

## **UDI Compliance using GS1 Identification**

**To our Valued Healthcare & Personal Care Members and Partners,**



**Are you producing/trading medical devices?**

**Did you know that you must comply with Unique Device Identification (UDI) regulations for overseas trading of medical devices?**

**Great News! GS1 is recognised as an Accredited Unique Device Identification (UDI) Issuing Agency for the identification of Medical Devices and is also the global identifier of choice for Pharmaceuticals!**

By supporting GS1 Standards and Keys for medical products identification, we help you to ensure compliance with global healthcare regulations.




## Global Adoption of GS1 Standards

- A. **US FDA:** GS1 is the first accredited UDI issuing agency, with over 85% of products submitted to the FDA's GUDID platform using GS1 barcodes. The Drug Supply Chain Security Act (DSCSA) uses GS1 standards for pharmaceutical traceability.
- B. **EU EUDAMED:** GS1 is recognised for medical devices and pharmaceuticals under the EU Medical Device Regulation (MDR). Submissions to the EUDAMED platform require the GS1 Global Model Number as a product identifier.
- C. **Malaysia:** GS1 Standards and 2D Datamatrix is recognised as the official identification for pharmaceuticals & medical devices under the upcoming National Track & Trace System (MYMEDITRACE), to be implemented in 2030. Leading Healthcare companies in Malaysia who are complying with UDI requirements:
- Pharmaniaga
  - Ideal Healthcare
  - Hartalega
  - Top Glove
  - Karex
- D. **China:** Medical device identification in China is mandated with GS1 unique identifiers. Manufacturers must register products with the National Medical Products Administration (NMPA).
- E. **South Korea & Saudi Arabia:** GS1 standards are used for medical product registration and traceability in both countries.
- F. **Other Countries:** GS1 standards are also being implemented in Australia, New Zealand, Singapore, India, and more.

Join our **Capacity Building & Implementation Sessions** where you get to learn about the benefits of GS1 Standards and Keys, Supply Chain Standards, Industry Risks, Challenges and Solutions and Rules & Regulations.



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

 	<p><b>Key Learnings from the Topic:</b></p> <ul style="list-style-type: none"><li>• Benefits on the use of GS1 Traceability Standards for healthcare products for <b>track &amp; trace, sustainability, and circularity</b>.</li><li>• Fulfilment of international and country-specific directives on <b>Healthcare Products</b>, such as US FDA GUDID, EU EUDAMED, China NMPA, UAE <u>BrandSync</u>, etc.</li></ul>	
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To apply, kindly provide 2 tentative dates & times and a list of the attendees to [databank@gs1my.org](mailto:databank@gs1my.org) for further processing.

1-3 pax = RM 500.00

4-6 pax = RM 800.00

7-10 pax = RM 1,500.00

**Kindly take note of GS1 Malaysia's **official communication channels**, as follows:**

- Email: [gs1malaysia@gs1my.org](mailto:gs1malaysia@gs1my.org)
- WhatsApp: **+6014-3933 228, +6011-1616 8228**
- Land Line: **+603-6286 7200**
- Website: <https://www.gs1my.org>

Thank You.