The Global Language of Business

GS1 – AHWP Liaison Member Updates

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GS1 is a global standards organisation

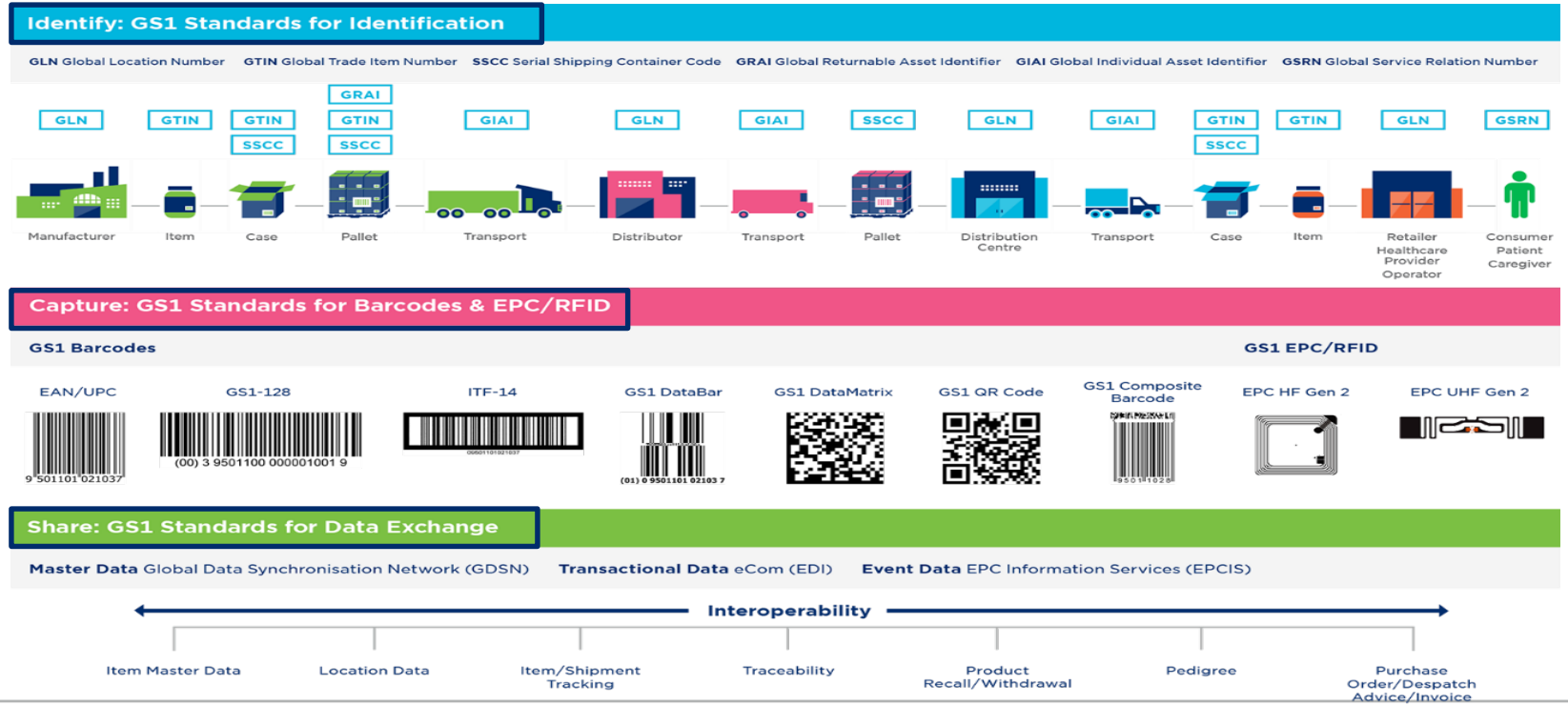
Neutral and not-for-profit

User-driven and governed

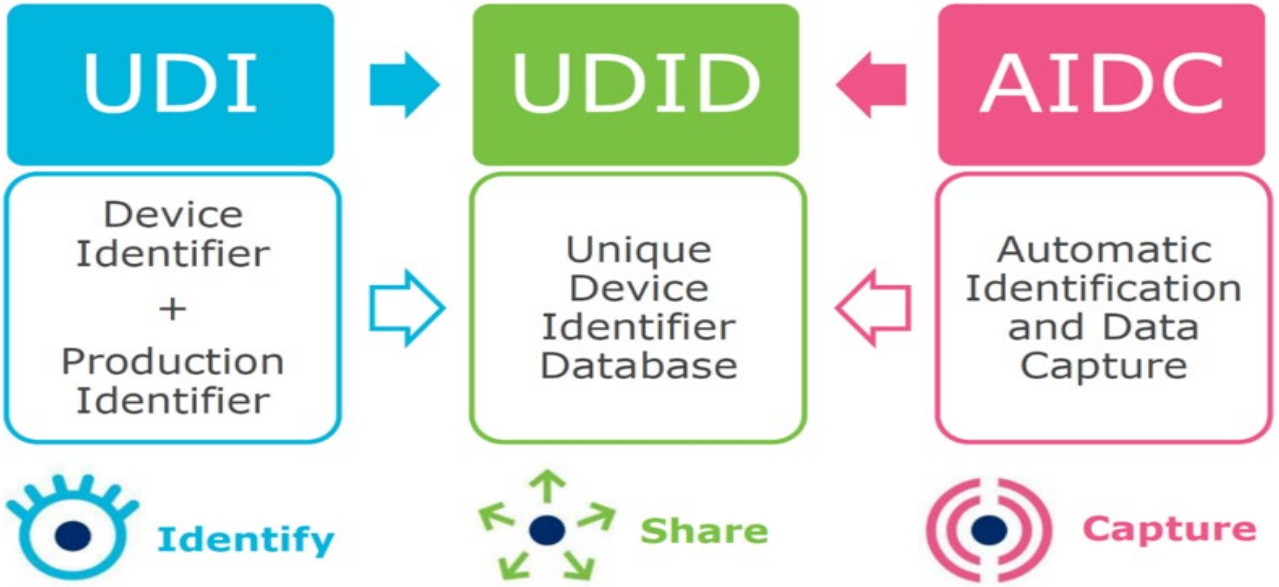
Global and local

Inclusive and collaborative

GS1: global system of standards



IMDRF UDI system and GS1 system



GS1 and UDI around the world…

Accredited as UDI Issuing Agency by the US FDA

Mandated by ANMAT for traceability of certain devices in Argentina

99% of medical devices identified with GTIN in Japan

MHLW Annual Survey, 2012

£3 million on average saved each year in every NHS hospital in England

Lord Carter interim report, 2015

UDI assigning entities listed in the EU MDR

91,8% of devices identified with GTIN in Turkey

Turkish National Drug and Medical Device Databank (TITUBB)

GS1 standards to be used for UDI implementation in **China, Saudi Arabia and South Korea.**

GS1 supporting regulators in developing UDI requirements (e.g. **Australia, Brazil, Egypt**)

Facilitating UDI implementation

UDI in GS1 AIDC terms

Required in the EU

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

EU specificity: “Basic UDI-DI” for illustration only

Identifier

AT100A

Basic UDI-DI

Before or after the supply chain, where Basic UDI-DI (GMN) is needed

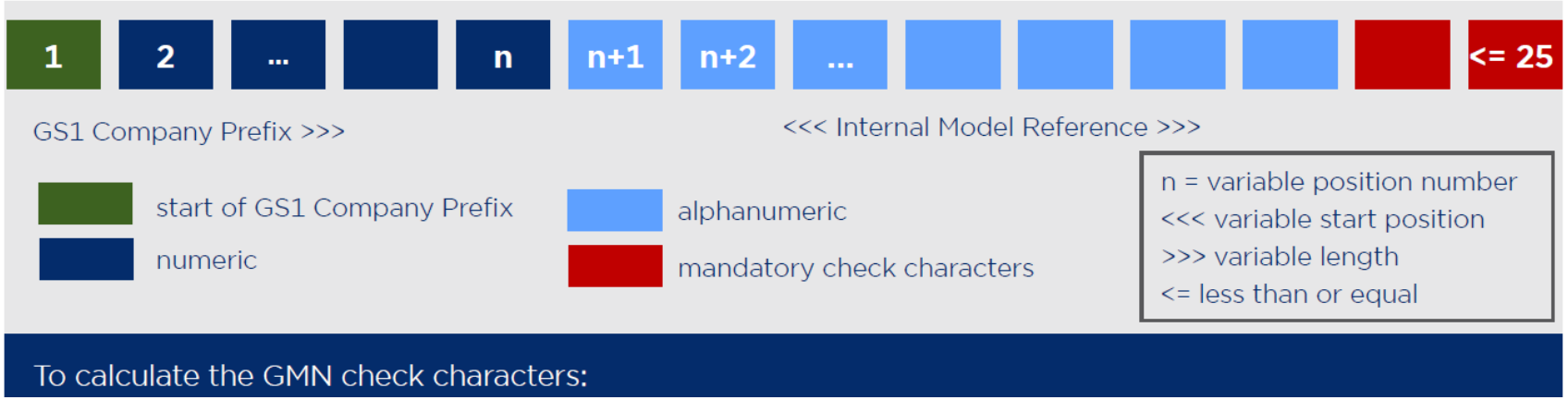
(see next slide)

Level	QTY	DI	
UoU UDI-DI			UDI Unit of Use
Base Pack	1	GTIN A	Base Package DI
2nd	50	GTIN B	Package DI
3rd	250	GTIN C	Package DI

In the supply chain, where trade item ID (GTIN) is used to order, deliver, or invoice

GTINs

Composition of the GMN (Basic UDI-DI in the EU)



https://www.gs1.org/services/check-character-calculator

GS1 Global Model Number (GMN) v.2

For regulated healthcare medical devices:

- GS1 Company Prefix + internal model reference + 2 check-characters (no special characters)

- alphanumeric
- Length: max 25 characters (23+2)

- independent of packaging
- never used in a data carrier
- Updated standard released and GS1 implementation guide to follow

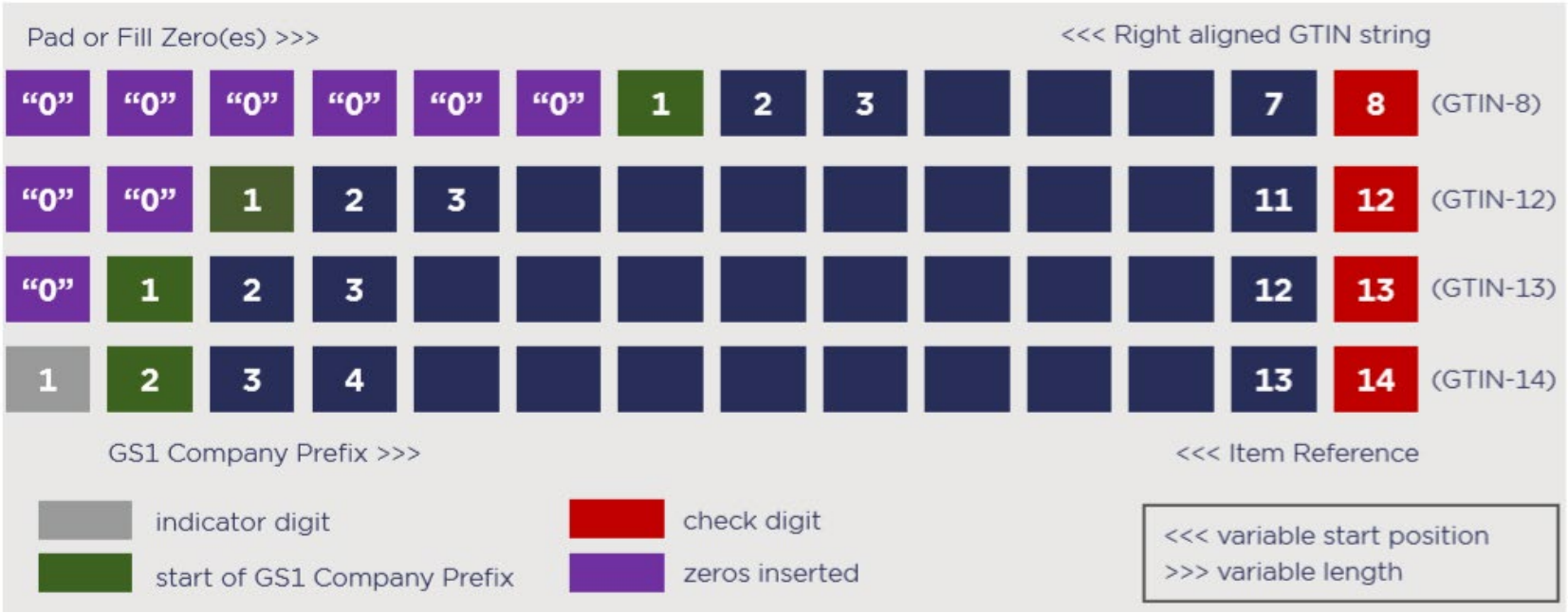
https://www.gs1.org/docs/barcodes/GSCN_19-012_GlobalModelNumberUpdate_v3.pdf

Example of Basic UDI-DI on regulated documentation:

GMN : 5149854J856MRN

Data title	GCP	Model reference number	Check character

Composition of the GTIN (UDI-DI)



https://www.gs1.org/services/check-digit-calculator

UDI-DI assignment

Packaging Levels:
The UDI should be in the AIDC data carriers (i.e. bar code symbol) and also in human-readable form on each applicable packaging level as defined by regulation.

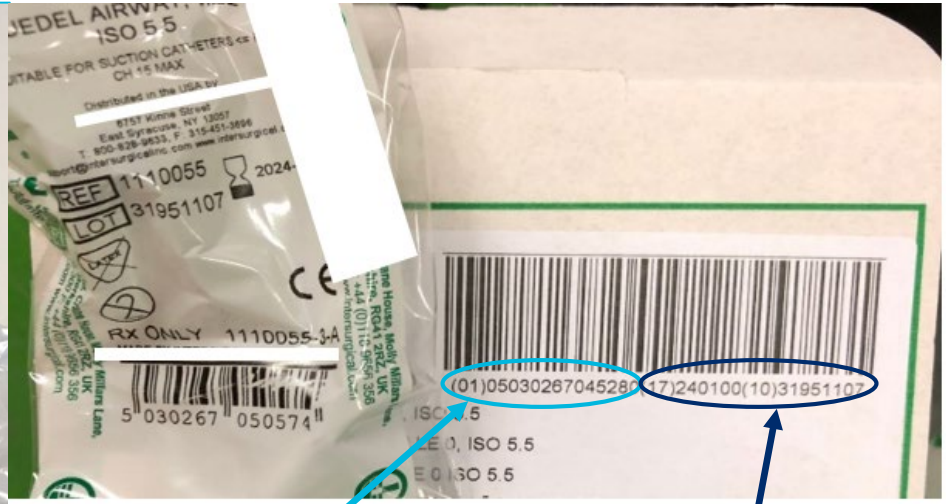
Each designated packaging level that is a trade item must have its own DI (GTIN).

NOTE: The GMN/Basic UDI-DI is never to be captured in AIDC and never to be applied on the packaging/label/devices

Single Unit Package	Multiple Unit Package	Case
GTIN A	GTIN B	GTIN C
00857674002010	10857674002017	40857674002018

Logistics units are exempt.
Unless they are considered a trade item and are identified with a GTIN

Each different packaging level requires a specific UDI-DI (GTIN) - examples



Device Identifier (DI)
"Static" portion
GTIN (product identifier)

Production Identifier (PI)
"Dynamic" portion
Application Identifiers
(e.g. serial number, lot number, expiry date)

UDI carriers

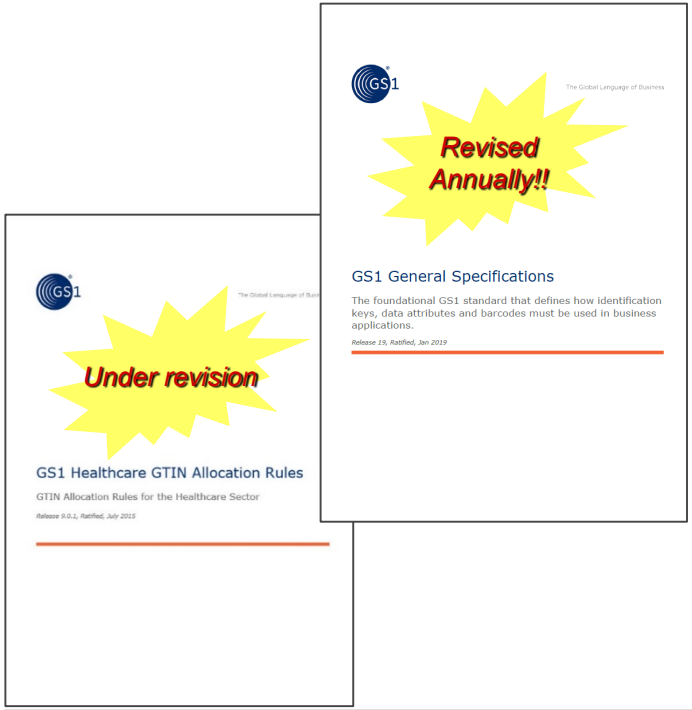
ISO compliant machine-readable Data Carriers on the product *(via label or Direct Marking)* or its packaging, which contain the UDI : 1D/Linear & 2D/Matrix bar code symbols, RFID.

Data Carriers

The manufacturer must determine whether their products fall under Direct Marking criteria or whether their products meet an existing exception.

"Direct Marking" - not "Direct Part Marking" - on devices that are "to be used more than once and reprocessed before use". It means that the mark must be useable for the useful life of the product.

Reference documents



GS1 General Specifications – describes how GS1 keys & data carriers should be used

http://www.gs1.org/barcodes-epcrfid-id-keys/gs1-general-specifications

GS1 Healthcare GTIN Allocation Rules – GTIN assignment in Healthcare with Healthcare specific examples

http://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

Providing a platform for collaboration on UDI

Requirements for medical device identification

And more coming

How to work with GS1 MOs

- To obtain a UDI, companies need to be a member of any of the 114 GS1 Member Organisation around the world

- GS1 Member Organisations assign a GS1 Company Prefix to the company that is then used to generate:
  - UDI-DIs (GTIN)
  - Basic UDI-DIs (GMN)

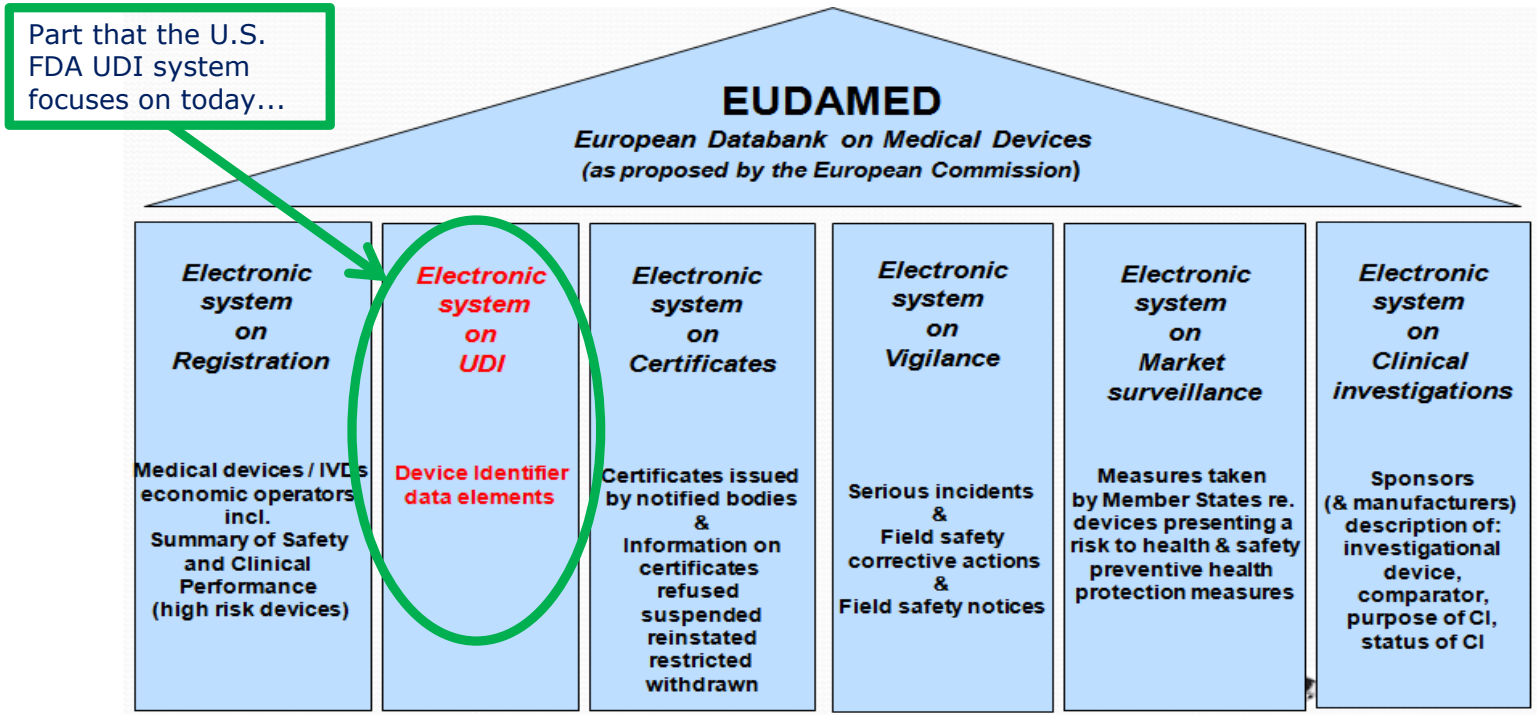
- GS1 Member Organisations also provide relevant support in applying GS1 standards in a consistent and harmonised way globally

GS1 is a Standards Development Organisation working with others

Joint Initiative Council

UDI Databases – need for alignment

UDI Databases – USA and EU



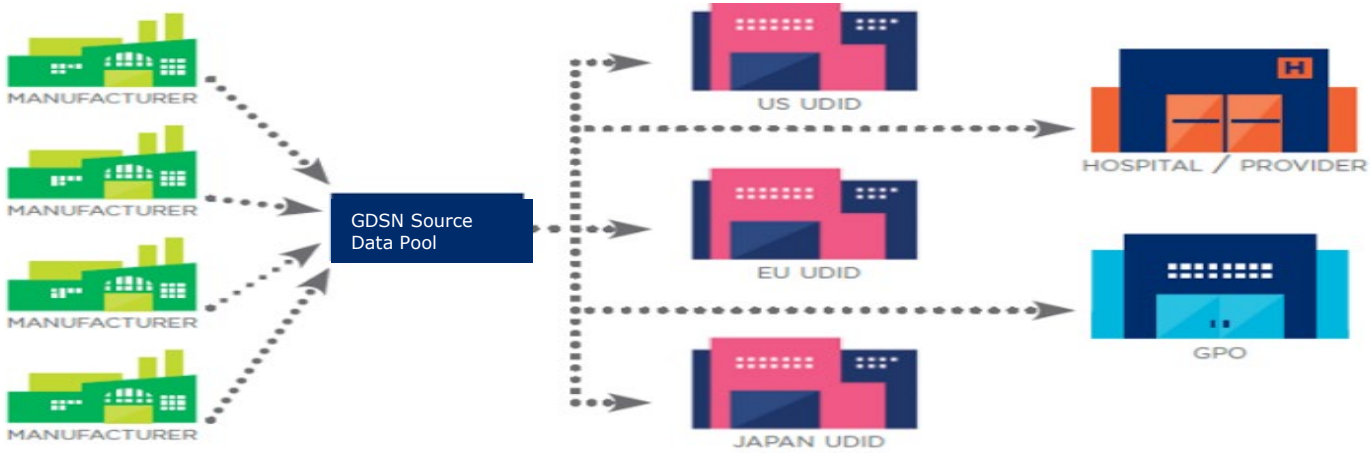
Data attributes

Appendix B - EUDID list of attributes

Data Element	Description	Data Entry Notes	Single or Multiple Entries	Mandatory (MAN) or Optional (OPT)	Data Type & Length	Entry List of Values	New DI Trigger
Issuing Agency	Organization accredited by EU to operate a system for the issuance of UDIs.	Choose a value from the drop down.	single	MAN	alphanum, 30	GS1; HIBCC; ICCBBA	Yes
Primary DI Number	An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The primary DI number will be located on the base package, which is the lowest level of a medical device containing full UDI.	GS1- 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- [illegible]	single	MAN	numeric or alphanum, 6-23 characters		Yes
Device Count	Number of medical devices in the base package. For example : Base Package = Box of 100 gloves; Primary DI = 101; Device Count = 100.	Enter a numeric value.	single	MAN	numeric, 7		Yes
Unit of Use DI Number	An identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient.	GS1- 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value If Device Count =1, cannot add Unit of Use DI Number.	single	MAN - if device count is > than 1	numeric or alphanum, 6-23 characters		No
Manufacturer DUNS Number	Business number issued by Dun & Bradstreet (D&B) that matches the Labeler (Company) name on device label.	Choose appropriate DUNS Number from drop down.	single	MAN	numeric, 9	from DUNS in real time	No

We will see local differences, but hopefully maximum alignment

Managing data and global standards: Global Data Synchronisation Network (GDSN)



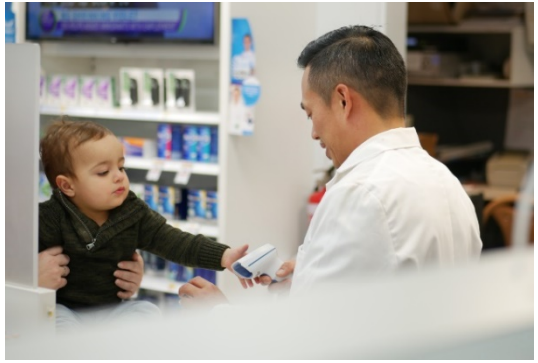
GDSN mappings are provided by GS1 Healthcare as a courtesy to the industry, it is not a requirement of an Issuing Entity*

*= UDI databases do not subscribe to the GDSN and are an out of network connection.
Data Pools offer the data registration as a value-added service to their customers. This is not governed by GDSN policy.

The need for harmonised UDI requirements

- UDI is very beneficial - it is crucial that regulators around the world align on the IMDRF Guidelines and ensure consistency when setting-up regional/national UDI system.

Ultimately, it is all about patient safety !
Safer, more efficient care starts with a simple scan.



http://www.gs1.org/healthcare/udi

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