

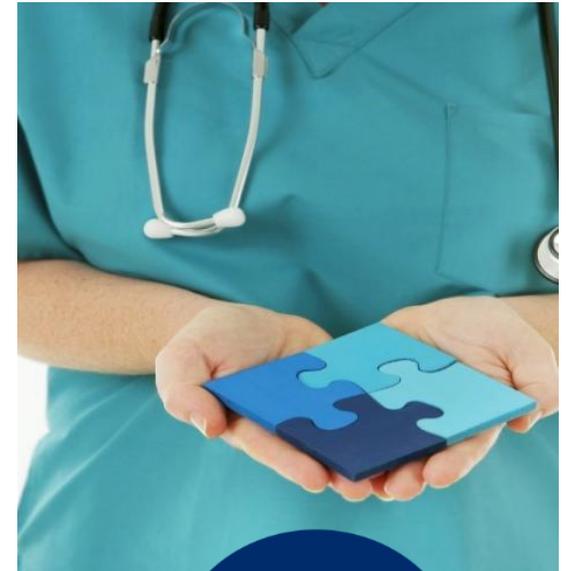


The Global Language of Business

GS1 DIY Self-Learn Materials

Unique Device Identification (UDI)

GS1 Malaysia Berhad



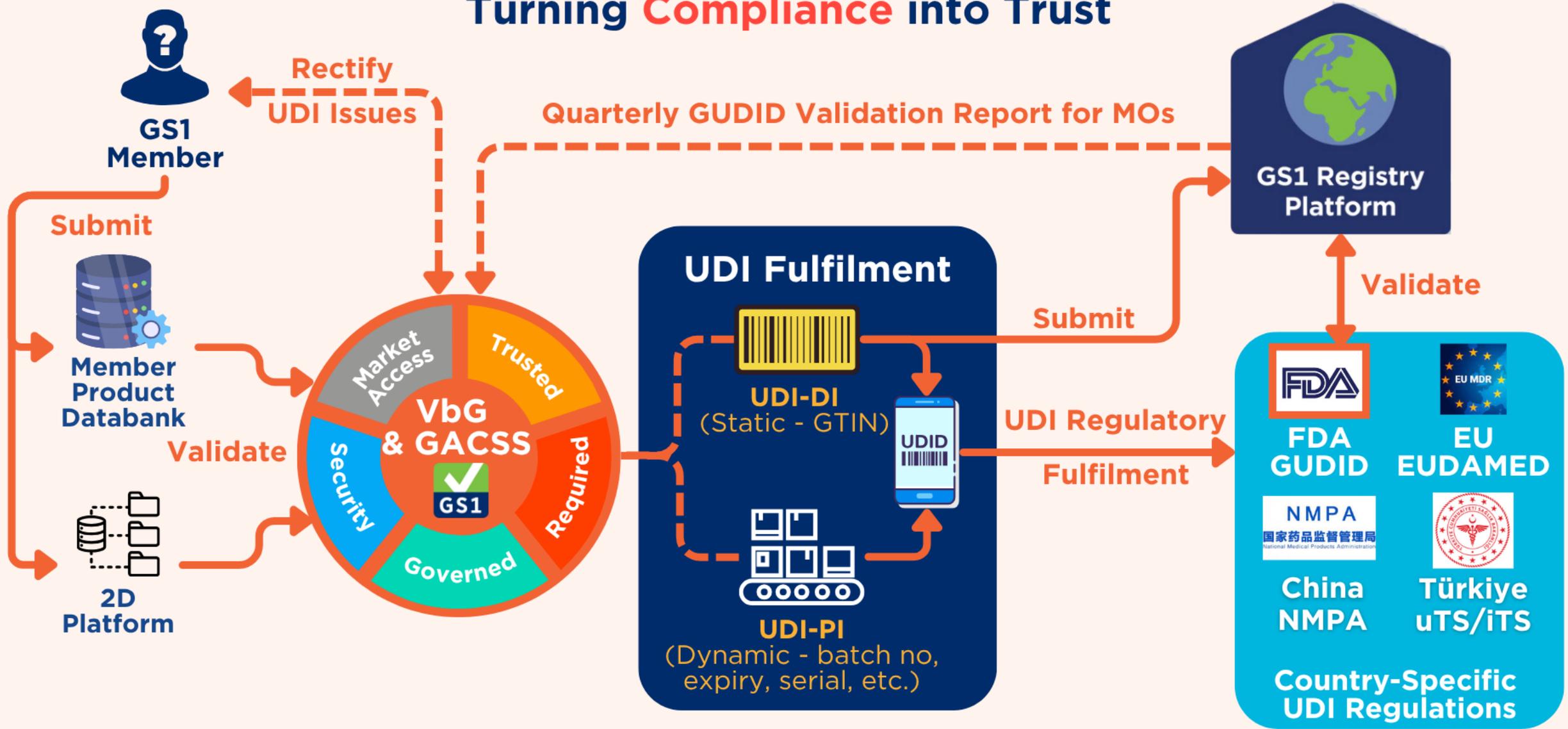


Preface

- 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**

Verified by GS1 (VbG) for Patient Safety & Regulatory Fulfilment

Turning Compliance into Trust



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.



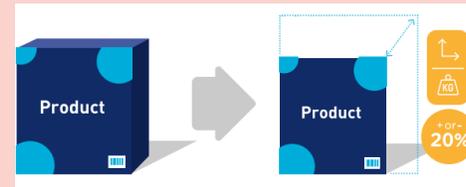
Unique Device Identifier (UDI)

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) <ul style="list-style-type: none">• Expiration Date AI(17) - e.g. 141120• Lot/Batch AI(10) - e.g. 1234AB• Serial Number AI(21) - e.g. 12345XYZ
<i>Production Identifier data will vary by medical device type and manufacturer current practice.</i>	
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 <i>(DI from agency either Primary or Secondary)</i>	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



Example Label

GS1 Healthcare Products
FMD (Fictitious Medical Device)

Manufacturer:
GS1 Global Office
Avenue Louise 326
BE 1050 Brussels
+32 2 788 7800

 **2014-11-20**

LOT **7654321D**



(01) 09504000059118
(17) 141120
(10) 7654321D
(21) 10987654d321

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!

How to adjust your GTIN-13 for Healthcare / UDI Product-Level Label Encoding

Barcode: GS1-128

(01) 0 5410013 11100 9 (17) 230527 (10) ABC123 (21) 12345678

Barcode: GS1-DataMatrix

1 (01) 0 5410013 11100 9 2 (17) 230527 3 (10) ABC123 4 (21) 12345678

1	Product Identifier (GTIN)
2	Expiration date
3	Batch / Lot Number
4	Serial number

NOTE:

- This is a **simplified** step and only works for **product-level labelling** and **cannot be used** for **cartons** or **pallets**.
- Must acquire and understand the use of **GS1 Application Identifiers (AIs)**, i.e. the codes in brackets



GS1 Application Identifiers



An element string that carries dynamic or “production” data that, in conjunction with the GS1 Key, provides additional information about the item identified at the point of acquisition.



(01) 1022222333334(17) 091231(10) A1345B(21) 1234



(01)10857674002017
(17)141120
(10)NYFUL01
(21)192837
(713)A1B2C3D4E5F6G

Encoding a Traceable Unit Barcode Symbol: GS1 Application Identifiers (AIs)

An **element string** that carries **dynamic** or “**production**” data that provides additional information about the item identified.

(01)19551234500005(17)250812(10)KULGS01

GS1 Application Identifier Code	Data Type	Data Length
01	Global Trade Item Number (GTIN-14)	Fixed, 14-digits
10	Batch or Lot Number	Variable, maximum 20
17	Expiry Date	Fixed, 6-digits
15	Manufacturing Date	Fixed, 6-digits
21	Serial Number	Variable, maximum 20
00	Serial Shipping Container Code (SSCC)	Fixed, 18-digits
02	GTIN of item within a Logistic Unit	Fixed, 14-digits
37	Count of Items within a Logistic Unit	Variable, maximum 8

Scan for full
AI List



Example: Application of UDI Labelling



Date Format = YYYY-MM-DD

Device Identifier **Production Identifiers**

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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.

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
<p>Basic UDI-DI « New » level of identification in the EU</p>	<p>GMN (Global Model Number) <i>No Application Identifier (AI) for regulated medical devices</i></p>
<p>UDI-DI * Device Identifier (DI)</p>	<p>GTIN * Global Trade Item Number</p>
<p>UDI-PI * Production Identifier (PI) <i>(if applicable)</i></p> <p><i>Production Identifier data will vary by medical device type and manufacturer current practice.</i></p>	<p>AI * Application Identifier (AI)</p> <ul style="list-style-type: none"> • 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
<p>UDI-DI + UDI-PI = UDI</p>	<p>GTIN or GTIN + AI(s) = UDI</p>

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

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.



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.



A

IMPROVE TRACEABILITY

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



B

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

STREAMLINE REGULATORY PROCESSES



C

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

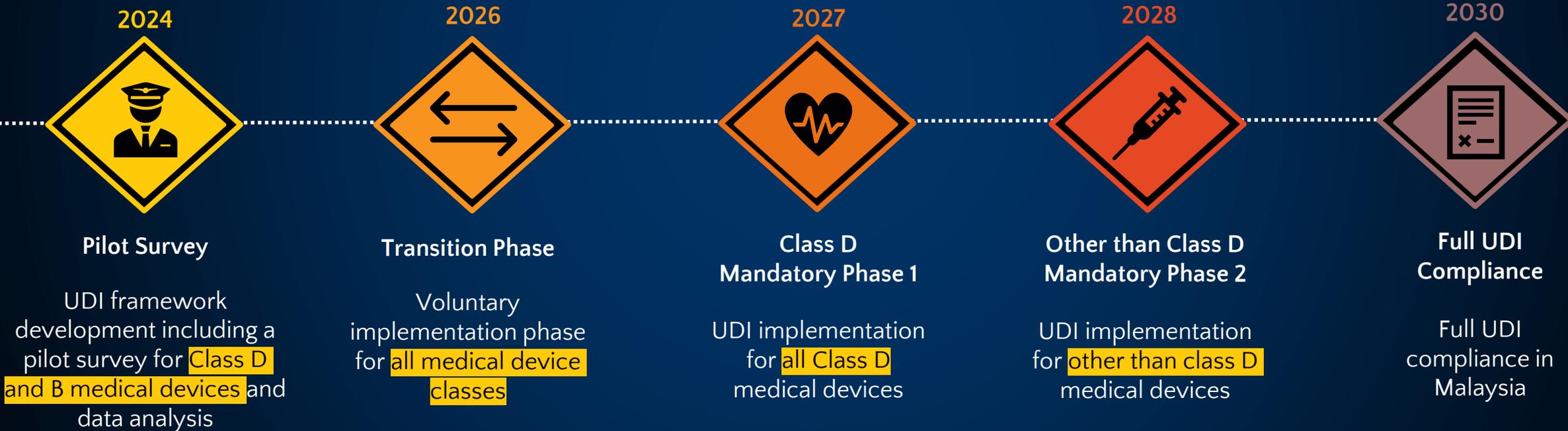
INCREASING MARKET TRANSPARENCY



D

Proposed UDI Timeline

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



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



Topic 1 - GS1 DIY Self-Learning - Overview of GS1 & Step By Step I...
Adobe Acrobat Document

Topic 2 - GS1 DIY Self-Learning - How to Generate & Assign Barco...
Adobe Acrobat Document

Topic 3 - GS1 DIY Self-Learning - How to Submit Product Listing
Adobe Acrobat Document

Topic 4 - GS1 DIY Self-Learning - What is Global Location Number ...
Adobe Acrobat Document

Topic 5 - GS1 DIY Self-Learning - GS1 Standards & Keys for Logistic...
Adobe Acrobat Document

Topic 6 - GS1 DIY Self-Learning - Unique Device Identification (UDI)
Adobe Acrobat Document

Topic 7 - GS1 DIY Self-Learning - Platforms & Services offered by G...
Adobe Acrobat Document

Topic 8 - GS1 DIY Self-Learning - GS1 Barcode Specifications
Adobe Acrobat Document

Topic 9 - GS1 DIY Self-Learning - Unauthorised Barcode Numbers - ...
Adobe Acrobat Document

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)

Official GS1 Malaysia Land Line

+603-6286 7200

Official GS1 Malaysia Emails

gs1malaysia@gs1my.org

membership@gs1my.org

payment@gs1my.org

databank@gs1my.org

Official GS1 Malaysia Website

www.gs1my.org