



**GS1 US Data Hub® | Product**  
Unique Device Identification (UDI) Creation  
User Guide

# Table of Contents

<b>UDI Requirements Overview.....</b>	<b>03</b>
<b>Unique Device Identification (UDI) Primary Device.....</b>	<b>04</b>
<b>Unique Device Identification (UDI) Unit of Use.....</b>	<b>05</b>
<b>Unique Device Identification (UDI) Higher Level Packaging.....</b>	<b>06</b>

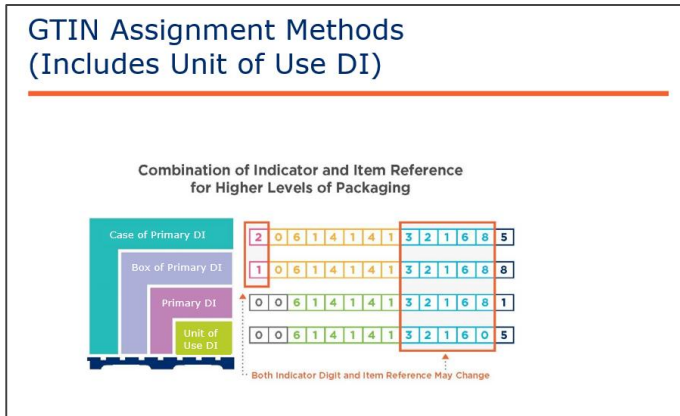
## GS1 US DATA HUB | PRODUCT UDI Requirements Overview

Prior to creating UDIs in GS1 US Data Hub | Product, please visit our [GS1 US Healthcare page](#). 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 can assist you with creating the DI (Device Identifier) for your **Primary Device** and **Higher Levels of Packaging**. It can also be used to create the **Unit of Use DI** if it is different from the **Primary Device DI**\*

The example to the right shows a packaging hierarchy that includes both the Primary Device DI and that for the Unit of Use. Two additional DIs are shown for higher levels of packaging.

This method is one option for creating GTINs for both the Primary Device and Unit of Use via GS1 US Data Hub | Product. For details on an alternative option please call our Member Support team.



During the creation of your DIs using GS1 US Data Hub | Product, you will be asked if your product is a **Regulated Healthcare Trade Item**.

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.

\***Unit of Use DI** is created when the **Primary Device** has a device count greater than one. Unit of Use DI is referenced as "Each" in GS1 US Data Hub | Product.



## Unique Device Identification (UDI) Primary Device

To create a new Unique Device Identification for your **Primary Device**, auto assign a GTIN to it, change the status to In Use, and create the barcode with production information, follow these steps.

### How to Create a New Primary Device Identification

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* that indicates that the item is a variable measure product
7. Leave the box *checked* that indicates that the item can be purchased by the consumer
8. Click **Save**
9. Click the **Auto Assign** button
10. If your company has more than one prefix, you will be prompted to choose which prefix you want to use. Otherwise, skip to the next step
11. Scroll to the bottom of the screen and locate the **Status** field. Select **In Use** from the drop-down
12. Click **Save**
13. The **Status Change to In Use** dialog box opens
14. Click **Continue**. The device is now created

### How to Create a UDI Compliant Barcode

1. Click the **Barcode** tab for the newly created product (**NOTE:** For the Barcode tab to display, a **GTIN** needs to be assigned and the product needs to be in the **In Use** status)

The screenshot shows a form with three dropdown menus. The first is labeled 'Application Area' and has 'Retail Pharmacy (Over-The-Counter Medication)' selected. The second is labeled 'Barcode Type' and has 'UPC-A' selected. The third is labeled 'Size' and has 'Target - 0.33000 mm X 22.85000 mm' selected.

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. Change if necessary
3. The **Barcode Type** defaults to UPC-A. Change if necessary
4. **Dimensions** defaults to the target barcode size. If needed, choose a different size to better fit your packaging
5. If you chose another barcode type besides UPC-A or ITF-14, scroll to the bottom to add Production Information. **Type \*\*** to view most common Application Identifiers. Enter the appropriate Production Information for the device.

The screenshot shows a table titled 'Additional Application Identifiers' with the instruction 'type in \*\* to select from the most common Application Identifiers'. The table has two columns: 'Application Identifier Code' and 'Application Identifier Value'. There are three rows of input fields, each with a clear button (x) to its right. The first row has code '\*\*10 - Batch or Lot Number' and value 'A12358'. The second row has code '\*\*11 - Production Date (YYMMDD)' and value '160930'. The third row has code 'Select an AI' and an empty value field.

6. Click **Preview Barcode** to view the barcode or to download the barcode image. Click **Export Definitions** to save barcode definitions to your computer to share with your print vendor
7. When finished, click **Product** from the menu bar to return to the main page

## Unique Device Identification (UDI) Unit of Use

To create a new Unique Device Identification for your **Unit of Use**, auto assign a GTIN to it, change the status to In Use, and create the barcode with production information, follow these steps.

### How to Create a New Unit of Use Device Identification

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* that indicates that the item is a variable measure product
7. Uncheck the box that indicates that the item can be purchased by the consumer
8. Click **Save**
9. Click the **Auto Assign** button
10. If your company has more than one prefix, you will be prompted to choose which prefix you want to use. Otherwise, skip to the next step
11. Scroll to the bottom of the screen and locate the **Status** field. Select **In Use** from the drop-down
12. Click **Save**
13. The **Status Change to In Use** dialog box opens
14. Click **Continue**. The device is now created

### How to Create a UDI Compliant Barcode

1. Click the **Barcode** tab for the newly created product (**NOTE:** For the Barcode tab to display, a **GTIN** needs to be assigned and the product needs to be in the **In Use** status)

The screenshot shows a form with three fields: 'Application Area' set to 'Regulated Healthcare: Point of Care or Point of Service', 'Barcode Type' set to 'GS1-128', and 'Size' set to 'Target - 0.49500 mm X 12.70000 mm'. Each field has a dropdown arrow on the right.

2. **Application Area** defaults to the Regulated Healthcare: Point of Care or Point of Service. Change if necessary
3. Several **Barcode Type** options exist including GS1-128 and GS1 Data Matrix. The GS1 Data Matrix is only available to Export the Barcode Definition. This option for the GS1 Data Matrix will supply you a file that you can share with your Print Vendor.
4. **Dimensions** defaults to the target barcode size. If needed, choose a different size to better fit your packaging
5. If you chose another barcode type besides UPC-A or ITF-14, scroll to the bottom to add Production Information. **Type \*\*** to view most common Application Identifiers. Enter the appropriate Production Information for the device.

The screenshot shows a table titled 'Additional Application Identifiers' with the instruction 'type in \*\* to select from the most common Application Identifiers'. The table has two columns: 'Application Identifier Code' and 'Application Identifier Value'. It contains three rows: 1) '\*\*10 - Batch or Lot Number' with value 'A12358'; 2) '\*\*11 - Production Date (YYMMDD)' with value '160930'; and 3) 'Select an AI' with an empty value field. Each row has a small 'x' icon in a square on the right.

6. Click **Preview Barcode** to view the barcode or to download the barcode image. Click **Export Definitions** to save barcode definitions to your computer to share with your print vendor
7. When finished, click **Product** from the menu bar to return to the main page

\***Unit of Use DI** is created when the **Primary Device** has a device count greater than one. See example of Packaging Hierarchy that includes the Unit of Use on page 2.

## Unique Device Identification (UDI) Higher Level Packaging

To create a new Unique Device Identification for your **Higher Level Packaging**, auto assign a GTIN to it, change the status to In Use, and create the barcode with production information, follow these steps.

### How to Create a New Device Identification for Higher Level Packaging

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**. See the [GS1 US Data Hub | Product Packaging Level Visual Aid](#) for more information.
6. Leave the box *unchecked* that indicates that the item is a variable measure product
7. Uncheck the box that indicates that the item can be purchased by the consumer
8. Click **Save**
9. Click **Add Contents**
10. From the displayed table, choose the device that is contained by clicking on that item's line in the table.
11. Click **Add to Container**
12. Click the **Auto Assign** button
13. If your company has more than one prefix, you will be prompted to choose which prefix you want to use. Otherwise, skip to the next step
14. Scroll to the bottom of the screen and locate the **Status** field. Select **In Use** from the drop-down
15. Click **Save**
16. The **Status Change to In Use** dialog box opens
17. Click **Continue**. The device is now created

### How to Create a UDI Compliant Barcode

1. Click the **Barcode** tab for the newly created product (**NOTE:** For the Barcode tab to display, a **GTIN** needs to be assigned and the product needs to be in the **In Use** status)

The screenshot shows a form with three sections: 'Application Area' with a dropdown menu set to 'Regulated Healthcare: Point of Care or Point of Service'; 'Barcode Type' with a dropdown menu set to 'GS1-128'; and 'Size' with a dropdown menu set to 'Target - 0.49500 mm X 12.70000 mm'.

2. **Application Area** defaults to the Regulated Healthcare: Point of Care or Point of Service. Change if necessary
3. Several **Barcode Type** options exist including GS1-128 and GS1 Data Matrix. The GS1 Data Matrix is only available to Export the Barcode Definition. This option for the GS1 Data Matrix will supply you a file that you can share with your Print Vendor.
4. **Dimensions** defaults to the target barcode size. If needed, choose a different size to better fit your packaging
5. Scroll to the bottom to add Production Information for barcode types other than the ITF-14. **Type \*\*** to view most common Application Identifiers. Enter the appropriate Production Information for the device

The screenshot shows a table titled 'Additional Application Identifiers' with the instruction 'type in \*\* to select from the most common Application Identifiers'. The table has two columns: 'Application Identifier Code' and 'Application Identifier Value'. It contains two rows of data and a 'Select an AI' dropdown at the bottom.

Application Identifier Code	Application Identifier Value
**10 - Batch or Lot Number	A12358
**11 - Production Date (YYMMDD)	160930

Select an AI

6. Click **Preview Barcode** to view the barcode or to download the barcode image. Click **Export Definitions** to save barcode definitions to your computer to share with your print vendor
7. When finished, click **Product** from the menu bar to return to the main page