, the Unit of Use item displays.

Click “View all ancestors” to view higher level packaging.

Click “View all associated products” to view any item that contains this item.

Packaging Level: Each	Purchasable by Consumer: <input checked="" type="checkbox"/>	Variable Measure: <input type="checkbox"/>
GTIN-14: 00830001480408	GTIN-12 (U.P.C.): 830001480408	GS1 Company Prefix: 083000148
Image URL: None	Target Market: US - United States Of America	Global Product Classification: None
Net Content 1 Count: None	Net Content 1 Unit of Measure: None	
Height: None	Width: None	Depth: None
Net Weight: None	Gross Weight: None	Weight Measure: None

Product Hierarchy

- Medical Syringe 20 ML - Cas... (Each)
- Medical Syringe (Unit of Use, Qty: 200)





## GS1 US DATA HUB | PRODUCT

### Option #2 – Unit of Use with “Each” Packaging Level

The **Unit of Use DI** is created when the **Primary Device** has a device count greater than one. This section discusses Option #2, in which you select the “Each” packaging level for the Unit of Use item.

#### Option #2: Select the “Each” Packaging Level for the Unit of Use DI

Packaging Level ?

Each

#### Why Use this Option:

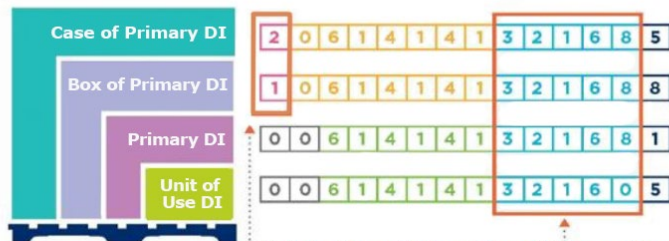
- If you have assigned the “Each” Packaging Level to Unit of Use items in the past, you can continue applying this option to ensure consistency.

**Note:** you can still assign the “Each” packaging level, even if the Unit of Use packaging level was enabled in GS1 US Data Hub.

- If there is a possibility that the individual device could become a saleable unit at some point, then using Option #2 could be beneficial, as a GTIN-12 is assigned, and a UPC-A can be generated at a future date.

#### GTIN Assignment Unit of Use DI - Option #2

##### Combination of Indicator and Item Reference for Higher Levels of Packaging



Both Indicator Digit and Item Reference May Change

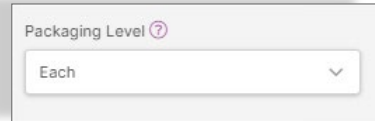


In this section are instructions for how to create a Primary Device with a count greater than one.



For this set of instructions:

- **You are assigning the “Each” Packaging Level to the Unit of Use item**
- You first create the Unit of Use DI item as an “Each” item, and then the Primary Device as an “Each” item.

In this scenario, these two items cannot be associated to each other in GS1 US Data Hub, unless the “Unit of Use” packaging level has been enabled.



Packaging Level ?  
Each

- 1** Create the Unit of Use Device and assign the “Each” packaging level.  

- 2** Create the Primary Device.  




# GS1 US DATA HUB | PRODUCT

## Option #2 – Unit of Use with “Each” Packaging Level (Continued)

The first step is to create the Unit of Use DI, selecting the “Each” packaging level. You will then continue to the next page to enter the Primary Device DI.

1

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



1. From the menu bar, click **Product**
2. Click **Add New Product**
3. Fill in the required fields: **Product Description** and **Brand Name**
4. For Industry, select **Regulated Healthcare**
5. Leave **Each** for the **Packaging Level**
6. Select “No” for **Purchasable by Consumer?**
7. Scroll to the bottom and click **Save and Continue**. The three “Get a GTIN for your Product” buttons are displayed.

8. Click the **Let Us Assign Your GTIN** button. If your company has more than one GS1 Company Prefix, you will be prompted to select the desired. Click the **Select** button. Click **Save and Continue**. Confirm the GTIN Assignment by clicking “Yes”. A GTIN-12 is assigned to this item.
9. The product is now in the **PreMarket** status. If the product is ready to share with the marketplace, click the **Set Status to In Use** button. The **Status Change to In Use** dialog box displays, click **Continue**. The GTIN is now subject to the [GS1 GTIN Management Standard](#).
10. The device has been created and you can now generate a barcode.

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 adding the Unit of Use DI, you can now create the Primary Device DI by selecting the “Each” packaging level.

# 2

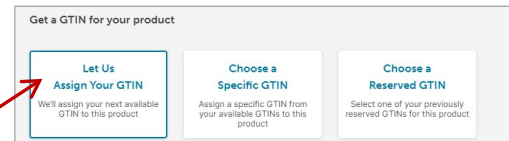
## How to Create the Primary Device Identifier



1. From the menu bar, click **Product**
2. Click **Add New Product**
3. Fill in the required fields: **Product Description** and **Brand Name**
4. For Industry, select **Regulated Healthcare**
5. Leave “Each” as the **Packaging Level**.
6. If this product is the lowest saleable unit and can be sold at retail point-of-sale, leave “Yes” selected for **Purchasable by Consumer?**

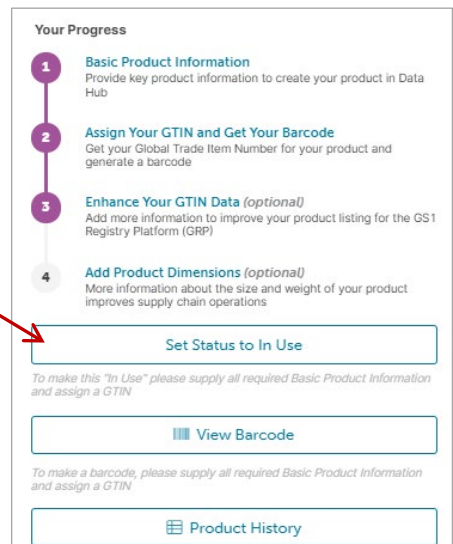
If this item is NOT sold at retail point-of-sale, then select “No”.

7. Click **Save and Continue**.
8. The three “Get a GTIN for your product” buttons are displayed. Click the **Let Us Assign Your GTIN** button.



If your company has more than one GS1 Company Prefix, you will be prompted to select the desired prefix. You should select the same prefix as the one assigned to the Unit of Use DI. Click the **Select** button. Click **Save and Continue**.

9. The product is now in the **PreMarket** status. If the product is ready to share with the marketplace, click the **Set Status to In Use** button.
10. The **Status Change to In Use** dialog box displays. Click **Continue**. The GTIN is now subject to the [GS1 GTIN Management Standard](#).
11. The device has been created and you can now generate a barcode.



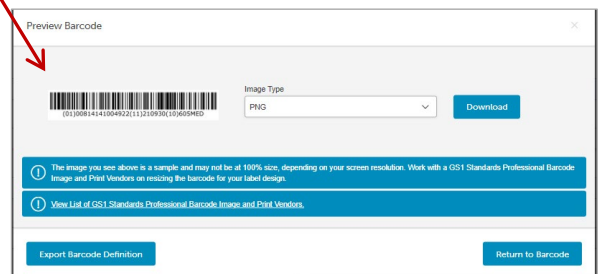
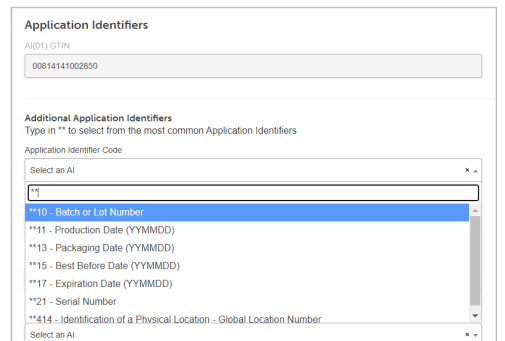
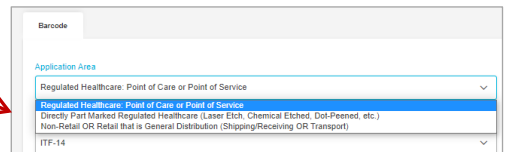
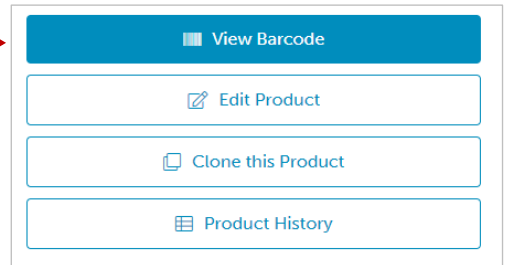
## GS1 US DATA HUB | PRODUCT

### Option #2 – Unit of Use with “Each” Packaging Level *(Continued)*

When you create the Primary Device DI, these instructions explain the barcode options if you selected “Yes” for Purchasable by Consumer. GS1 US Data Hub defaults to the UPC-A barcode option.

#### Primary Device DI: Generate a Barcode

1. Click the **View Barcode** button for the newly created product.
2. **Note:** To create a scannable barcode, a **GTIN** needs to be assigned and the product needs to be in the **In Use** status.
3. **Application Area** defaults to Regulated Healthcare: Point of Care or Point of Service. Choices will vary based on barcode type selection. Change if necessary.
4. 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.
5. The **Size** defaults to the “Target” barcode size. You can select “Minimum” to better fit your packaging.
6. Click **Preview Barcode** to view the barcode or to download the barcode image for the GS1-128 only (the GS1 DataMatrix image file cannot be downloaded). If you want to share barcode definitions with a print vendor, click the **Export Barcode Definitions** to save a barcode definitions file
7. When finished, click **Product** from the menu bar to return to the main page.

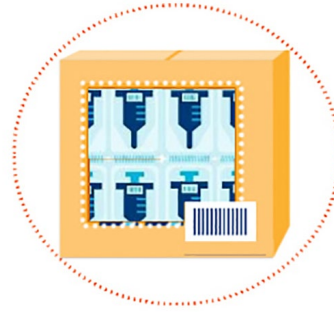


## GS1 US DATA HUB | PRODUCT Higher Level Packaging

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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 **Add New Product**
3. Fill in the required fields: **Product Description** and **Brand Name**
4. For 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. "Yes" is selected for **For Shipping Purposes Only?**
7. Click the **Add Contents** button. Choose which items will be included in the packaging level by check marking each item. The **Choose a product to add to this container** dialog box opens. Check the box for the item that's going into this packaging. Click **Add to Container**. In the **Qty** field, enter how many items go into this packaging. Then click **Save and Continue**.
8. Click the **Let Us Assign Your GTIN** button. If your company has more than one GS1 Company Prefix, you will be prompted to select the desired prefix (select the same prefix as the one assigned to the Unit of Use DI). Click the **Select** button. Click **Save and Continue**. If you have only one GS1 Company Prefix, skip to the next step. Confirm the GTIN Assignment by clicking "Yes". A GTIN-14 is assigned to the Primary DI:

Case of Primary DI

2 0 6 1 4 1 4 1 3 2 1 6 8 5

9. The product is now in the **PreMarket** status. If the product is ready to share with the marketplace, click the **Set Status to In Use** button.
10. The **Status Change to In Use** dialog box displays. Click **Continue**. The GTIN is now subject to the [GS1 GTIN Management Standard](#).
11. The higher level packaging item has been created and you can now generate a barcode.

DRAFT

Product Description \*required  
Medicil 10ML Dual Syringe

Brand Name \*required  
Medicil

Industry ⓘ  
Regulated Healthcare  
General  
CPG  
Regulated Healthcare  
Foodservice  
Apparel

Cancel

Packaging Level  
Case

Case Contents  
00814141000988 - Medicil 10 ML Dual Syringe - Each, Qty: 30 [AddMarket] [Remove]

Case [Add to Container] [Save and Exit] [Save and Continue]

Get a GTIN for your product

Let Us Assign Your GTIN  
We'll assign your next available GTIN to this product

Choose a Specific GTIN  
Assign a specific GTIN from your available GTINs to this product

Choose a Reserved GTIN  
Select one of your previously reserved GTINs for this product

Your Progress

- 1 Basic Product Information  
Provide key product information to create your product in Data Hub
- 2 Assign Your GTIN and Get Your Barcode  
Get your Global Trade Item Number for your product and generate a barcode
- 3 Enhance Your GTIN Data (optional)  
Add more information to improve your product listing for the GS1 Registry Platform (GRP)
- 4 Add Product Dimensions (optional)  
More information about the size and weight of your product improves supply chain operations

Set Status to In Use

To make this "In Use" please supply all required Basic Product Information and assign a GTIN

View Barcode

To make a barcode, please supply all required Basic Product Information and assign a GTIN

Product History



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

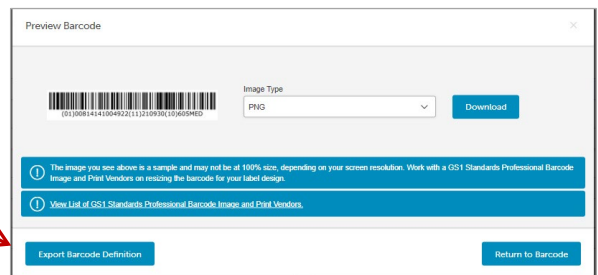
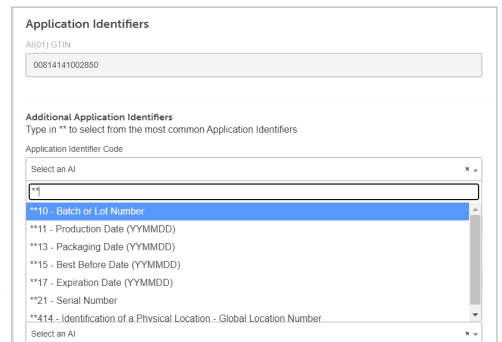
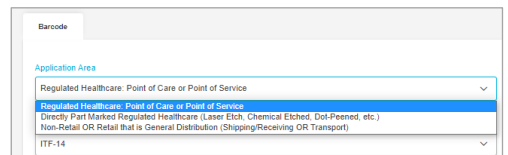
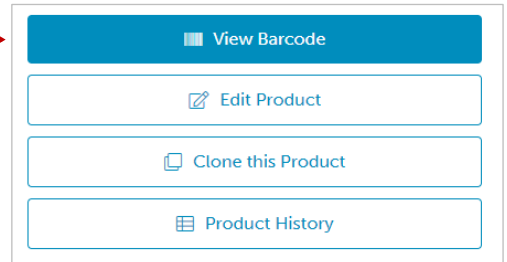
Complete these steps after you have created your Primary Device DI, to create **Higher Level Packaging**, such as a case.

### Higher Level Packaging: Generate a Barcode

1. Click the **View Barcode** button 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. 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 Barcode Definitions** to save a barcode definitions file.
7. When finished, click **Product** from the menu bar to return to the main page.





## Appendix A - Import Products

Rather than entering multiple products through the GS1 US Data Hub user interface, you can save time by adding all products in bulk via a "Product Import" Template.

**Note:** You cannot use the import templates to create new "Unit of Use" items. Also, the import template will not generate GTIN-14s for higher level packaging. If you want to assign GTIN-14s to higher level packaging items, you will have to download the blank template and enter the GTIN-14s manually.

**1. From the menu bar, click Product.**

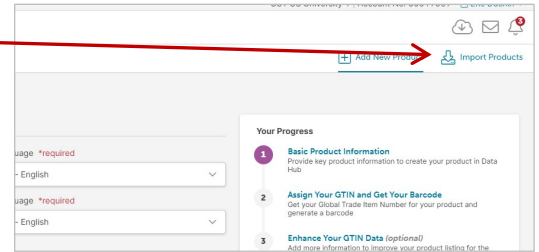
**2. Click Import Products.**

**3. Click the Download Template tab.**

**4. You have two template options.**

You can import products and assign GTINs, or you can import products that already have GTINs:

- To import products and assign available GTINs, select the GS1 Company Prefix under the **Download an Assigned GTINs Template** heading. Select the number of products you want to create. Then click **Download Template** and open the file.
- To import products that already have GTINs, click the **Download a Blank Template** link at the bottom of the screen and open the file.



**5. Select "Create" in the Action Column.**

View the [Product Import User Guide](#) to learn what to enter in each column. Here are specific requirements for medical device products:

- It's recommended that you first enter "Each" items, and then enter higher level packaging level items in another template.
- Remember to select "Regulated Healthcare" in the **Industry** column.

A	B	C	D	E	F	G	H	I	J	K	L	
Action	GS1CompanyPrefix	GTIN	PackagingLevel	Description	Desc1L	BrandName	BrandStatus	Industry	IsVariable	IsPurchasable		
2	Create	083000381	00830003810760	Each	Medicil Syringe 10 ML - Pack of 10	en	Medicil	en	In Use	Regulated Healthcare	N	Y
3	Create	083000381	00830003810777	Each	Medicil Syringe 20 ML - Pack of 10	en	Medicil	en	In Use	Regulated Healthcare	N	Y
4	Create	083000381	00830003810784	Each	Medicil Syringe 30 ML - Pack of 10	en	Medicil	en	In Use	Regulated Healthcare	N	Y
5	Create	083000381	00830003810791	Each	Medicil Syringe 40 ML - Pack of 10	en	Medicil	en	In Use	Regulated Healthcare	N	Y



**Note:** GTINs should be entered with 14 digits, with two leading zeroes.



## Appendix A - Import Products (Continued)

### 6. Save the file to your computer.

Make sure you did not change any column headings or rearrange columns in the template. Do not use the following special characters in your file name. Otherwise, you will receive an error and the file will not process: ; / ? : @ = & " < > # % { } | \ ^ ~ [ ] ` ( ) .

### 7. Click the Import/Modify Products tab.

You can drag and drop the file into the gray upload box. Or click **Browse File**.

Locate the updated file on your computer and click "Open." The file name displays in the **File Input** field.

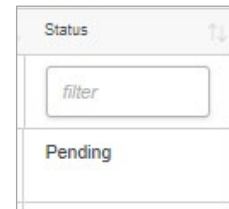


### 8. Click Import Products.

GS1 US Data Hub begins to process the file. The time it takes for the file to process will vary based on the volume of import files being submitted during this time. Scroll down on the screen to view all uploaded files for your company. The file you just uploaded displays at the top of the list.

### 9. Check the Status column.

The Status will move from **File Uploaded** to **Pending** to **Complete**. Click **Refresh Table** until the **Complete** status displays. Until then, you can leave this page and return at a later time.



### 10. Verify that the records processed successfully.

When the file displays **Complete**, you can take these steps:

- Verify that all records processed correctly. If successful, the **# Errors column** will display 0 (zero).
- If a number displays in the **# Errors** column, click the **File Name** hyperlink to open the "Results" file. View Column B for the error message. To learn more about an error message and how to resolve the issue, view the [Product Import User Guide, Column B](#).
- Within the Results file, the **Results** column (Column A) indicates **Success** or **Fail** for each item. If you did receive an error, delete any rows that were successfully imported in the original spreadsheet before you make the corrections and re-submit the file.



**Note:** If the message **File Format error. Please use the current Data Hub Import Template**, make sure you used the most recent template and haven't changed a column name, deleted a column, or added a column.

