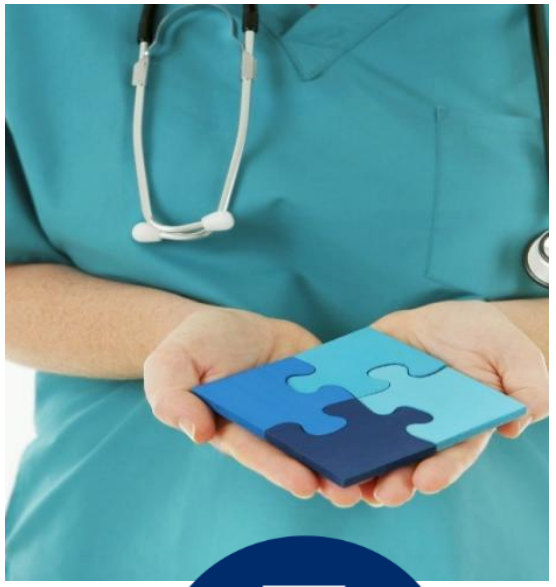
The Global Language of Business

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.

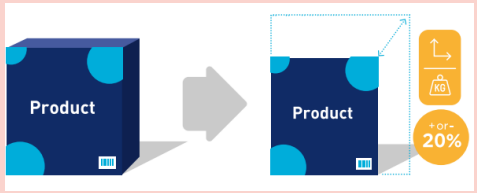
UDI = Device Identifier (DI) + Production Identifier/s (PI)

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

Unique Device Identification (UDI) & GS1 Standards

UDI : Unique Device Identification

- **Identification for medical devices.**
- **Enabled by: GS1 Standards.**

GS1 Global

- **Accreditation as a UDI issuing agency:**
  - Recognized by:
  - ✓ **US Food & Drugs Administration (FDA) – Sept 2014**
  - ✓ **EU Medical Device Regulation (MDR) and In-vitro Device Regulation (IVDR) - April 2017**

- **Submission: UDI information to:**
  - ✓ **FDA's Global Unique Device Identification Database (GUDID)**
  - ✓ **EU's European Database on Medical Devices (EUDAMED)**

Other Countries that recognize GS1 as a UDI Issuing Agency:

1) South Korea - **2016**
2) Singapore – **2018**
3) China - **2019**
4) Türkiye – **2019**
5) Saudi Arabia - **2021**
6) Taiwan - **2021**
7) Brazil - **2021**
8) Egypt – **2021**
9) New Zealand - **2021**
10) Australia - **2025**

NOTE: *While GS1 Global is the issuing agency, GS1 MOs are referred to as agents to issue UDI for subscriber members.*

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!

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**

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

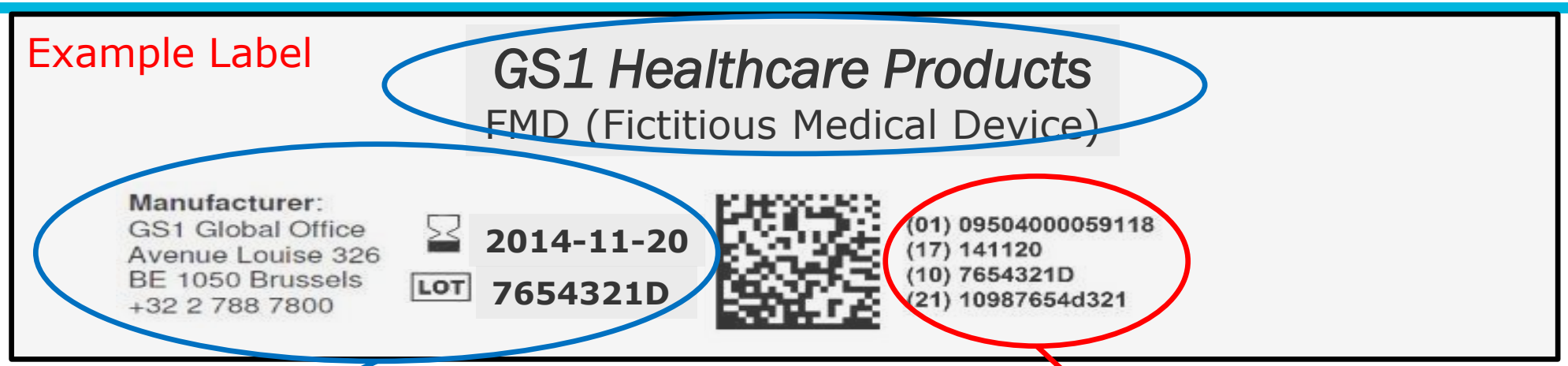
US FDA GUDID Analysis			
Total Number of Unique Primary Devices Currently Listed in GUDID	**1,335,933**		
Total Number of Devices by Issuing Agency ***(DI from agency either Primary or Secondary)***	**GS1**	**1,142,813**	**85.5%**
	HIBCC	192,968	14.5%
	NDC\NHRIC	97	0.007%
	ICCBBA	55	0.004%

HIBCC - The Health Industry Business Communications Council®

ICCBBA - International Council for Commonality in Blood Banking Automation

NDC - National Drug Code

UDI Label Requirements



Non-HRI Text

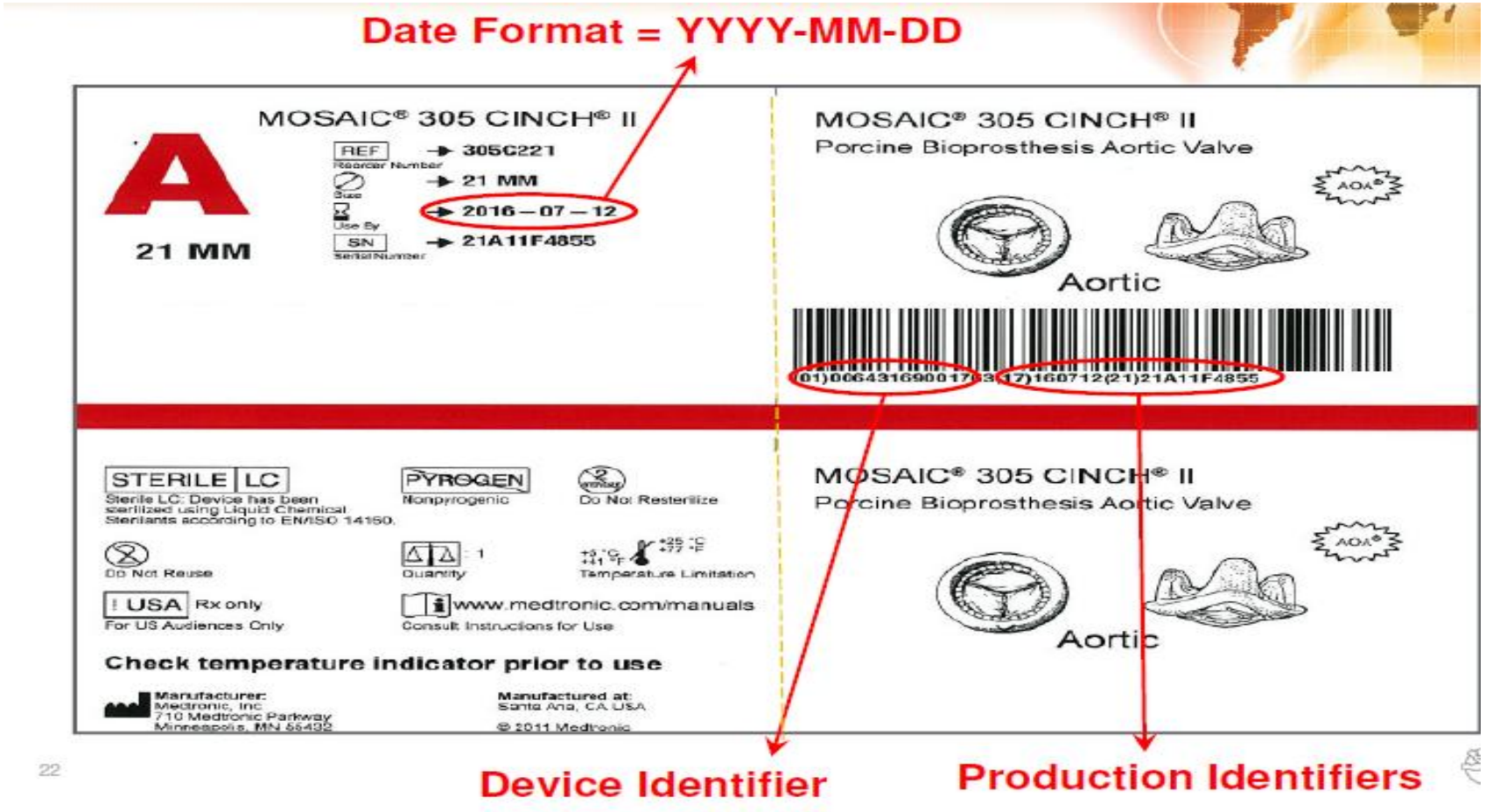
Information formatted for normal human reading

HRI (Human Readable Interpretation)

Information formatted for machine reading (numbers at the side to show what's encoded)

Note: Both information must match!

Example: Application of UDI Labelling



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

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

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

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**

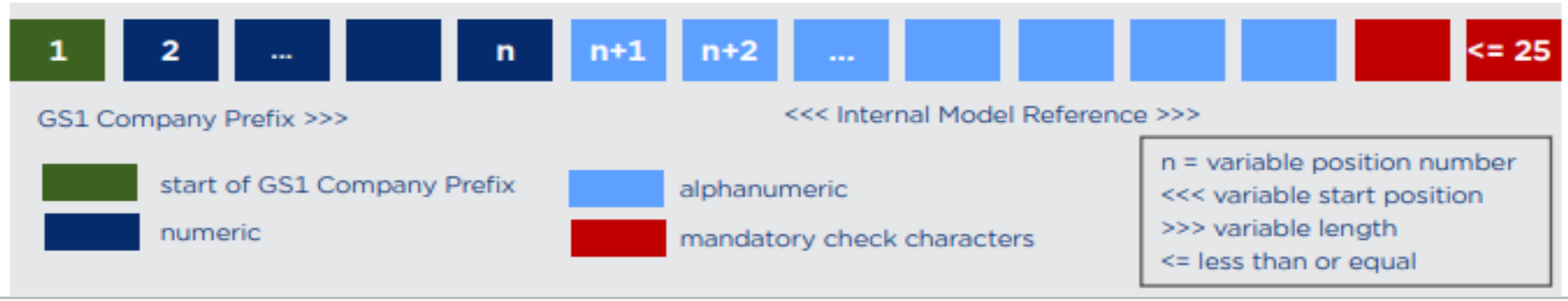
* The **HRI Format** shall follow the rules of the UDI Issuing Entity

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)



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 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.

Overview of Medical Device Industry in Malaysia

80%

World's demand for **catheters**

60%

World's demand for **rubber gloves** including medical gloves

US$4.78 B

Projected Malaysian MD market volume in **2028**

US$1.8 B

Malaysian MD market size in **2020**

Source: MIDA – Malaysia's Medical Devices Industry: Immense Growth Potential

Why Malaysia Wants to Follow Suit

ENHANCE PATIENT SAFETY

UDI ensures accurate device identification, reducing errors and enabling quick recalls.

IMPROVE TRACEABILITY

UDI tracks devices from manufacturing to patient use, aiding surveillance, adverse event reporting, and recalls.

UDI makes it easier for manufacturers to comply with regulations and for regulators to monitor the market.

STREAMLINE REGULATORY PROCESSES

UDI helps medical device providers make informed decisions and builds trust among stakeholders.

INCREASING MARKET TRANSPARENCY

Proposed UDI Timeline

*once decided and assuming MeDC@St 3.0+ is completed

2024

Pilot Survey

UDI framework development including a pilot survey for Class D and B medical devices and data analysis

2026

Transition Phase

Voluntary implementation phase for all medical device classes

2027

Class D Mandatory Phase 1

UDI implementation for all Class D medical devices

2028

Other than Class D Mandatory Phase 2

UDI implementation for other than class D medical devices

2030

Full UDI Compliance

Full UDI compliance in Malaysia

Want to learn how to generate GMN and more?

Attend GS1 Malaysia's

Capacity Building & Implementation Program

to find out more!

GS1 MALAYSIA CAPACITY BUILDING FREE BRIEFINGS

(1) Fulfilling Market & Regulatory Guidelines Using GS1 Standards	(2) GS1 2D Standards and VbG & GACSS Fulfil Sustainability & Circularity	(3) GS1 Malaysia 2D Repository Platform	(4) The Impact of GS1 Global Location Numbers (GLN) on Business, Social, Regulation & Customer
• Understand why GS1 Standards & Keys is widely recognised and accepted • Learn why GS1 Standards & Keys protects product identity integrity and improves the Customer Buying Experience.	• Learn how GS1 supports the growing Green movement's calls for sustainability & circularity through GS1's for greater product visibility, traceability, and authentication.	• Experience how 2D track & trace works with the GS1 Malaysia 2D Repository Platform! • An intermediary repository before the future National Pharmaceutical Track & Trace system.	• Supporting compliance to EU directives such as EUDR, ESPR, CEAP, etc. on Sustainability and Circularity using GS1 unique identification (GLN) • Fulfil Digital Product Passport (DPP) requirements
3.00pm to 4.00pm (Every Monday & Wednesday) Zoom Link: https://us06web.zoom.us/j/89614519211	11.00am to 11.45am (Every Thursday) Zoom Link: https://us06web.zoom.us/j/89770665451	3.00pm to 4.00pm (Every Tuesday) Zoom Link: https://us06web.zoom.us/j/82513900764	11.00am to 11.45am (Every Friday) Zoom Link: https://us06web.zoom.us/j/86884634932

** GS1 Malaysia reserves the right to adjust the sessions based on availability & minimum attendance.*

GS1 MALAYSIA PREMIUM CAPACITY BUILDING TRAINING SCHEDULE

Premium Capacity Building Training Sessions

Industry Focus Forums (Chargeable)

Topic 1	Topic 2
Supply Chain Optimisation and Regulatory Fulfilment using Global Location Number (GLN) and GS1 Services	Meeting Global Healthcare and UDI Guidelines using GS1 Standards
• *Comply with **Retail Merchandising Principles*** • *Fulfil **Global Regulatory Compliance*** • *Track & Trace using GS1 Traceability guidelines and 2D Datamatrix.*	• *Achieve compliance with international and country-specific directives on Healthcare Products, such as **US FDA GUDID, EU EUDAMED, China NMPA, UAE BrandSync, etc.***

In-House Training & Business Consultation (Chargeable)

- *Training is **tailored** to company's requirements*
- *Can be conducted at **company's premises of choice** or via **Zoom***
- *Full day session includes **quiz activity***
- ***Travelling charges** will be incorporated into the training fees*

1-3 pax: **RM 500.00**	*4-6 pax:* **RM 800.00**	*7-10 pax:* **RM 1,500.00**	***Scan the QR for in-house session fee breakdown***

Contact GS1 Malaysia at **gs1malaysia@gs1my.org** to arrange for a session.

GS1 Malaysia reserves the right to adjust the sessions based on availability & minimum attendance.

In-House Training & 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:

Build your Staff Competence with GS1 Member Capacity Building Initiative

Free of charge!

GS1 Member Capacity Building Initiative

Jointly Organised with FMM Institute

Provides **FREE comprehensive training programs (Commercial value - RM 1,400/pax/topic)** to GS1 Members that are essential for **business and employee growth**. Covers a wide range of topics:

1. Administration, Customer Service & Operations
2. Marketing, Data Analytics & Logistic Management
3. Regulations, Governance & Best Practices
4. Accounts & Finance
5. Business Development & Leadership and **many more.**

- ***FREE** for **Active GS1 Members Only***
- *Session conducted **physically at FMM Branches** and via **Zoom***

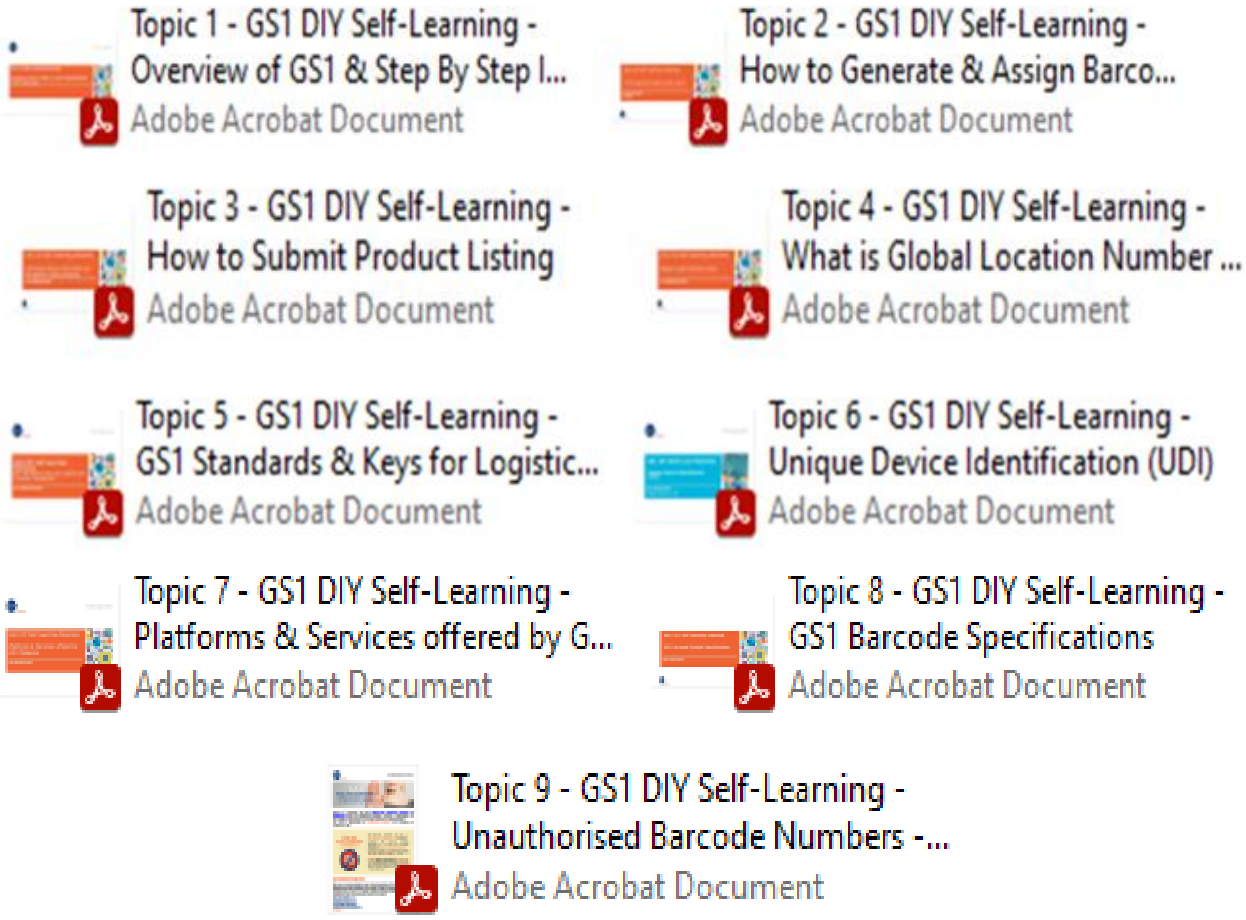
For further details, contact us at: gs1malaysia@gs1my.org

Curated to answer your enquiries!
GS1 DIY Self-Learning Materials!

Access the guide here:
https://gs1my.org/?q=gs1-malaysia-diy-self-learning-materials

OR

Scan to View



Official GS1 Communications Channels

Official GS1 Malaysia WhatsApp

+6014-3933 228
(Membership, Services & Support)

+6011-1616 8228
(Membership, Services & Support)

+6016-2455 228
(Strictly for Payment Only)

+6012-2722 646
(Strictly for Payment Only)

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Official GS1 Malaysia Website

www.gs1my.org