The Global Language of Business

GHWP Annual Meeting
Global Standards for Global Health

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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 role in UDI across the world

GS1 is supporting the IMDRF and is a Liaison Member to the GHWP … supporting global harmonisation

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 issuing agency/entity in China, EU, Saudi Arabia, South Korea, Singapore, U.S.A. – and more to come

91,8% of devices identified with GTIN in Turkey

Turkish National Drug and Medical Device Databank (TITUBB)

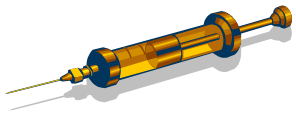
GS1 standards also used for identification of medical devices in Netherlands, Qatar, UK …

GS1 provides support to regulators as they develop and implement their UDI requirements

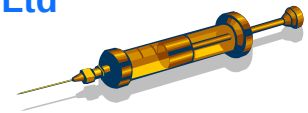
Nomenclature or device identification ?

Generic Device Group
e.g. WHO nomenclature, GMDN Term

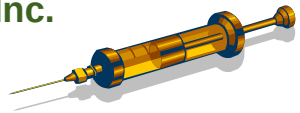
Hudson Co.



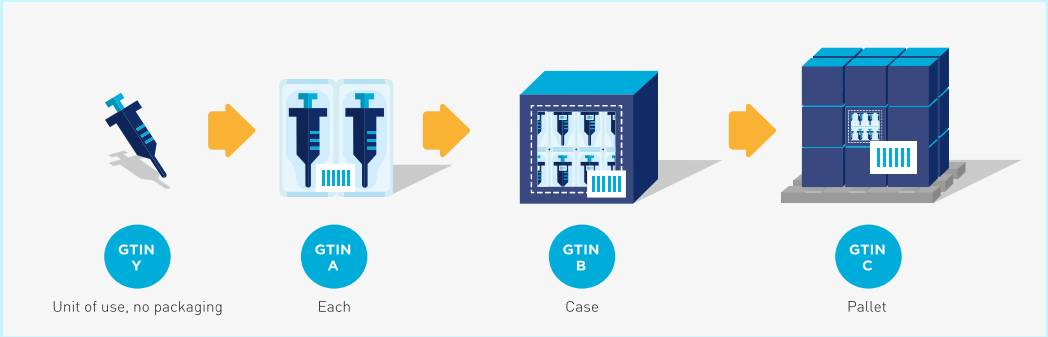
Brooks Ltd



Woods Inc.



Unique identification of devices at each level of packaging



A single UDI (GTIN) identifies one particular device from one manufacturer

A nomenclature code identifies a group of devices with identical characteristics, from various manufacturers

U.S. FDA GUDID Attributes “snapshot”

Device Identifier (DI) Information
- Issuing Agency
- Primary DI Number
- Device Count
- Unit of Use DI Number
- Labeler DUNS Number
- Company Name
- Company Physical Address
- Brand Name
- Version or Model Number
- Catalog Number
- Device Description (max 2000 characters)

Commercial Distribution
- DI Record Publish Date (mm/dd/yyyy)
- Commercial Distribution End Date (mm/dd/yyyy)
- Commercial Distribution Status

Secondary DI
- Secondary DI Issuing Agency
- Secondary DI Number

Package DI
- Package DI Number
- Quantity per Package
- Contains DI Package
- Package Type
- Package Discontinue Date
- Package Status

Support Contact
- Support Contact Phone
- Support Contact Email

Direct Marking (DM)
- Device Subject to Direct Marking (DM), but Exempt
- DM DI Different from Primary DI
- DM DI Number

Device Status
- Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)
- Kit
- Combination Product

FDA Product Code
- Product Code
- Product Code Name

FDA Listing
- FDA Listing Number

Premarket
- Device Exempt from Premarket Submission
- FDA Premarket Submission Number
- Supplement Number

GMDN (Global Medical Device Nomenclature)
- Code
- Name
- Definition

Device Characteristics
- For Single-Use

Production Identifier(s) on Label
- Lot or Batch Number
- Manufacturing Date
- Serial Number
- Expiration Date

Latex Information
- Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)
- Device labeled as "Not made with natural rubber latex"

Prescription Status
- Prescription Use (Rx)
- Over the Counter (OTC)

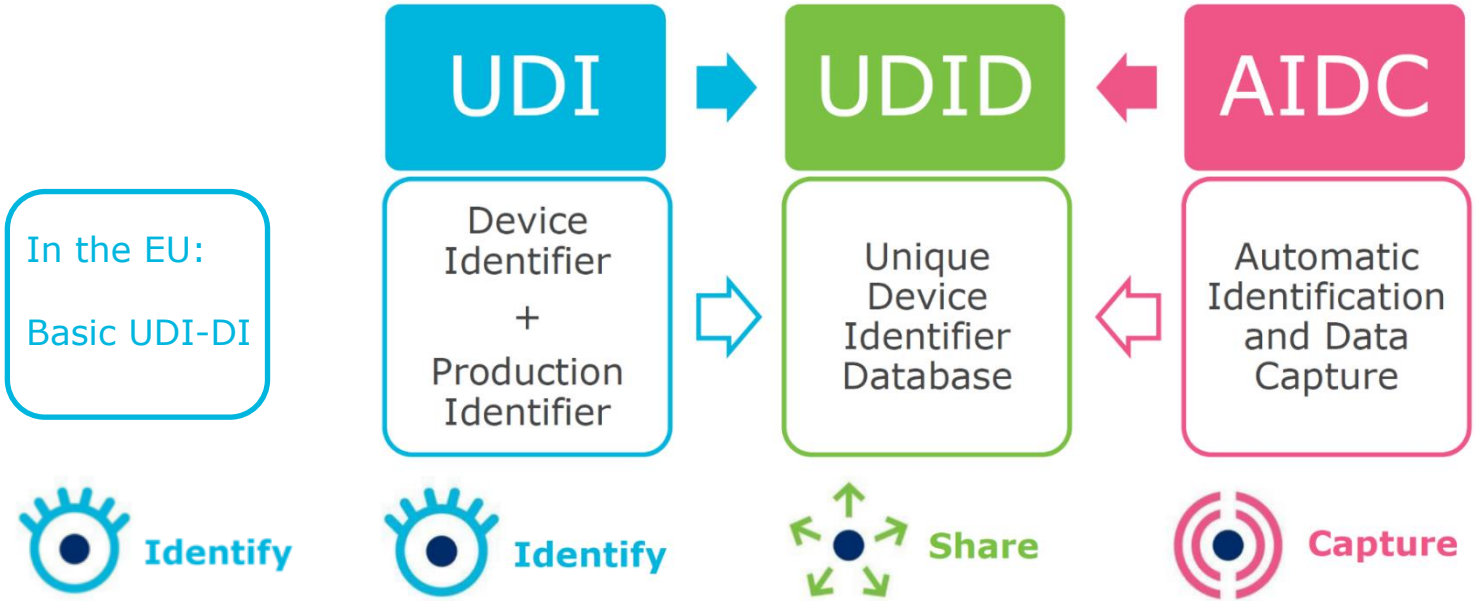
MRI Safety Status
- Is the device labeled for MRI Safety?

Clinically Relevant Size
- Size Type
- Size Value
- Size Unit of Measure
- Size Type Text
- Storage and Handling

Storage and Handling Type
- High Value
- Low Value
- Unit of Measure
- Special Storage Conditions

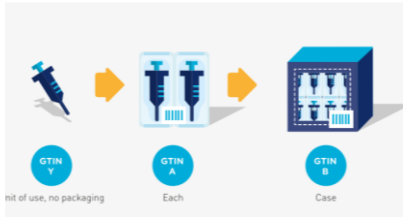
Sterilization Method
- Device Packaged as Sterile
- Requires Sterilization Prior to Use

UDI and the GS1 System of Standards



Identify: UDI in GS1 AIDC terms

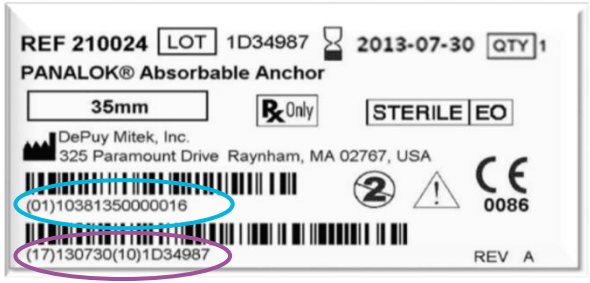
UDI regulatory requirements	GS1 Standards
Required in the EU **Basic UDI-DI** « New » level of identification in the EU	**GMN** (Global Model Number) *No Application Identifier (AI) for regulated medical devices*
UDI-DI * Device Identifier (DI)	**GTIN** * Global Trade Item Number
UDI-PI * Production 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

Capture: Examples of UDI marking using GS1

Label Example



Direct Part Marking

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

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

Why UDI? Patient safety and traceability

REGULATOR

- market surveillance, along across borders
- identification and documentation of devices placed on the market and used in hospitals
- customs control and fight falsified devices
- others: insurance, price control, tender requirements, inventory management

HOSPITAL / PROVIDER

- electronic health records
- purchasing, inventory, invoicing
- safety alerts and fields safety corrective actions (FSCA)
- no relabelling and less medical errors

MANUFACTURER

- compliance with regulations and tender requirements
- costs optimisation
- data synchronisation and processes efficiency

Safer, more efficient care starts with a simple scan

The need to align on a global UDI framework

- UDI is very beneficial - it is crucial that regulators around the world align on the IMDRF Guidelines and ensure consistency when setting-up regional or national UDI system:
  - N7:2013 Unique Device Identification guidance document
  - N48:2019 Unique Device Identifier (UDI) Application Guide
  - N53:2019 IMDRF guidance on data elements, use of Data Elements across IMDRF Jurisdictions

➢ This will ensure :
- highest levels of patient safety beyond borders
- harmonised identification systems for medical devices globally

Contact details

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