The Global Language of Business

GS1 – UDI Terms Explained

Overview

1. GS1 is a **designated and accredited issuing agency** for Unique Device Identifiers (UDI) by the **US Food and Drug Administration (FDA)** and the **European Union (EU)**.

2. This in effect means that GS1 Standards for product identification (**aka your product's 13-digit barcode number**) are recognized as **UDI-DI**.

3. If your company is an active GS1 Subscriber and is actively using GS1 Barcode Keys on your products for traceability, you are already in compliance with UDI-DI.

4. Other countries that accept and recognize UDI and GS1's role as a UDI issuing agency:

    - South Korea - **2016**
    - Singapore – **2018**
    - China - **2019**
    - Türkiye – **2019**
    - Saudi Arabia - **2021**
    - Taiwan - **2021**
    - Brazil - **2021**
    - Egypt – **2021**
    - New Zealand - **2021**
    - Australia - **2025**

What is Unique Device Identification (UDI)?

1. A UDI code is typically made up of a combination of 2 parts: **UDI-DI** and **UDI-PI.**

    a. **UDI-DI = GS1 barcode number**
    b. **UDI-PI = production information, such as batch/lot no., expiry date, manufacturing date, serial number, etc.**

2. However, **not all products must have UDI-PI**. So you can just have the UDI-DI, aka your barcode number, on your product alone.

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3. You must **check with your compliance department or agency representative** to determine if you need to include UDI-PI on your labelling.

4. If you need to include it, you will need to use **GS1 Application Identifiers** and **FNC1 group separators** to identify each section of your barcode symbol, as well as to follow the encoding and labelling guidelines that I showed you during your session.

EU's UDI Addition: Basic UDI-DI

1. Europe UDI has an additional requirement, must prepare **Basic UDI-DI**.

    a. **Basic UDI-DI** is an identifier for **product categories / models**. It is also known as **Global Model Number or GMN.**
    b. It is **NOT your GTIN / barcode number** (otherwise known as **UDI-DI**).
    c. **"Basic UDI-DI" and "UDI-DI" are NOT the same**.
    d. To get a GMN, you need to **generate it yourself**. (See attached guide)
    e. GMN is **NOT printed** or **encoded** into **any barcode symbol** or **label**. You **cannot** use GMN to label your products or cartons!
    f. GMN is only used when you **submit product technical documentation** into **EUDAMED**.

UDI Implementation Checklist

Implementing UDI for your products can be broken down into 5 sections:

1. Make sure all your products have their **own unique 13-digit barcode number.**

2. Determine **what you need to include on your labelling** (UDI-DI only? Must include UDI-PI? Label size? Product or carton label? Etc.)

3. **Encode the required information** into a **compatible barcode symbol.**

    a. If only UDI-DI, EAN-13 barcode symbol.

    b. If full UDI code, then GS1-128 and/or 2D Datamatrix. (*Must determine if your trading partners have 2D barcode scanners before 2D barcode use*)

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c. If label meant for distribution to Europe, reminder, **DO NOT ENCODE BASIC UDI-DI**.

4. **Print** the label and **affix** to your product or trade item.

5. **Submit** your product's **technical information** to the respective regulatory agency's data repository:

   a. US FDA = **GUDID**
   b. European Union (EU) = **EUDAMED**
      i. **Must include Basic UDI-DI code.**

Want to learn more about UDI? Join our industry focus topic on the use of GS1 Standards to fulfil global healthcare guidelines!

Comply with Global Unique Device Identification (UDI) Regulation and other Directives of Healthcare using GS1 Standards

Key Learnings from the Topic:

- *Benefits on the use of GS1 Traceability Standards for healthcare products for **track & trace**, **sustainability**, and **circularity**.*
- *Fulfilment of international and country-specific directives on **Healthcare Products**, such as US FDA GUDID, EU EUDAMED, China NMPA, UAE BrandSync, etc.*

Medium: **Remote** via **Zoom for Meetings**
Duration: **2 Hours**
Fees:

- 1 to 3 pax – RM 500.00
- 4 to 6 pax – RM 800.00
- 7 to 10 pax – RM 1,500.00

Requirements:

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1. Provide **2 tentative dates**.
2. Provide us with the **list of the attendees**.
3. Provide **payment proof**.
4. All above must be submitted **at least 3 days before** the training commencement.
5. Additional attendees **exceeding agreed upon number** will be **charged** accordingly.

The Zoom meeting details will be sent after we have received your details and payment.

Participants:

No.	Attendee Name	Designation	Contact Email
1			
2			
3			
4			
5			

Tentative Date 1: _____

Tentative Date 2: _____

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