The Global Language of Business

GS1 Ireland Healthcare User Group (HUG) Information Day

Overview of US and EU UDI regulation and unique identification requirements

Geraldine Lissalde-Bonnet, GS1 Global Office

28th March 2017

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Overview on US and EU UDI and unique identification requirement

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28 March 2017, Dublin - Ireland

UDI purpose & objective

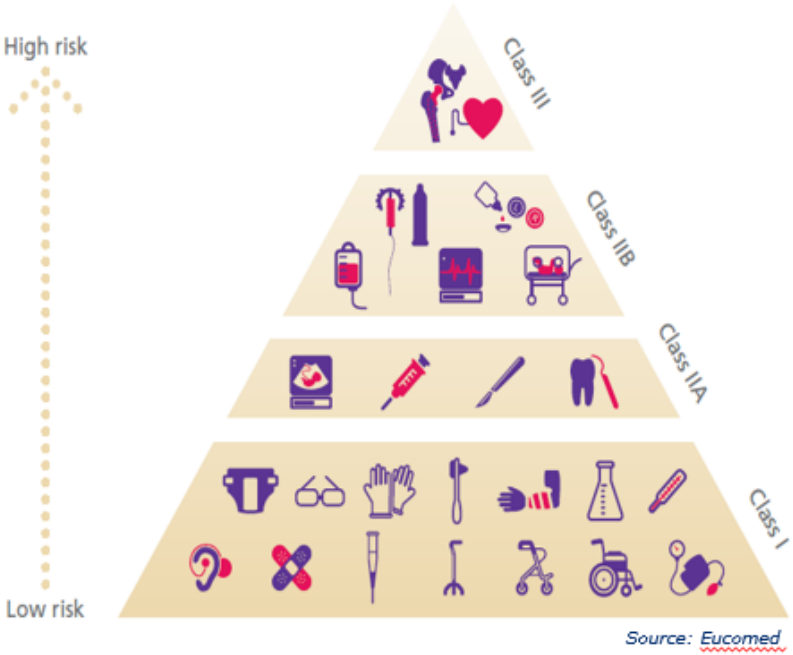
Worldwide system for product identification

A common, worldwide system for product identification should eliminate differences between jurisdictions and offer significant benefits to manufacturers, users and/or patients, and regulatory authorities.

UDI scope… medical devices…

The US FDA and the EU classifications are different.

Manufacturers should identify the relevant class for their devices



Source: Eucomed

Exception/exemptions:
- US FDA special procedure
- Nothing in the EU MDR

Stock or consignment:
- Grandfathering in the USA
- Device must by supplied to the final user within 5 years after the date of application

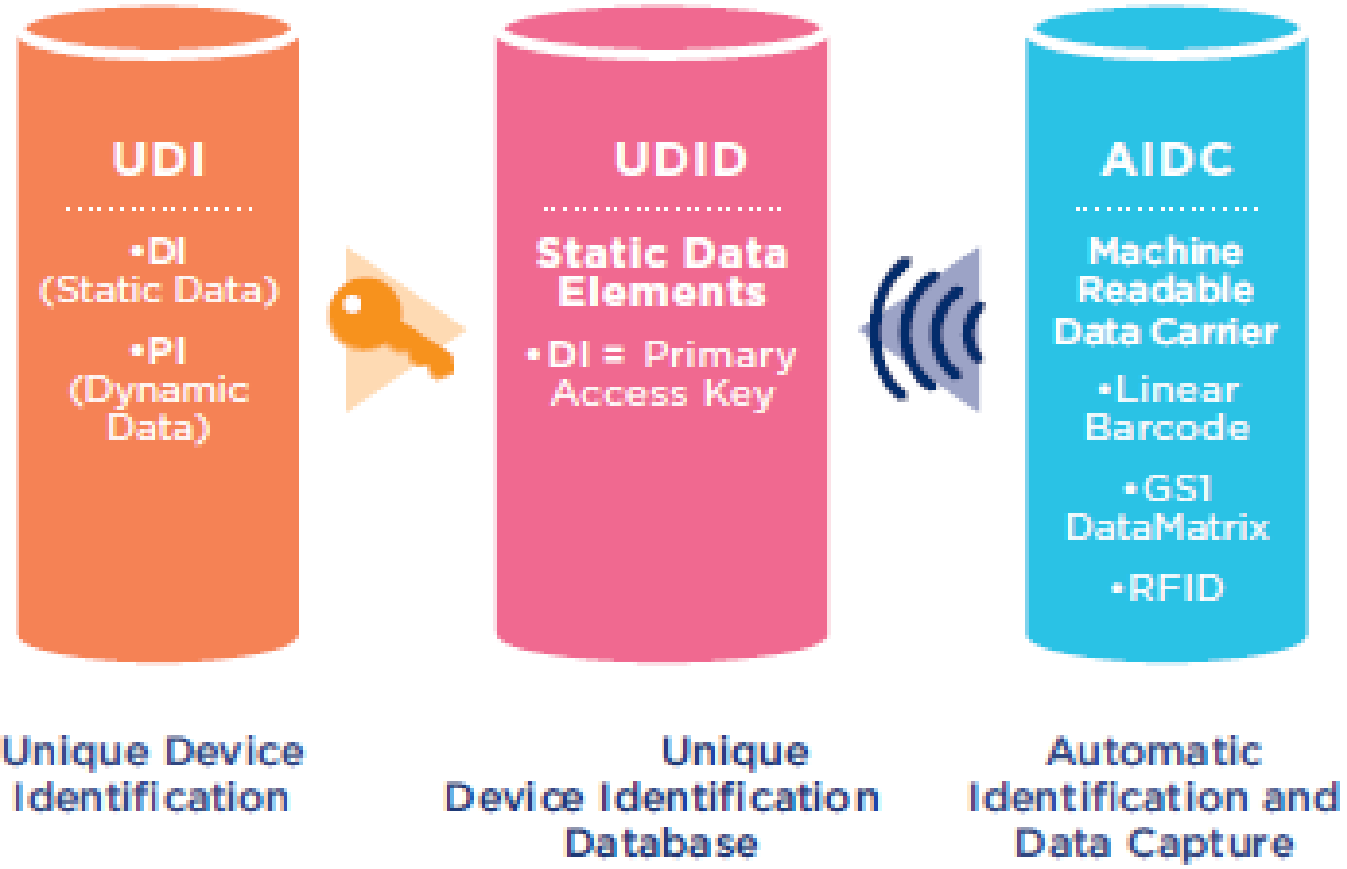
UDI system… approach & setup

1. Assign a globally unique standardised identifier : the "UDI"
2. Place that "UDI" on the label / package / item in both plain human readable text and also in an appropriate form or type of Automatic Identification and Data Capture (AIDC) data carrier

   Apply "direct marking" for those devices which are intended to be reused or reprocessed
3. Submit the required data related to the product to the relevant database
4. In the EU only: store the UDI for certain type of devices – this apply also to the health institutions and healthcare professionals
5. IMPLEMENT for all medical devices as and when required…

UDI system…

…based on the IMDRF… same in the USA and the EU



Storage and traceability requirements in the EU

Requirements in the EU only

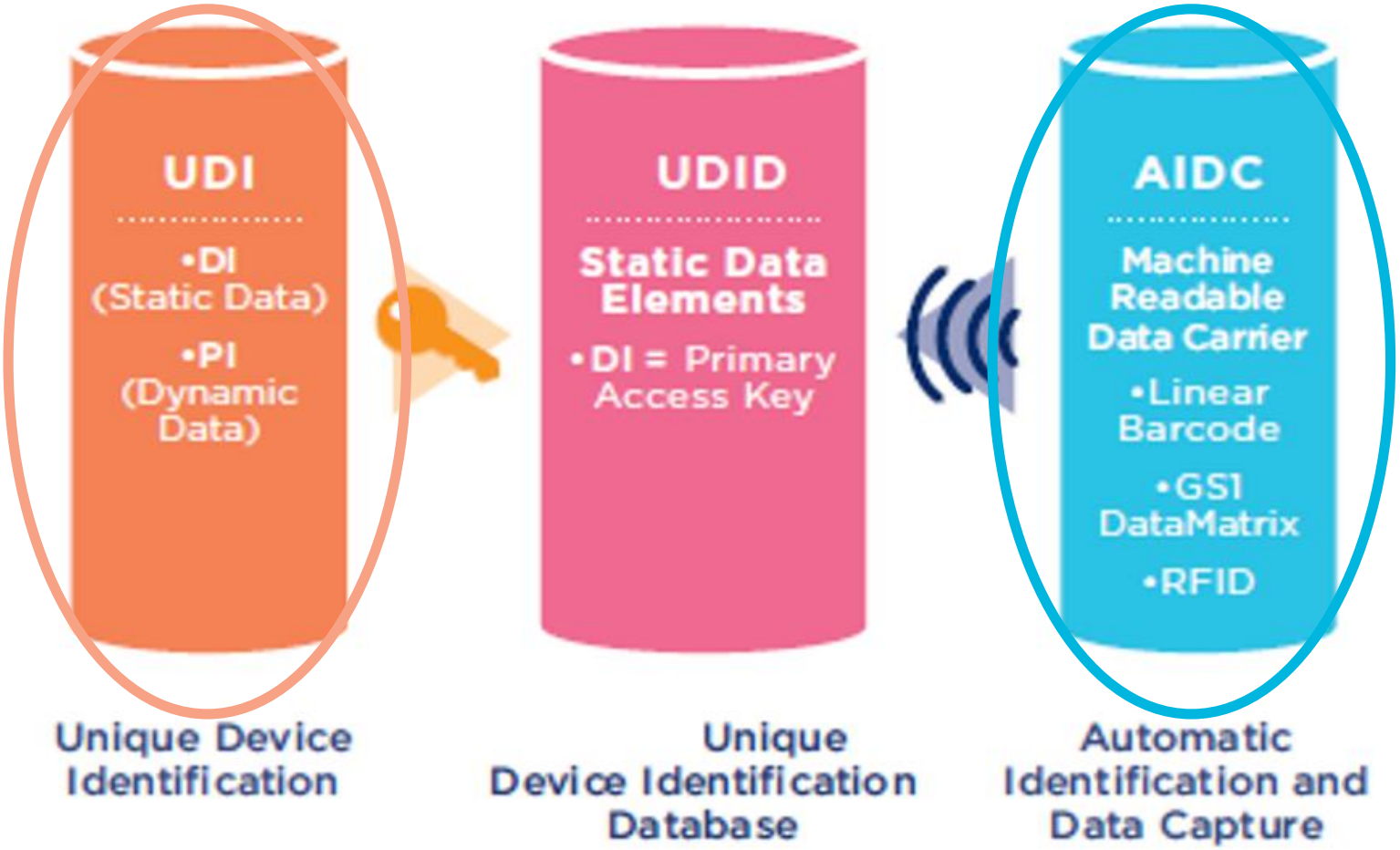
Storage:

- Economic operators shall store and keep, *preferably by electronic means*, the UDI for class 3 implantable devices and for devices identified via implementing acts
- Only class 3 implantable devices for health institutions (Member States should encourage to extend the scope)

Traceability:

- Economic operators shall be able to identify any operators/health institution to whom they have directly supplied a device and any operator who has directly supplied them with a device: one-up-one-down model
- The UDI shall be included in the field safety notice for reporting serious incidents and field safety corrective actions.

“Basic” UDI system... GS1 AIDC



UDI in GS1 AIDC terms… identify

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**

The **HRI format** shall follow the GS1 GTIN Management Standard.

Refer to the appropriate UDI regulation and the GS1 GTIN Management Standard for complete details on **DI / GTIN change**.

UDI in GS1 AIDC terms… identify

Packaging Levels:
The UDI (DI, i.e. GTIN and PIs, i.e. AIs) 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).

Logistics units are exempt.

NOTE: GTINs below for illustration only

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

Placement: Bar code symbols are to be positioned to allow ready access for scanning when the product is stored or stocked on shelves.

UDI in GS1 AIDC terms… capture

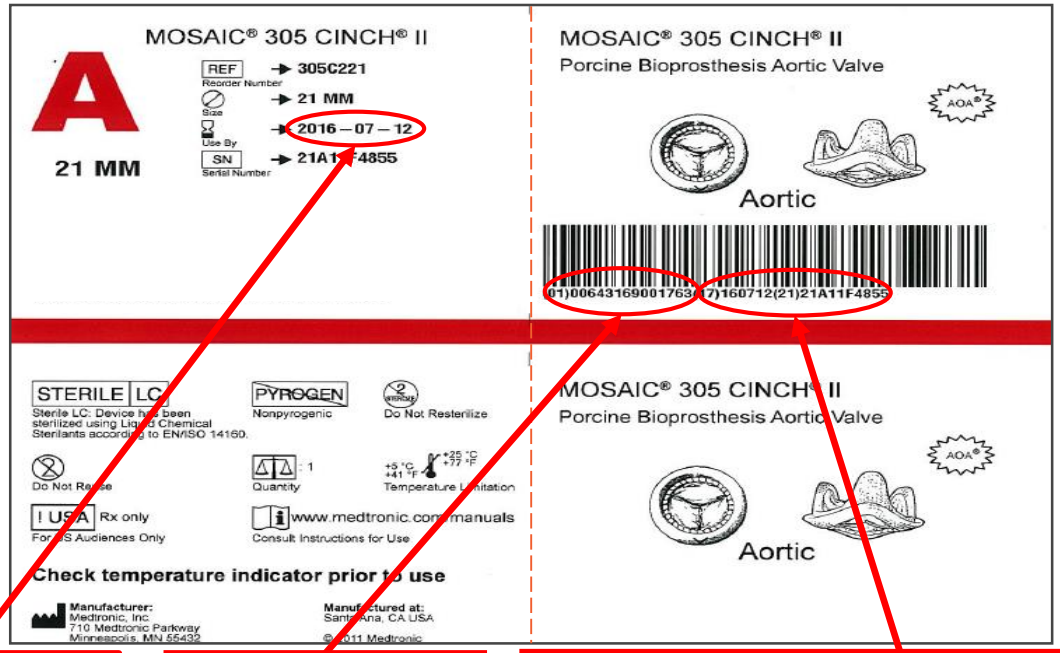
ISO compliant machine-readable Data Carriers on the product *(via label or Direct Marking)* or its packaging, which contain the UDI : 1D/Linear & 2D/Matrix bar code symbols, RFID.

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.

UDI Example – Medtronic label

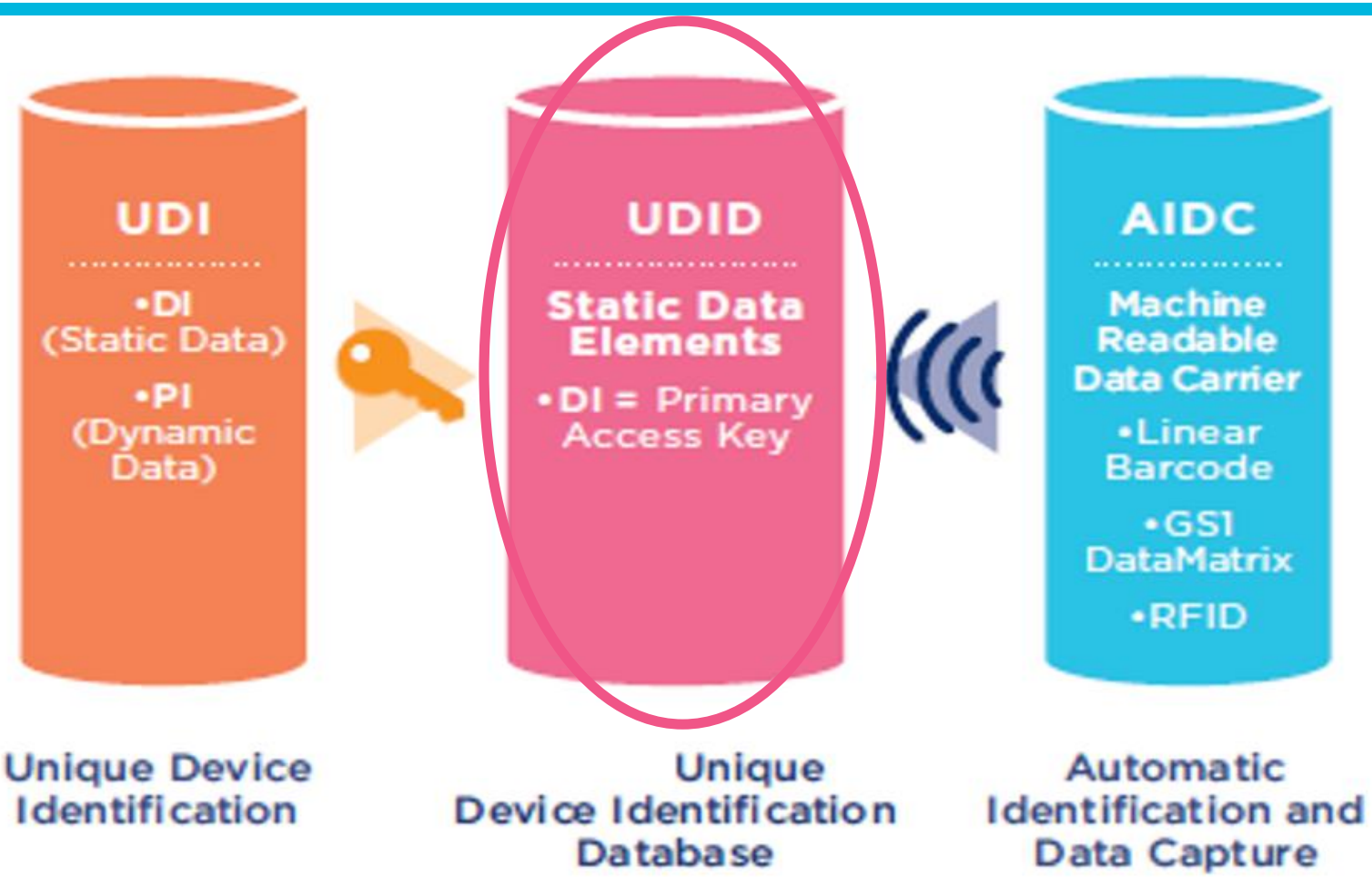


ISO 8601 date format

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

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

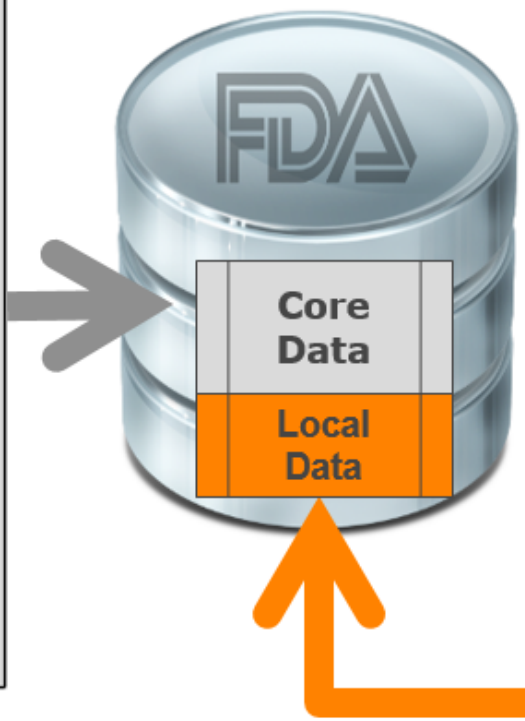
UDI system…UDI Database



UDI Databases:
Global Core Data + Local Data

- Packaging Hierarchy, per pack. level
  - DI / Unit of Measure / Quantity
- Unit of Use DI
- Manufacturer Name, Address, Contact info
- Authorized Representatives (list of countries)
- Nomenclature + Term (e.g. GMDN code)
- Brand Name
- Device Model or Version
- Reference Number (REF No./catalog no.)
- Controlled by (e.g. exp. date, lot no., serial no)
- Clinical Size (Size/Volume/Length/Gauge…)
- Special Storage Conditions
- Special Handling Conditions
- Labeled as 'single use'
- Sterility / Package sterile
- Need to be sterilized before use + Method
- Restricted number of reuses
- License / Marketing Authorization
- URL for additional information
- Critical warnings / contraindications as labeled
  - labeled as containing Latex
  - labeled as containing DEHP

Global core data elements defined by the IMDRF



Additional local data elements defined by the FDA

- DUNS Number
- Authorisation Number (510K)
- Product Code
- FDA Listing Number
- Product Exemption from PMA
- Prescription Product
- Kit Product
- Combo Product
- Contains Human Cell / Tissue
- MR Safety
- …

GUDID basics

- Data registration is the responsibility of the "Labeler" : defined as the entity responsible for the contents of the label. In GS1 terms, this is the Brand Owner. In the EU the responsible is the "Legal manufacturer".

- Data is loaded for the Device Identifier (DI) only
  - UDI is a Device Identifier (DI) and Production Identifier (PI)
  - Only the DI is used in the GUDID

- Data provided is master data and is used for public consumption, however, there are some data elements which are for FDA only for internal administrative use only

- Labelers can load data into the GUDID via:
  - Web Portal using a graphic user interface on the FDA's website data can be loaded one device at a time
  - Structured Product Language (SPL) developed by HL7 the SPL is a computer language similar to XML

Challenges faced by manufacturers in preparation for the GUDID

PROJECT ORGANISATION

- What is the mission?
- How big is the project - Who, What, When?
- What is the real duration?
- How do we structure the data?
- How do we control cost?
- What is the deadline and how do you meet it?
- How do *you* define success?
- What does being *finished* look like?

RESOURCES

- How do we identify the resources?
- How do we secure them?
- How do we educate them?

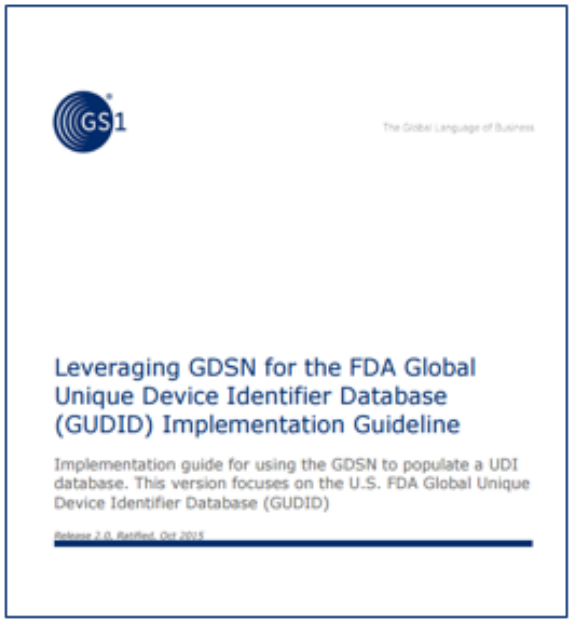
DATA

- What data do we need?
- How do we manage it?
- Who has it/owns it?
- What format is it in?
- How do we convert it?
- Can we trust it?
- How to digitise it?
  (Manually, copying, scanning)

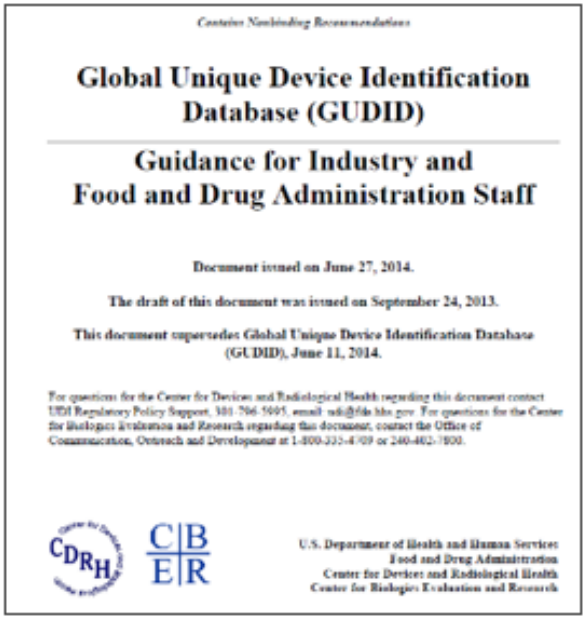
Other Considerations

- How many products does your company sell and which country?
- Is your company already using a GDSN data pool to share product data commercially?
- Does your company already submit new product introductions to the FDA via internally supported processes?
- What is your company's IT expertise in the UDI requirements? GS1 Standards?
- How will your company respond to sharing data with third parties? (legal, purchasing, regulatory, quality, commercial, IT)

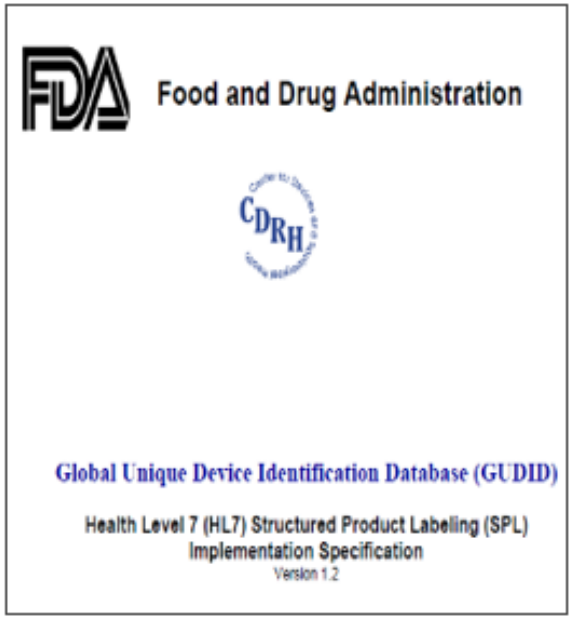
Supporting documents



http://www.gs1.org/sites/default/files/docs/gdsn/guidelines/GS1_GDSN_GUDID_Implementation_Guide.pdf

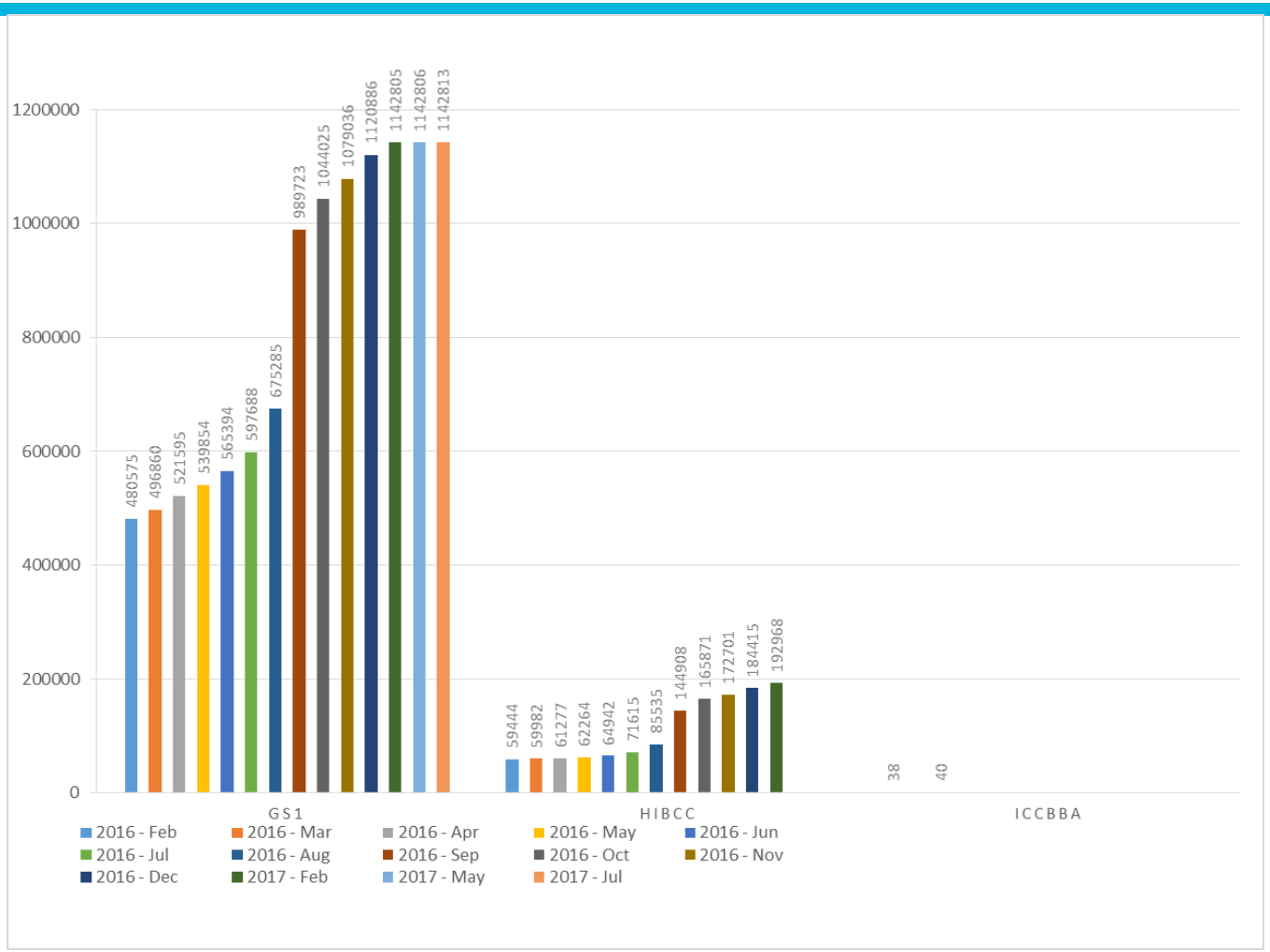


http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification



http://www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/globaludidatabasegudid/ucm416122.htm

More than 85% of products in US FDA GUDID carry GS1 as UDI primary DI



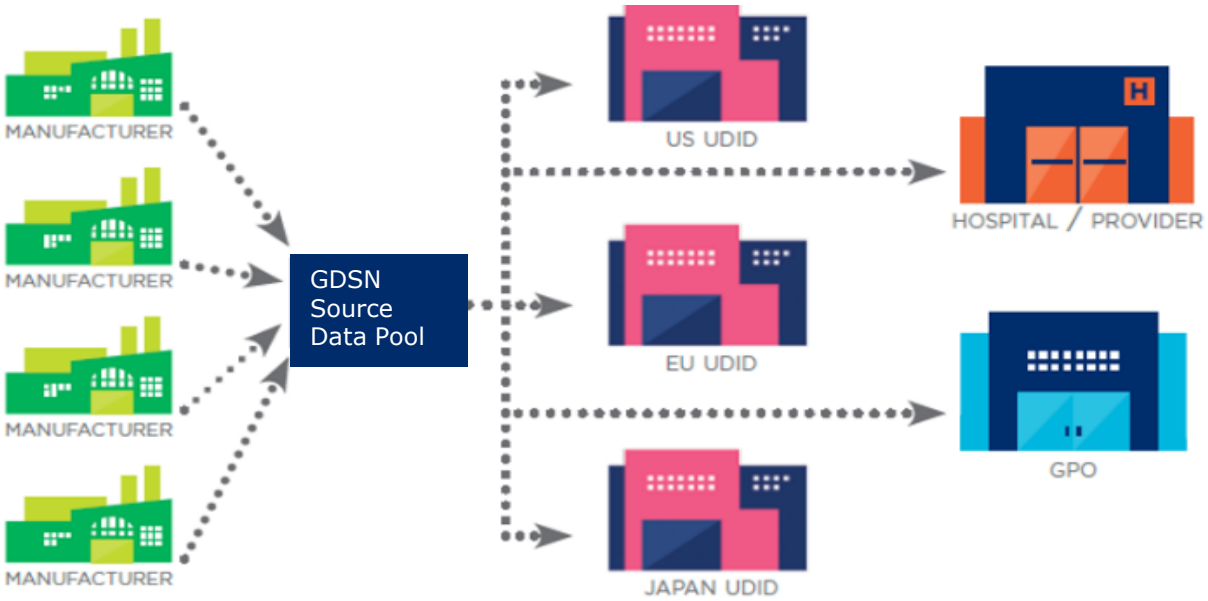
EUDAMED

- Manufacturers can upload the data into EUDAMED via web-portal (manually) or XML (machine-to-machine)
- Divided into **product registration, UDI registration and economic operators registration**
- Delegated/implementing acts to provide more details on implementation

- Annex V provides a list of the data elements. 1WS support for the mapping with GDSN for UDI

- Deadline for implementation should cover all class of MD
- Open points :
  - deadline for EUDAMED to be operational?
  - HL7/SPL acceptance? need to design the XML structure ?
  - Nomenclature to be used?

Managing data and global standards: Global Data Synchronisation Network



Manufacturers are able to provide data to all UDI databases and their customers (hospitals, distributors, wholesalers, GPOs) simultaneously, with a single connection

Benefits

- All UDI databases would be easily updated with the latest information from the manufacturer, via any GDSN Data Pool
- Manufacturers would be able to provide data to all UDI databases and their customers (hospitals, distributors, wholesalers, GPOs) simultaneously, with one single connection
- All supply chain partners and regulatory bodies would operate from the same set of data, provided by the Source

GS1 role as UDI assigning entity

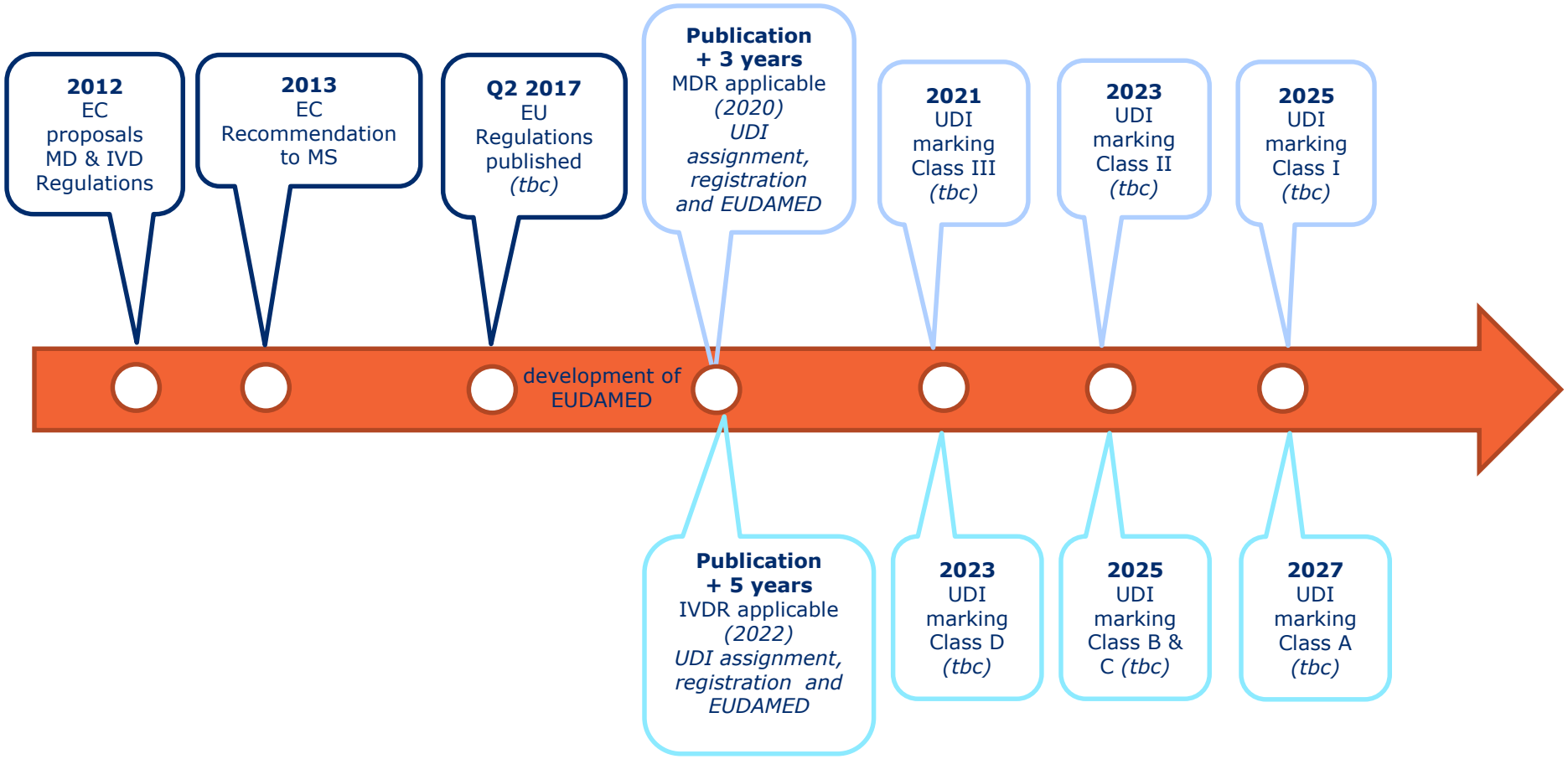
- GS1 was the first accredited UDI issuing agency by the US FDA
- GS1 is listed in the EU Regulation as "UDI assigning entities" until the EU Commission potentially designates others

- All GS1 MO's are supporting their users throughout implementation including training and education

Compliance Dates – U.S.A.

- 24 Sept. 2014: Class III
- 24 Sept. 2015: Life supporting/sustaining devices
- 24 Sept. 2016: Class II
- 24 Sept. 2017: Soft Contact Lens given a GUDID UDI compliance extension
- 24 Sept. 2018: rest of Class II, Class I, unclassified
- each timeline by +2 years: Direct Marking

EU - UDI: the EU roadmap



+ 2 years for DPM, when applicable

Time for change is now…

Keep yourself informed

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

http://www.gs1ie.org/healthcare

31st Global GS1 Healthcare Conference

4 to 6 April 2017, Berlin, Germany

- Traceability, Unique Device Identification (UDI) and global regulatory developments
- Use cases and implementations from manufacturers, wholesalers and hospitals – what are the experiences, the benefits
- Patient safety and quality of care – how to improve those
- **ThinkTank for regulatory bodies**
- Followed by side visits

Participation free for regulatory bodies and hospitals



Contact Details

Geraldine Lissalde Bonnet
Director Public Policy Healthcare
GS1 Global Office, Brussels
E geraldine.lissalde.bonnet@gs1.org
W www.gs1.org/healthcare