GS1 DIY Self-Learn Materials

Unique Device Identification (UDI)

GS1 Malaysia Berhad
Preface

- This DIY Self Learn Material will provide insights into:
  - What is UDI
  - How GS1 can help your business to **meet UDI requirements**
  - The **requirements** to list products in GUDID and EUDAMED
  - Details about **Basic UDI-DI**
  - Other **cross-border UDI regulations**
Unique Device Identifier

- What is UDI?
- US FDA UDI
- EU UDI
Unique Device Identifier (UDI)

What is UDI?
Identifier/code on device label and packaging or, on the device itself.

UDI = Device Identifier (DI) + Production Identifier/s (PI)

• DI (static) – specific to a device version or model.
• PI (dynamic) – one or more currently used information for control/production identifiers, e.g. lot/batch number, serial number, manufacturing date, expiration date.

The UDI must appear on the label in a human readable format, as well as in a manner that can be read by automatic identification and data capture (AIDC) technology.
Unique Device Identifier (UDI)

When should you allocate a new UDI:

- Change to quantity/quantity of devices provided in a package
- Change of Brand/Trade Name
- New Version/Model
- New Issuing Agency
- Change of Clinically Relevant Size
- Labeled as Single Use
- Labeled as containing natural rubber latex
- Add/Remove MRI safety information
- Device Packaged as Sterile
- The device requires sterilization before use
UDI & GS1 Standards

**UDI Unique Device Identification**

...is enabled by GS1 Standards !!

...GS1 Global is the first accredited UDI issuing agency by the US FDA and EU.

UDI information is submitted to FDA’s Global Unique Device Identification Database (GUDID) and EU’s European Database on Medical Devices (EUDAMED)

**NOTE:** While GS1 Global is the issuing agency, GS1 MOs are referred to as agents to issue UDI for subscriber members.
All listed jurisdictions recognise GS1 as an issuing agency!
# UDI in GS1 Terms

<table>
<thead>
<tr>
<th>UDI</th>
<th>GS1 Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unique Device Identification</td>
<td>Product Identification</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DI</th>
<th>GTIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Identifier (DI)</td>
<td>Global Trade Item Number</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PI</th>
<th>AI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production Identifier (PI)</td>
<td>Application Identifier (AI)</td>
</tr>
<tr>
<td>(if applicable)</td>
<td>• Expiration Date AI(17) - e.g. 141120</td>
</tr>
<tr>
<td></td>
<td>• Lot/Batch AI(10) - e.g. 1234AB</td>
</tr>
<tr>
<td></td>
<td>• Serial Number AI(21) - e.g. 12345XYZ</td>
</tr>
</tbody>
</table>

*Production Identifier data will vary by medical device type and manufacturer current practice.*

**DI + PI = UDI**  
**GTIN or GTIN + AI(s) = UDI**
More than 85% of products in U.S. FDA GUDID carry GS1 as UDI primary DI

<table>
<thead>
<tr>
<th>US FDA GUDID Analysis</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Unique Primary Devices Currently Listed in GUDID</td>
<td>1,335,933</td>
<td></td>
</tr>
<tr>
<td>Total Number of Devices by Issuing Agency (DI from agency either Primary or Secondary)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GS1</td>
<td>1,142,813</td>
<td>85.5%</td>
</tr>
<tr>
<td>HIBCC</td>
<td>192,968</td>
<td>14.5%</td>
</tr>
<tr>
<td>NDC\NHRIC</td>
<td>97</td>
<td>0.007%</td>
</tr>
<tr>
<td>ICCBBA</td>
<td>55</td>
<td>0.004%</td>
</tr>
</tbody>
</table>

**HIBCC** - The Health Industry Business Communications Council®

**ICCBBA** - International Council for Commonality in Blood Banking Automation

**NDC** - National Drug Code
UDI Label Requirements

Example Label

**Non-HRI Text**
Information formatted for normal human reading

**HRI (Human Readable Interpretation)**
Information formatted for machine reading (numbers at the side to show what’s encoded)

*Note: Both information must match!*

GS1 Healthcare Products
FMD (Fictitious Medical Device)

Manufacturer:
GS1 Global Office
Avenue Louise 326
BE 1050 Brussels
+32 2 768 7800

2014-11-20
7654321D

(01) 09504000059118
(17) 141120
(10) 7654321D
(24) 10987654d321
Example: UDI Application

Date Format = YYYY-MM-DD

Device Identifier

Production Identifiers
Rules applicable to the use of GS1 System for UDI

• Usage of GS1 prefixes for UDI will be reported to FDA and other regulators by GS1 every year.

• Should deficiencies be found, a member will be informed and must correct the deficiencies within a specific time period from when they were informed, known as the Correction Period.

• Upon expiry of the Correction Period, the local GS1 will attempt to meet and resolve any issues with the member after the expiry. If corrections are not made, it will be considered as a repeated or deliberate misuse of GS1 Standards related to UDI.

• GS1 Malaysia can and will revoke the GS1 Membership of any member who does not correct the issue or provide a suitable reason for the delay. All revocations will be informed to GS1 Global, FDA and other regulation bodies.
Rules applicable to the use of GS1 System for UDI

• Examples of Deficiencies:
  - Wrong GTIN recorded
  - Wrong GCP recorded
  - Incorrect Product/Company Details
  - Changes in Company Status and contact information not updated with GS1
  - Missing Product/Company Details
  - GS1 Membership not active
Example of an actual report sent to GS1 Malaysia from GS1 Global when **discrepancies** are found

<table>
<thead>
<tr>
<th>companyName</th>
<th>gs1_prefix</th>
<th>GCP</th>
<th>Data</th>
<th>total_records</th>
</tr>
</thead>
<tbody>
<tr>
<td>B********Y (M) SDN. BHD.</td>
<td>955</td>
<td></td>
<td>(M) Sdn Bhd</td>
<td>Kepong</td>
</tr>
<tr>
<td>B********Y (M) SDN. BHD.</td>
<td>955</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D*****.**D (MALAYSIA) SDN. BHD.</td>
<td>955</td>
<td></td>
<td>(Malaysia) Sdn Bhd</td>
<td>Kota Damansara</td>
</tr>
<tr>
<td>D*****.**D (MALAYSIA) SDN. BHD.</td>
<td>955</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I** A*** P****C SDN. BHD.</td>
<td>955</td>
<td></td>
<td>(Malaysia) Sdn Bhd</td>
<td>Kota Damansara</td>
</tr>
<tr>
<td>S***<em><strong><strong>N O</strong></strong></em>X SDN. BHD.</td>
<td>955</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T******X INC</td>
<td>955</td>
<td></td>
<td>Primary</td>
<td>0955</td>
</tr>
<tr>
<td>T******X INC</td>
<td>955</td>
<td></td>
<td>Primary</td>
<td>0955</td>
</tr>
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</table>

**Company name does not match GS1 licensee name, GCP 9555**
GS1 Standards used in EU UDI Regulations

- The EU Medical Device Regulation (MDR) & IN-vitro Diagnostic Regulation (IVDR) will use GS1 Standards & Keys to support patient safety & supply chain security.

- This adoption was finalised on 5th April 2017 and published on 5th May 2017. Actual implementation will begin in 2020 for MDR and 2022 for IVDR.

- GS1 was designated as an UDI issuing agency by the European Commission in 7th June 2019. Submission of product data is to be sent to EUDAMED (European Database on Medical Devices), to be launched on May 2024.

- Manufacturers will need to include the Basic UDI-DI or Global Model Number (GMN) in their technical documentation and during their submission to EUDAMED.

# EU UDI in GS1 Terms

<table>
<thead>
<tr>
<th>UDI regulatory requirements</th>
<th>GS1 Standards</th>
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</thead>
<tbody>
<tr>
<td><strong>Basic UDI-DI</strong></td>
<td>GMN (Global Model Number)</td>
</tr>
<tr>
<td>« New » level of identification in the EU</td>
<td>No Application Identifier (AI) for regulated medical devices</td>
</tr>
<tr>
<td><strong>UDI-DI</strong>&lt;sup&gt;*&lt;/sup&gt;</td>
<td>GTIN&lt;sup&gt;*&lt;/sup&gt;</td>
</tr>
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<tr>
<td></td>
<td>• Serial number Al(21) - e.g. 12345XYZ</td>
</tr>
<tr>
<td></td>
<td>• Manufacture date Al(11) - e.g. 250717</td>
</tr>
</tbody>
</table>

Production Identifier data will vary by medical device type and manufacturer current practice.

UDI-DI + UDI-PI = UDI

GTIN or GTIN + Al(s) = UDI

*The HRI Format shall follow the rules of the UDI Issuing Entity*
What is Basic UDI-DI?

- In compliance with European Union guidelines for UDI-DI issued on June 2019, a new identifier; the Basic UDI-DI, must be included in any submission of regulated healthcare medical devices under the EU Medical Device Regulation (MDR) and EU In-Vitro Device Regulation (IVDR) to EUDAMED (EU’s UDI repository).

To express the Basic UDI-DI in GS1 Terms, the GS1 Global Model Number, or GMN is used.
How to assign a Basic UDI-DI

- How is the Basic UDI-DI / GMN assigned?

  ➢ A GMN is used to identify product categories or models, for example:
    - A hip implant from a medical device company is given a GMN.
    - That model of implant may have different variants (size, gender, etc.), but because they all share the same base/design, therefore they carry the same GMN.
      - E.g. Hip implant for men – different colors or sizes, same GMN.
    - If the base is different i.e. a different model, you must assign a new GMN.
      - E.g. Hip implant for men and for women, different base or mold to make, different GMN.
Other Cross-Border UDI Regulations

- **China** – Medical device products must be labelled/identified with GS1 unique identifiers and must submit their product information for registration and upload into the National Medical Products Administration’s (NMPA) Database. (https://udi.nmpa.gov.cn/)

- **South Korea** - Medical products traded in South Korea must be registered in the Integrated Medical Device Information System (IMDIS), as per Ministry of Food and Drug Safety (MFDS) notification No. 2020-29.

- **UAE** - The Dubai Health Authority has announced that they will be relying on GS1 UAE’s BrandSync Platform for product information on all existing and new products supplied to Dubai Health Authority, such as medical devices traded in the UAE.
Want to learn how to generate GMN and more?

Attend GS1 Malaysia’s

Capacity Building & Implementation Program to find out more!
Effective Implementation of GS1 Standards and Keys – FREE to attend!

**Effective Implementation of GS1 Standards & Keys**

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Highlights</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monday to</td>
<td>3.00 PM -</td>
<td>• Learn how to assign GS1 barcode numbers.</td>
</tr>
<tr>
<td>Friday</td>
<td>4.00 PM</td>
<td>• Upload your product information to our online repository for visibility &amp; authenticity.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Why an active GS1 Membership is important for your Business.</td>
</tr>
</tbody>
</table>

*Subject to change*

**JOIN US NOW ON ZOOM!**
Migration to “Data-Rich 2D” Initiative (FOC)

**Migration to “Data-Rich 2D” Zoom Link:**
https://us06web.zoom.us/j/82513900764

**Key Learnings:**
- Learn about how GS1 supports the **global migration towards the 2D Data matrix** for greater product visibility, traceability and authentication
- Case studies about successful 2D barcode usage & implementation in Healthcare and Retail around the world.

**Date**
Every WED
9.00AM - 10.00AM

*Subject to change

JOIN US NOW VIA ZOOM!
**Verified by GS1 – Product Databank Support & Services**

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Highlights</th>
</tr>
</thead>
</table>
| Every Thursday of the Month | 11.00 AM - 11.30 AM | - WHAT is VbG-PDSS?  
- WHY is VbG-PDSS so Important?  
- The Services & Platforms Managed by VbG-PDSS |

*Subject to change*

**VbG-PDSS Zoom Link:**
[https://us06web.zoom.us/j/89770665451](https://us06web.zoom.us/j/89770665451)

**JOIN US NOW ON ZOOM!**

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GS1 Malaysia Industry Focus Forums

<table>
<thead>
<tr>
<th>TOPIC 1</th>
<th>TOPIC 2</th>
<th>TOPIC 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply Chain Optimisation and Regulatory Fulfilment using Global Location Number (GLN) and GS1 Services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comply with Global Unique Device Identification (UDI) Regulation &amp; Directive of Healthcare using GS1 Standards</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Importance of GS1 Global Location Number (GLN)</td>
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<td></td>
</tr>
</tbody>
</table>

Key Learnings:
- Comply with Retail Merchandising Requirements
- Fulfill Global Regulatory Compliance
- Track & Trace using the GS1 2D Datamatrix

Key Learnings:
- Achieve compliance with international directives and country-specific regulations on medical devices and pharmaceutical products
- Fulfilling regulatory compliance required by US FDA GUDID, EU EUDAMED, China NMPA, UAE BrandSync, and many more.

Key Learnings:
- Comply with international directives and country-specific regulations on location and entity identification such as the Russian certificate of conformity for all products originating outside of EAEU and the use of GLN by NPRA-MOH for COVID-19 vaccine track and trace.

*Chargeable:
1-5 people – RM 500
6-10 people – RM 1000

Write to databank@gs1my.org to book your session!
In-House Business Consultation

Need a special tailor-made In-House Business Consultation session? GS1 Malaysia can provide advisory support for you to meet your specific needs.

Each session can be half-day or full day.

Scan here for the Fee Structure:
Official GS1 Communications Channels

Official GS1 Malaysia WhatsApp

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(Membership, Services & Support)

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(Strictly for Payment Only)

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