The Global Language of Business

GS1 DIY Self-Learn Materials

Unique Device Identification (UDI)

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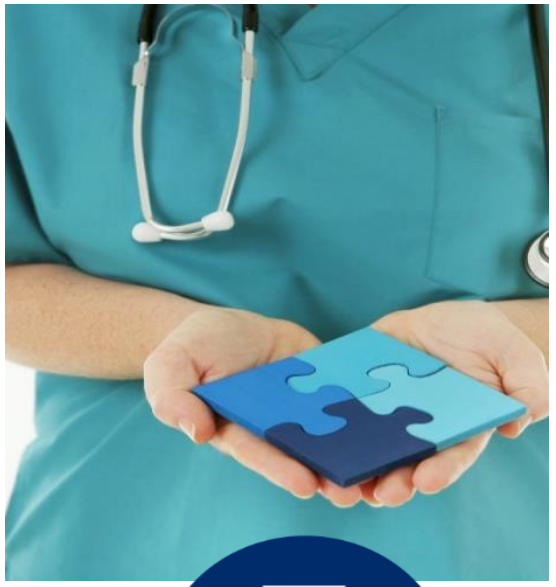

Preface

- 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**

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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.

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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

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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.

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UDI Issuing Agencies

Jurisdiction	EU	USA	China	Saudi Arabia	Taiwan	South Korea	Australia	Brazil
Designated issuing entities	GS1	GS1	GS1	GS1	GS1	GS1	GS1	GS1
	HIBCC	HIBCC		HIBCC	HIBCC	HIBCC	HIBCC	HIBCC
	ICCBBA	ICCBBA		ICCBBA	ICCBBA	ICCBBA	ICCBBA	
	IFA GmbH							
			ZIIOT					
			Ali Health					

All listed jurisdictions recognise GS1 as an issuing agency!

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UDI in GS1 Terms

UDI Unique Device Identification	**GS1 Standards** Product Identification
DI Device Identifier (DI)	**GTIN** Global Trade Item Number
PI Production Identifier (PI) (If applicable)	**AI** Application Identifier (AI) • Expiration Date AI(17) - e.g. 141120 • Lot/Batch AI(10) - e.g. 1234AB • Serial Number AI(21) - e.g. 12345XYZ
Production Identifier data will vary by medical device type and manufacturer current practice.	
DI + PI = UDI	**GTIN or GTIN + AI(s) = UDI**

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More than 85% of products in U.S. FDA GUDID carry GS1 as UDI primary DI

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

HIBCC - The Health Industry Business Communications Council®

ICCBBA - International Council for Commonality in Blood Banking Automation

NDC - National Drug Code

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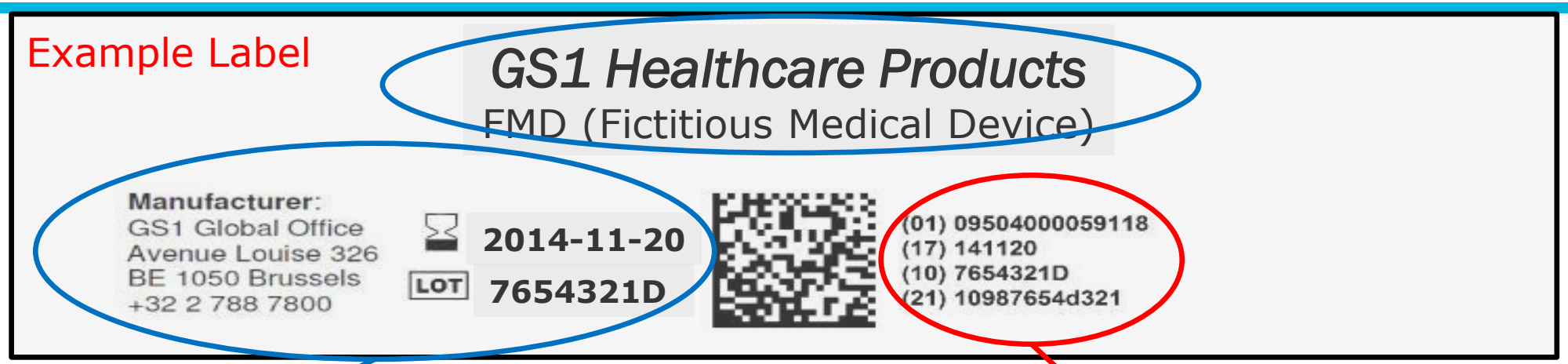
UDI Label Requirements



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!

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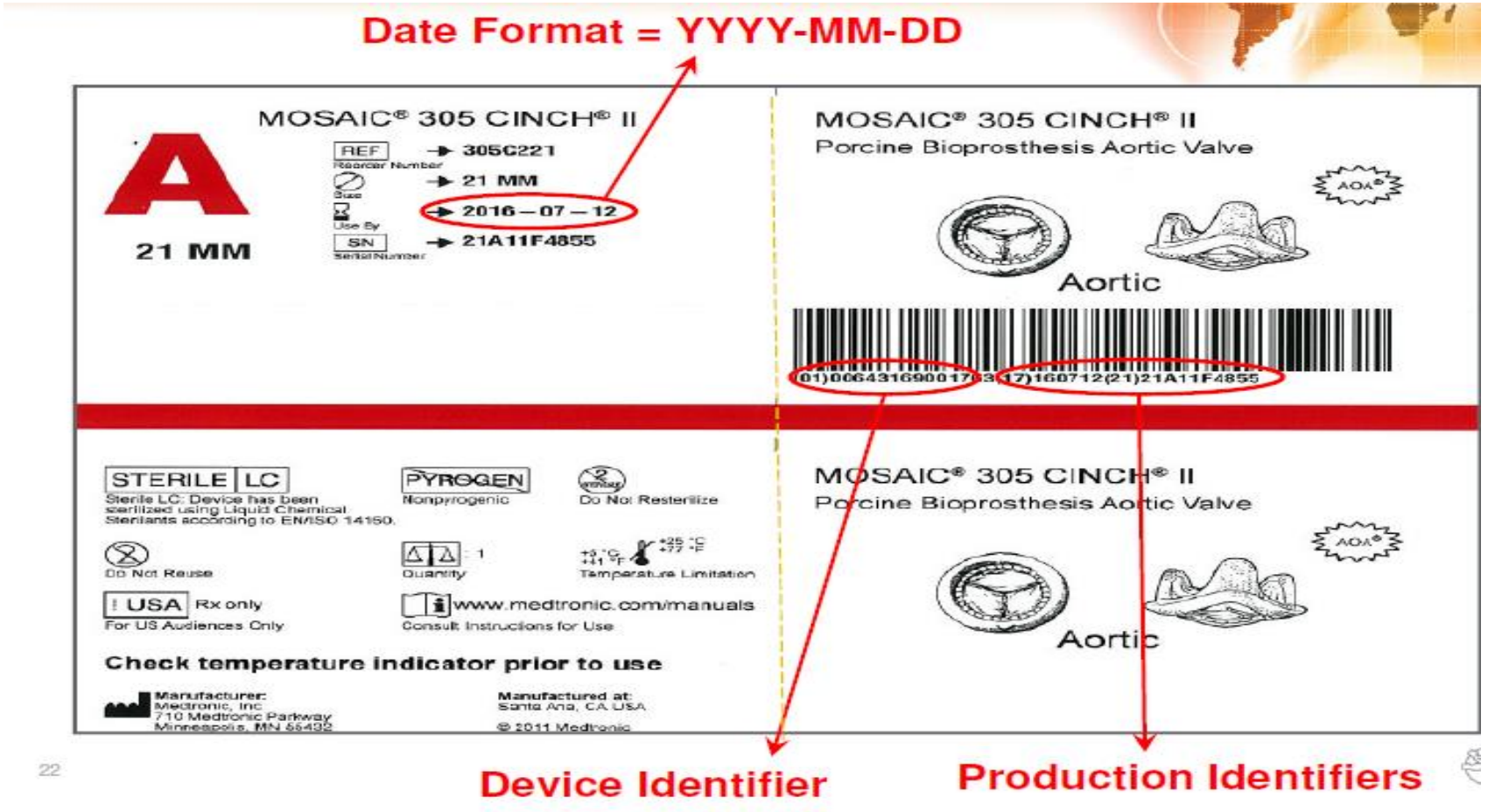
Example: UDI Application



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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.

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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

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GS1 FDA GUDID - UDI validation in action

Example of an actual report sent to GS1 Malaysia from GS1 Global when discrepancies are found

companyName	gs1_prefix	GCP	Line	Data	total_records
B********Y (M) SDN. BHD.	955		A	(M) Sdn Bhd | Kepong | Malaysia	1
B********Y (M) SDN. BHD.	955		B	Primary | | 31-Jul-2017:31-Jul-2017 | I/I	1
D****-**D (MALAYSIA) SDN. BHD.	955		A	(Malaysia) Sdn Bhd | Kota Damansara | Malaysia	79
D****-**D (MALAYSIA) SDN. BHD.	955		B	Primary | 0955 09555 | 04-Nov-2016:17-Dec-2018 | I/N	79
I** A*** P*****C SDN. BHD.	955	no match	B	Primary | 0955 195552 | 29-Mar-2019:21-Aug-2019 | I/I	22
S**********N O*****X SDN. BHD.	955	no match	B	Primary | 0955 -0955 | 10-Jun-2019:10-Jun-2019 | I/I	53
T******X INC	955		A%	| 34600 Kamunting | Malaysia	23
T******X INC	955		B	Primary | 0955 :19555 | 16-Sep-2016:16-Sep-2016 | I/I	23
T******X INC	955		C	Company name does not match GS1 licensee name, GCP 9555	23

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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.

https://ec.europa.eu/health/sites/default/files/md_eudamed/docs/md_eudamed_udi-devices-user-guide_en.pdf

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EU UDI in GS1 Terms

UDI regulatory requirements	GS1 Standards
Basic UDI-DI « New » level of identification in the EU	**GMN** (Global Model Number) *No Application Identifier (AI) for regulated medical devices*
UDI-DI * Device Identifier (DI)	**GTIN** * Global Trade Item Number
UDI-PI * Production Identifier (PI) *(if applicable)*	**AI** * Application Identifier (AI) • Expiration date AI(17) - e.g. 141120 • Batch – lot AI(10) - e.g. 1234AB • Serial number AI(21) - e.g. 12345XYZ • Manufacture date AI(11) - e.g. 250717
Production Identifier data will vary by medical device type and manufacturer current practice.	
UDI-DI + UDI-PI = UDI	**GTIN or GTIN + AI(s) = UDI**

* The **HRI Format** shall follow the rules of the UDI Issuing Entity

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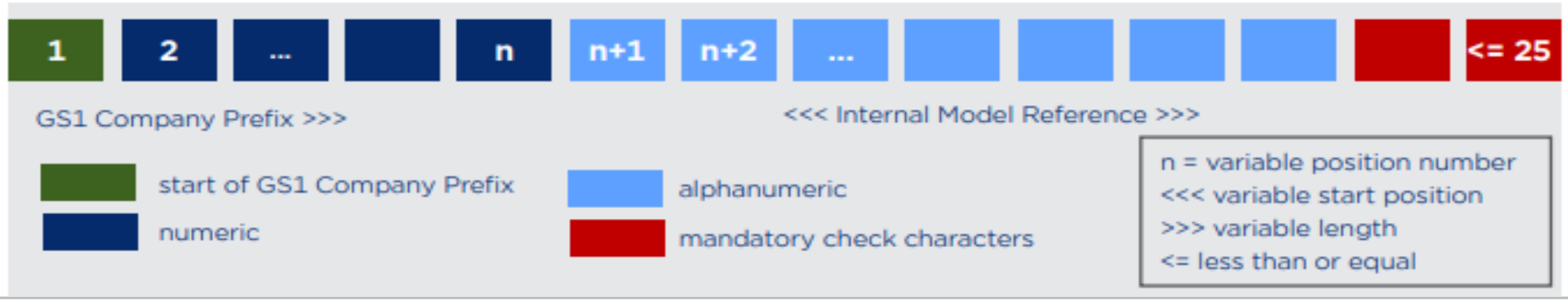
What is Basic UDI-DI?

- 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.

Composition of the GMN (Basic UDI-DI)



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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.*

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Other Cross-Border UDI Regulations

- **China** – Medical device products must 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.

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Want to learn how to generate GMN and more?

Attend GS1 Malaysia's

Capacity Building & Implementation Program

to find out more!

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Effective Implementation of GS1 Standards and Keys – FREE to attend!

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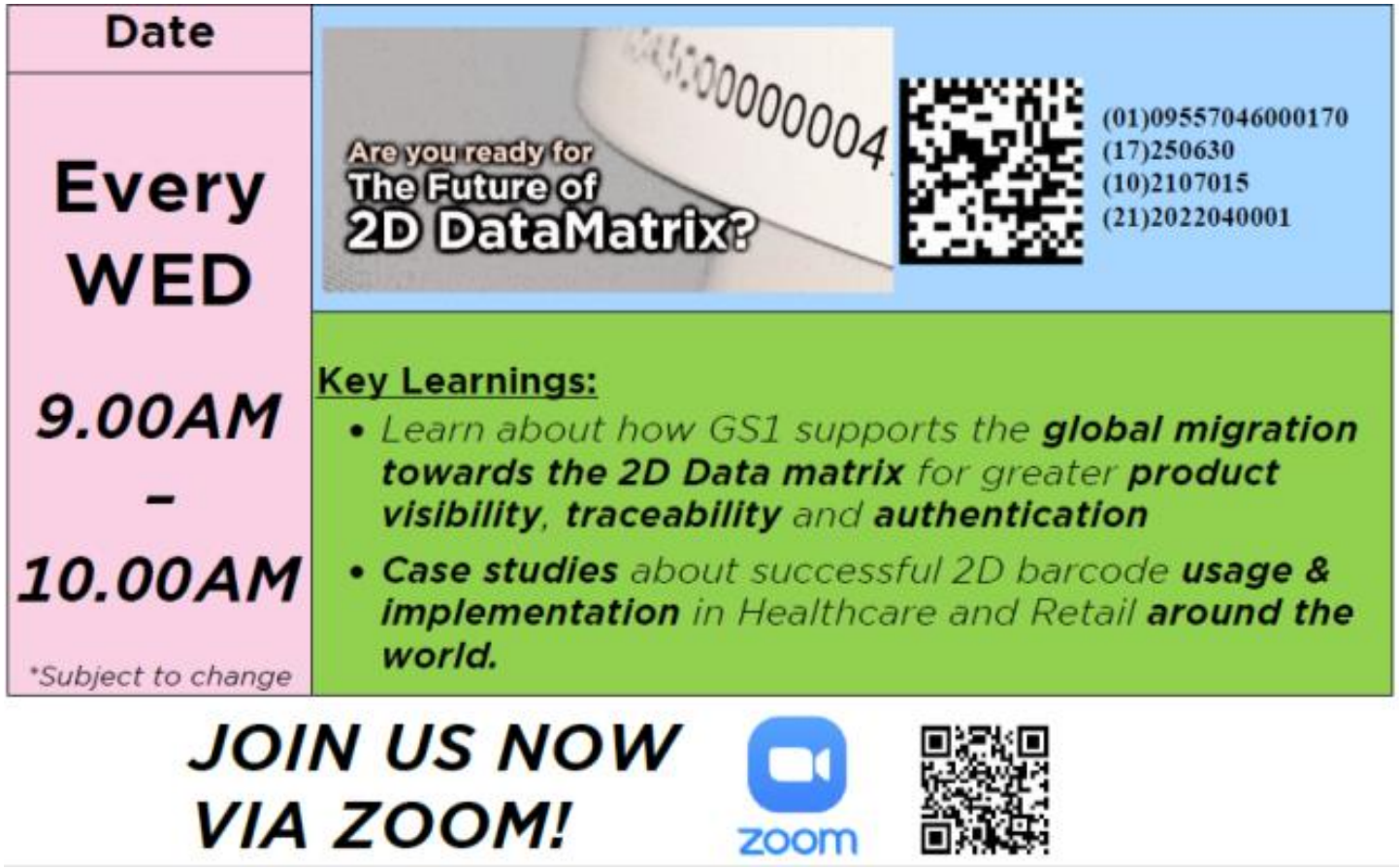
Migration to “Data-Rich 2D” Initiative (FOC)



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

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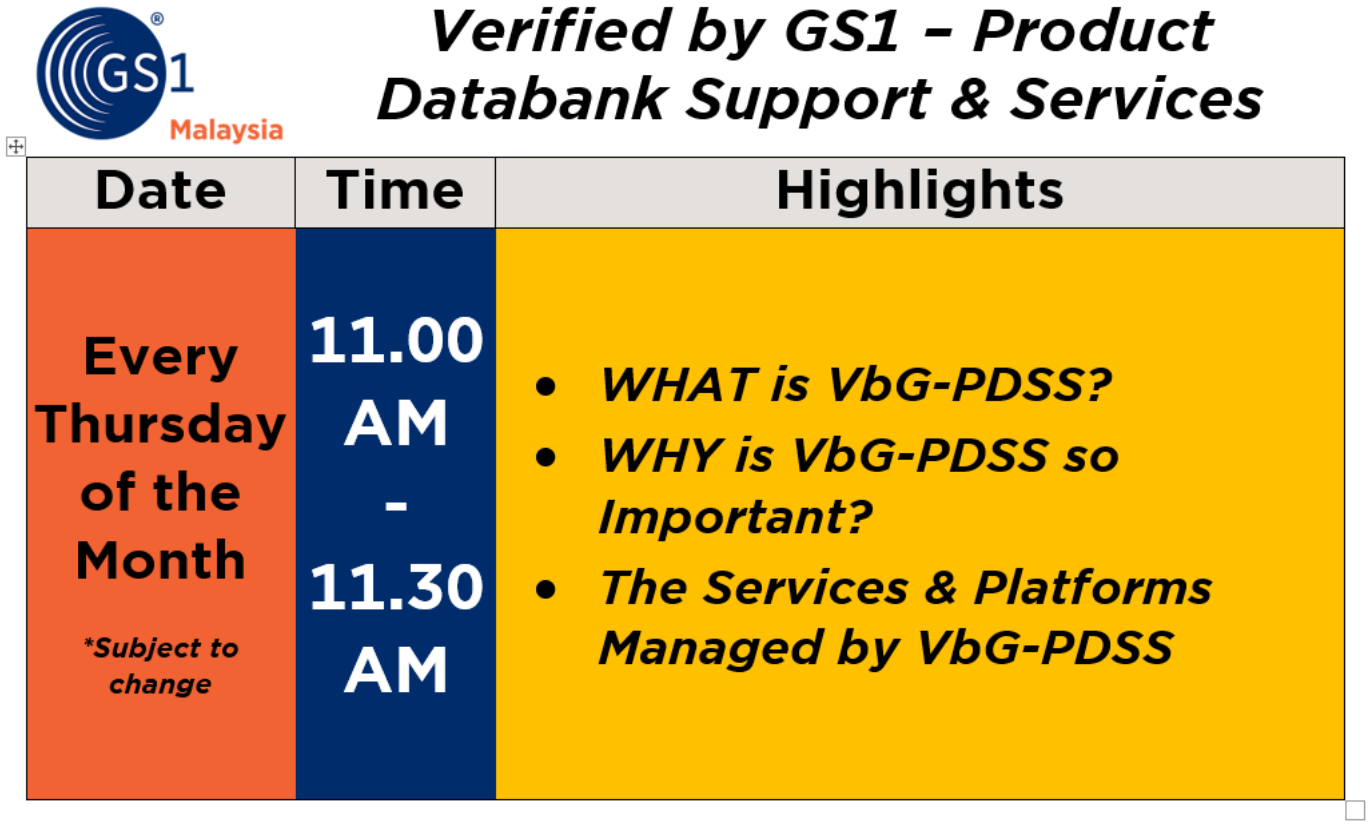
Verified by GS1 – Product Databank Support & Services



VbG-PDSS Zoom Link: https://us06web.zoom.us/j/89770665451

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GS1 Industry Focus Forums

GS1 Malaysia Industry Focus Forums

TOPIC 1	TOPIC 2	TOPIC 3
Supply Chain Optimisation and Regulatory Fulfilment using Global Location Number (GLN) and GS1 Services	**Comply with Global Unique Device Identification (UDI) Regulation & Directive of Healthcare using GS1 Standards**	**The Importance of GS1 Global Location Number (GLN)**
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.*

Write to databank@gs1my.org to book your session!

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

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Each session can be **half-day** or **full day**.

Scan here for the Fee Structure:

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