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Engineering the extraordinary

Global UDI Compliance: Strategies for Navigating Unique Device Identification Standards Worldwide

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Agenda

1 UDI

2 Global UDI Roadmap

3 UDI Implementation

4 Leveraging UDI Data

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What Does UDI Mean to You?

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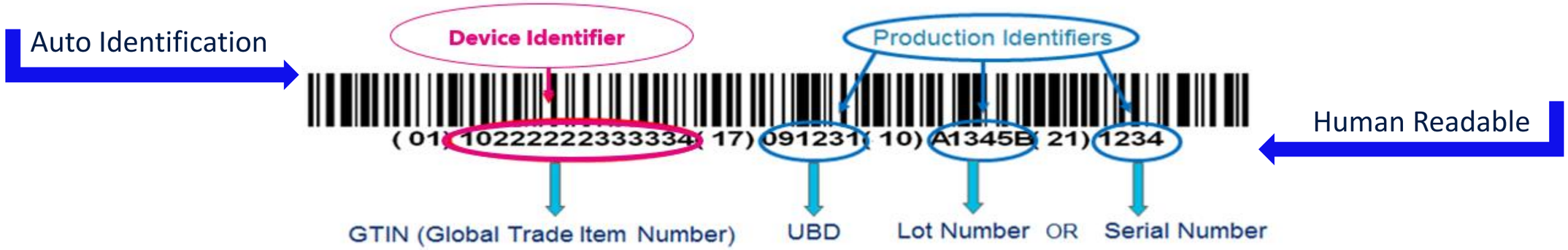
UDI Format and Structure

GS1-128 Format

UDI = DI + PI



Device Identifier (DI)

A mandatory, fixed portion of a UDI that identifies the specific Product Number of a device and the labeler of that device; for Medtronic products, this is the GS1 Global Trade Item Number (GTIN).

Production Identifier (PI)

A conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:

- The **lot or batch** within which a device was manufactured;
- The **serial number** of a specific device;
- The **expiration date** of a specific device;
- The **date** a specific device was **manufactured**

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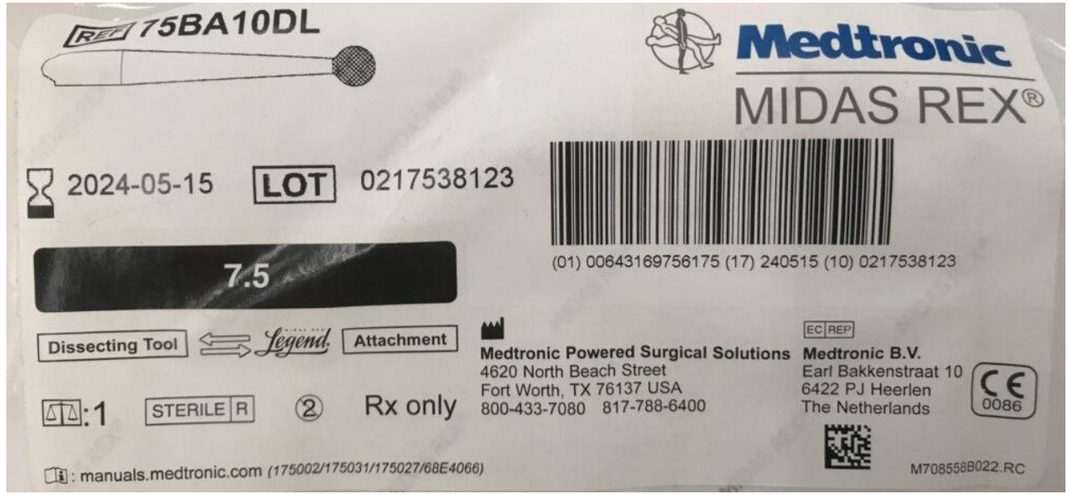
Barcode Examples



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Barcode Examples

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14-digit GTIN format

N1 Digit:

- Always 0 for consumer sale unit (GTIN-12, GTIN-13)
- Possibly 1-8 for logistic unit not sold at point-of-sale (case, pallet, etc.); in which case it is called the "indicator" digit

GS1 Company Prefix

- Allocated by GS1 to the company that allocates the specific GTIN (typically, but not necessarily, the brand owner)
- Between 4 and 11 digits in length (see footnote, page 16)
- First 3 digits are the GS1 Prefix, indicating which GS1 MO provided the numbering capacity from which this GTIN was allocated

Item Reference

- Allocated by the recipient of the GS1 Company Prefix to identify a specific trade item
- Between 6 and 1 digits in length, depending on the length of the GS1 Company Prefix (always 12 in total)

Check Digit

- Calculated as a function of the other digits, to protect against keying errors

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Unique Device Identification

Fundamentals

1. Development of a standardized system of Unique Device Identifiers
2. Placing of UDI on the package, label or device in Human Readable and Automatic ID formats
3. Registry of UDI data in a public database (i.e., GUDID, Eudamed, TUDID)

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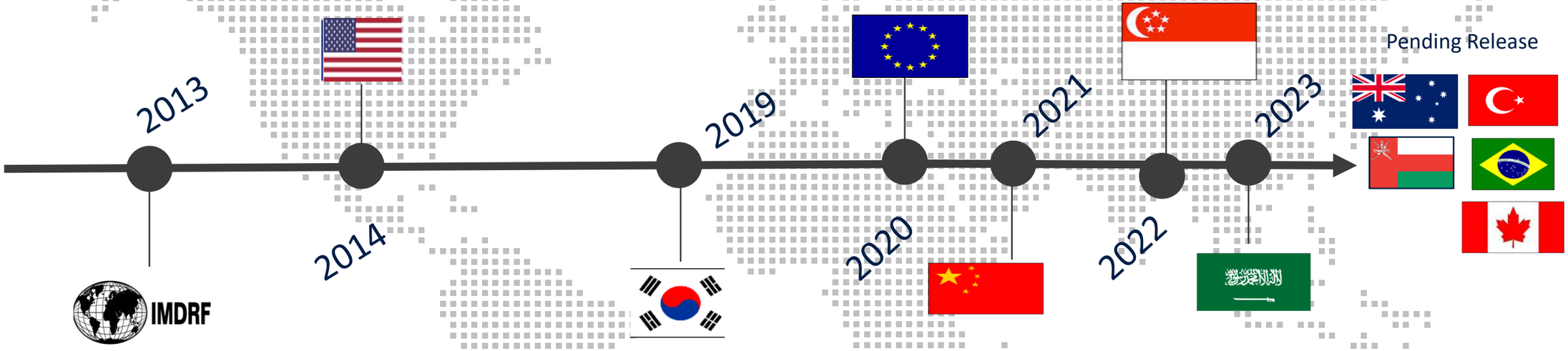
Global UDI Road Map

- **UDI will be a continuing effort to maintain the global view of regulatory product data and provides a means to connect our clinical environments.**



IMDRF Guidance
UDI for Medical
Devices
Final Version
December 9, 2013

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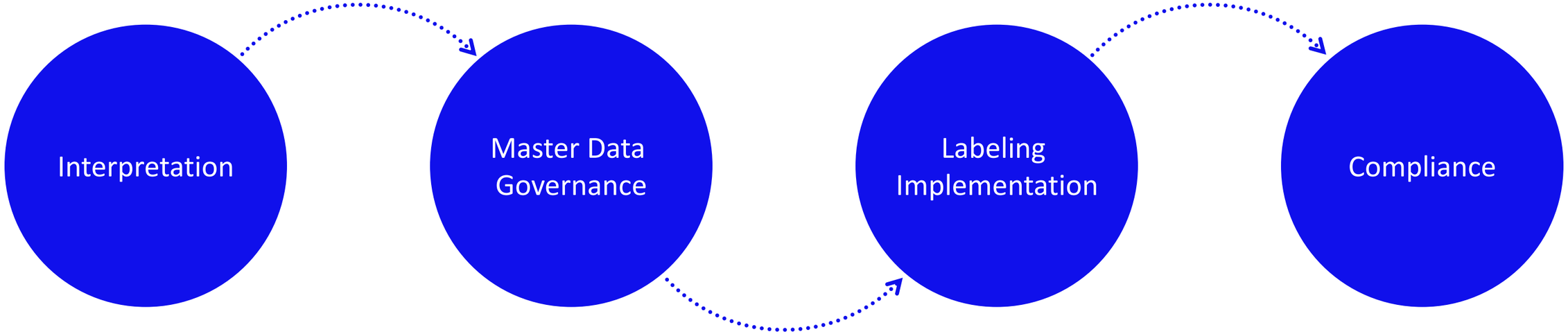
US UDI Implementation

Setting up the Initial Strategy

Setting up program structure with executive sponsorship support and committed stakeholders is key to successful implementation.



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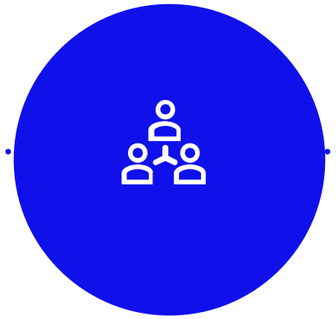
Data Management

Roles & Responsibilities



- Who is responsible for data attributes?
- Who creates/updates data?

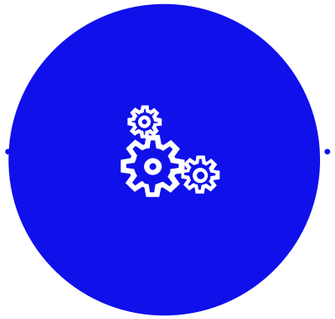
Data Governance

- How will data be handled?
- When can data be changed?
- Implementing standards

Data Quality & Validation

- What values are allowed?
- What format is acceptable?
- Edit rules

Data Maintenance



- Product change management
- Update data internally/externally
- Lifecyle management

Importance of Master Data is similar to the Importance of Product Quality

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EUDAMED

MODULE OVERVIEW

EUDAMED
European Database on Medical Devices

Actor	Device	Certificate*	Vigilance	Clinical Investigation	Market Surveillance*
Registration of Economic Operators (EO), including manufacturers, importers and authorized representatives	Registration of BASIC-UDIs (reflects common properties of a product group) and UDI-DIs (contains only product-specific information)	Repository of certificates issued by Notified Bodies and validated SSCPs uploaded by Notified Bodies	Repository of serious incident data, including Periodic Safety Update Report (PSUR), Complaint Handling, MIR, and Field Safety Corrective Action (FSCA)	Repository of clinical investigation data	Repository of market surveillance results completed by Member States

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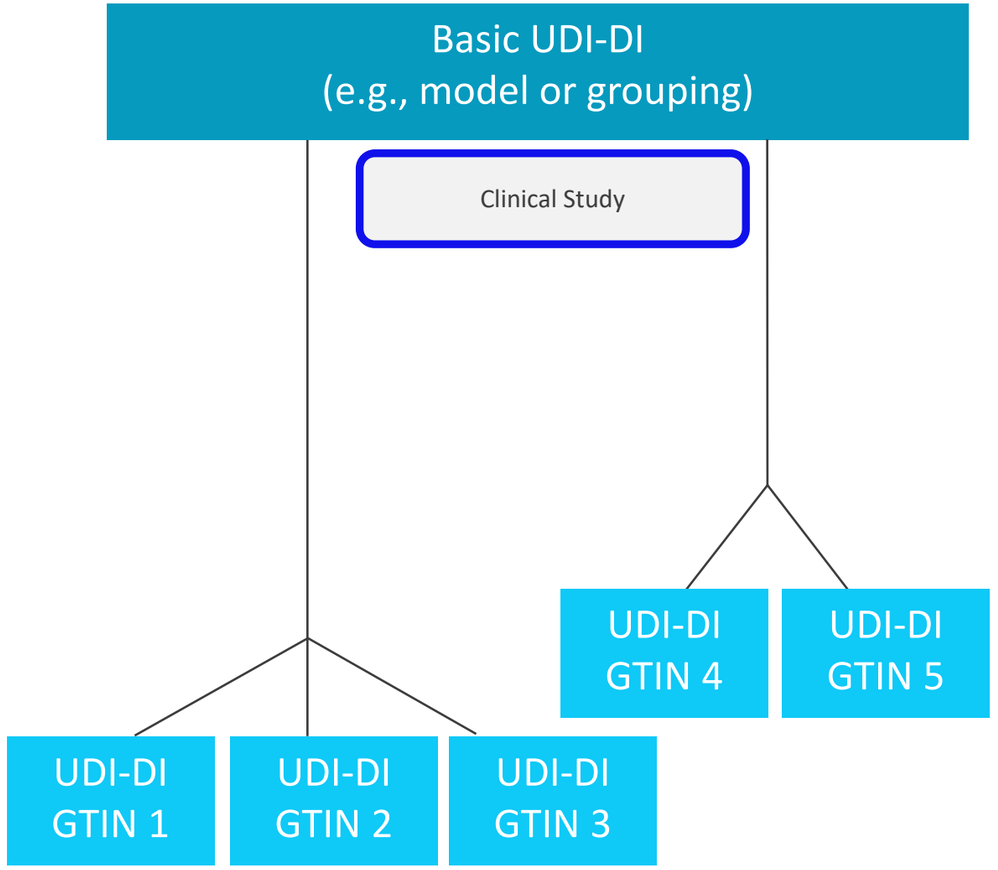
EU MDR/IVDR

Basic UDI-DI

- EU MDR introduces an additional device identifier to be captured in Eudamed called **Basic UDI-DI**.
- 1 Basic UDI-DI can be related to 1 or many UDI-DI(s).
- A single UDI-DI cannot be related to more than 1 Basic UDI-DI.
- If the Basic UDI-DI changes, the GTIN must change**.**



The Basic UDI-DI will not be used on labeling and packaging; it is only for linking Product Data within Eudamed.

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EUDAMED Data

Manufacturer details
Basic UDI-DI details
Certificates
UDI-DI details
Clinical investigation references
Market distribution
SS(C)P

Telephone number	0041916014051
Email	info@devintecpharma.com

→ View full manufacturer data

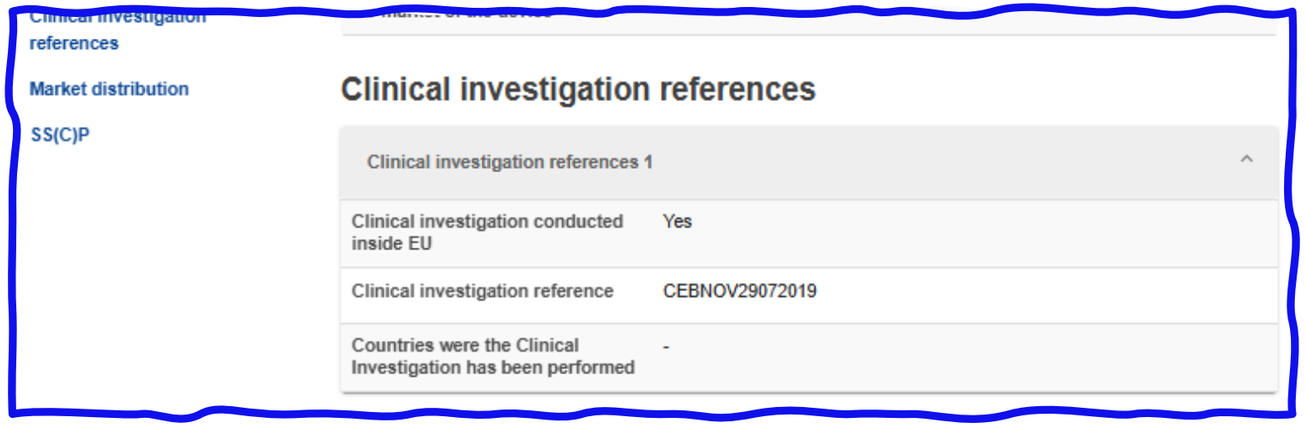
Basic UDI-DI details

Version 1 (Current) | Last update date: 2023-12-19

Applicable legislation	MDR (REGULATION (EU) 2017/745 on medical devices)
Basic UDI-DI/EUDAMED DI / Issuing entity	7649993626FT42306VN / GS1
System/Procedure which is a device in itself	No
Authorised representative	ES-AR-000020256 - DEVINTEC HEALTH S.L. - 99 CALLE GENERAL PARDIÑAS MADRID - Spain
Risk class	Class III
Implantable	No
Is the device a suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip or connector?	No
Measuring function	No
Reusable surgical instrument	No
Active device	No
Device intended to administer and / or remove medicinal product	No
Device name	Sectacol

Tissues and cells

Presence of human tissues and cells or their derivatives	No
Presence of animal tissues and cells or their derivatives	No

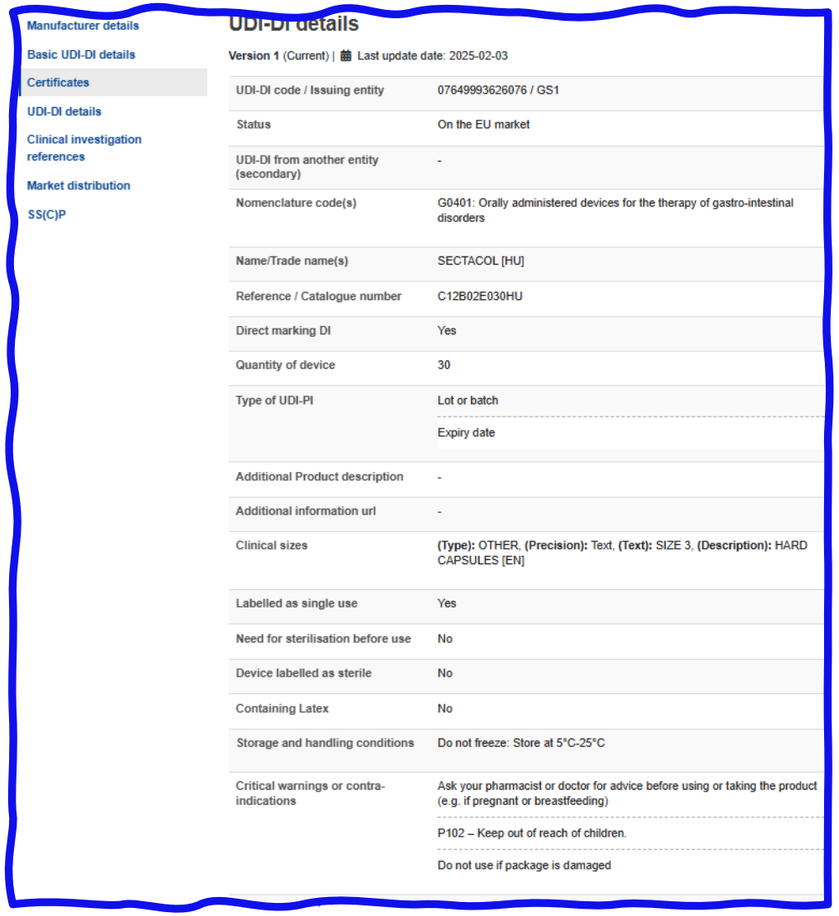


Clinical investigation references
Market distribution
SS(C)P

Clinical investigation references

Clinical investigation references 1

Clinical investigation conducted inside EU	Yes
Clinical investigation reference	CEBNOV29072019
Countries were the Clinical Investigation has been performed	-



Manufacturer details
Basic UDI-DI details
Certificates
UDI-DI details
Clinical investigation references
Market distribution
SS(C)P

UDI-DI details

Version 1 (Current) | Last update date: 2025-02-03

UDI-DI code / Issuing entity	07649993626076 / GS1
Status	On the EU market
UDI-DI from another entity (secondary)	-
Nomenclature code(s)	G0401: Orally administered devices for the therapy of gastro-intestinal disorders
Name/Trade name(s)	SECTACOL [HU]
Reference / Catalogue number	C12B02E030HU
Direct marking DI	Yes
Quantity of device	30
Type of UDI-PI	Lot or batch Expiry date
Additional Product description	-
Additional information url	-
Clinical sizes	**(Type):** OTHER, **(Precision):** Text, **(Text):** SIZE 3, **(Description):** HARD CAPSULES [EN]
Labelled as single use	Yes
Need for sterilisation before use	No
Device labelled as sterile	No
Containing Latex	No
Storage and handling conditions	Do not freeze: Store at 5°C-25°C
Critical warnings or contra-indications	Ask your pharmacist or doctor for advice before using or taking the product (e.g. if pregnant or breastfeeding) P102 – Keep out of reach of children. Do not use if package is damaged

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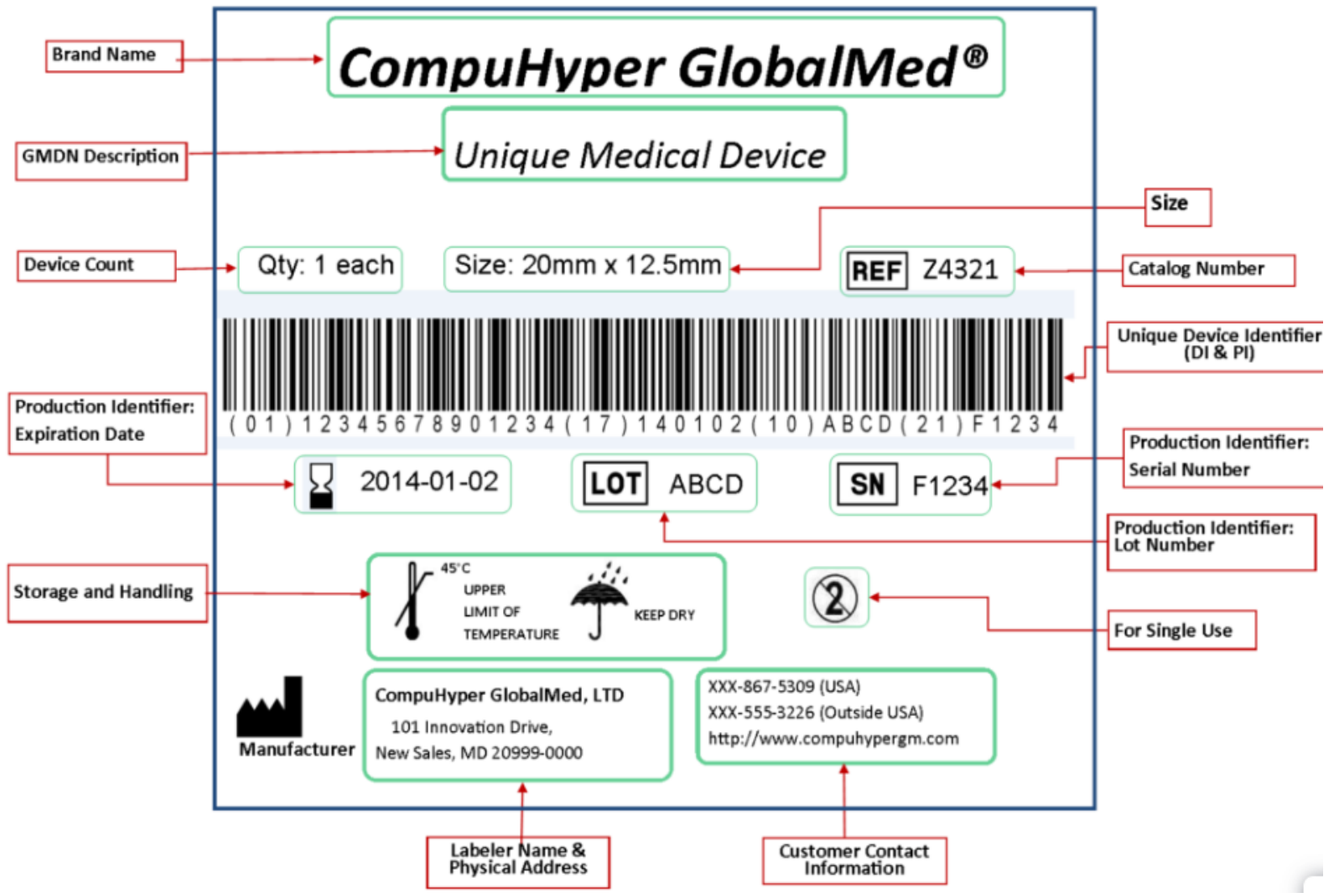
UDI Beyond the Label

FDA and Form 3500A



3500A field	3500A field name	GUDID Field
D1	Brand Name	Brand Name
D2b	Procode	Product Code
D3	Manufacturer Name, City, and State	Company Name
D4	Model #	Version or Model
D4	Lot #	Production Identifier(s) in UDI: If present on device label, "Lot or Batch Number" should be listed as "Yes" However, if not on the label and you have the information, please provide in MDR and explain in Additional Manufacturer Narrative that data is not on the label as PI
D4	Catalog #	Catalog Number
D4	Expiration Date	Production Identifier(s) in UDI: If present on device label, "Expiration Date" should be listed as "Yes" However, if not on the label and you have the information, please provide in MDR and explain in Additional Manufacturer Narrative that data is not on the label as PI
D4	Serial #	Production Identifier(s) in UDI: If present on device label, "Serial Number" should be listed as "Yes" However, if not on the label and you have the information, please provide in MDR and explain in Additional Manufacturer Narrative that data is not on the label as PI

3500A field	3500A field name	GUDID Field
D4	Unique Device Identifier (UDI) #	Primary DI Number: the Device Identifier (DI) portion of the full UDI must match the Primary DI number field. For more information on UDI formats, please see here
G4	PMA/510(k) #	FDA Premarket Submission Number
G4	Combination product	Combination Product
H4	Device Manufacture Date	Production Identifier(s) in UDI: If present on device label, "Manufacturing Date" should be listed as "Yes" However, if not on the label and you have the information, please provide in MDR and explain in Additional Manufacturer Narrative that data is not on the label as PI
H5	Labeled for Single Use?	For Single-Use

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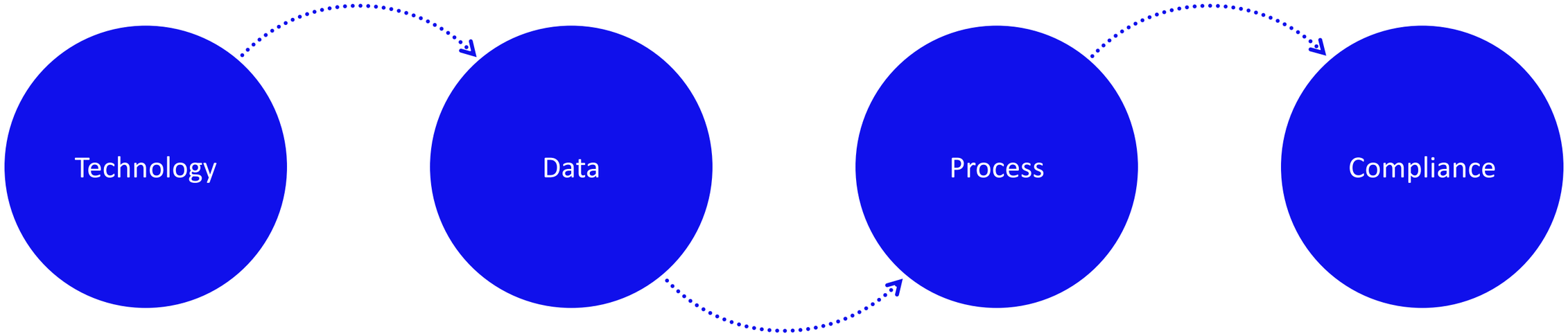
Evolving UDI Requirements

Changing the Strategy

There are many challenges to overcome with implementing new UDI requirements which are not always harmonized.



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Global UDI Strategy

Evolving the Strategy

Advocacy

Interpretation

Develop single interpretation for addressing each UDI requirement

Governance

Process and System

Define and implement company wide process and system changes to compile and submit UDI attribute data globally

Training

Implementation

Change Management & Communication

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UDI

- Forces us think about how we can connect our different functional environments with UDI information resources to create product master data files.
- Changes how we think of data in existing systems and processes and creates new opportunities for connecting regulatory data for reuse and multi-purposing.
- More than a project with a beginning, middle and end - UDI will be a continuing effort to maintain the global view of regulatory product data and provides a means to connect our clinical environments.

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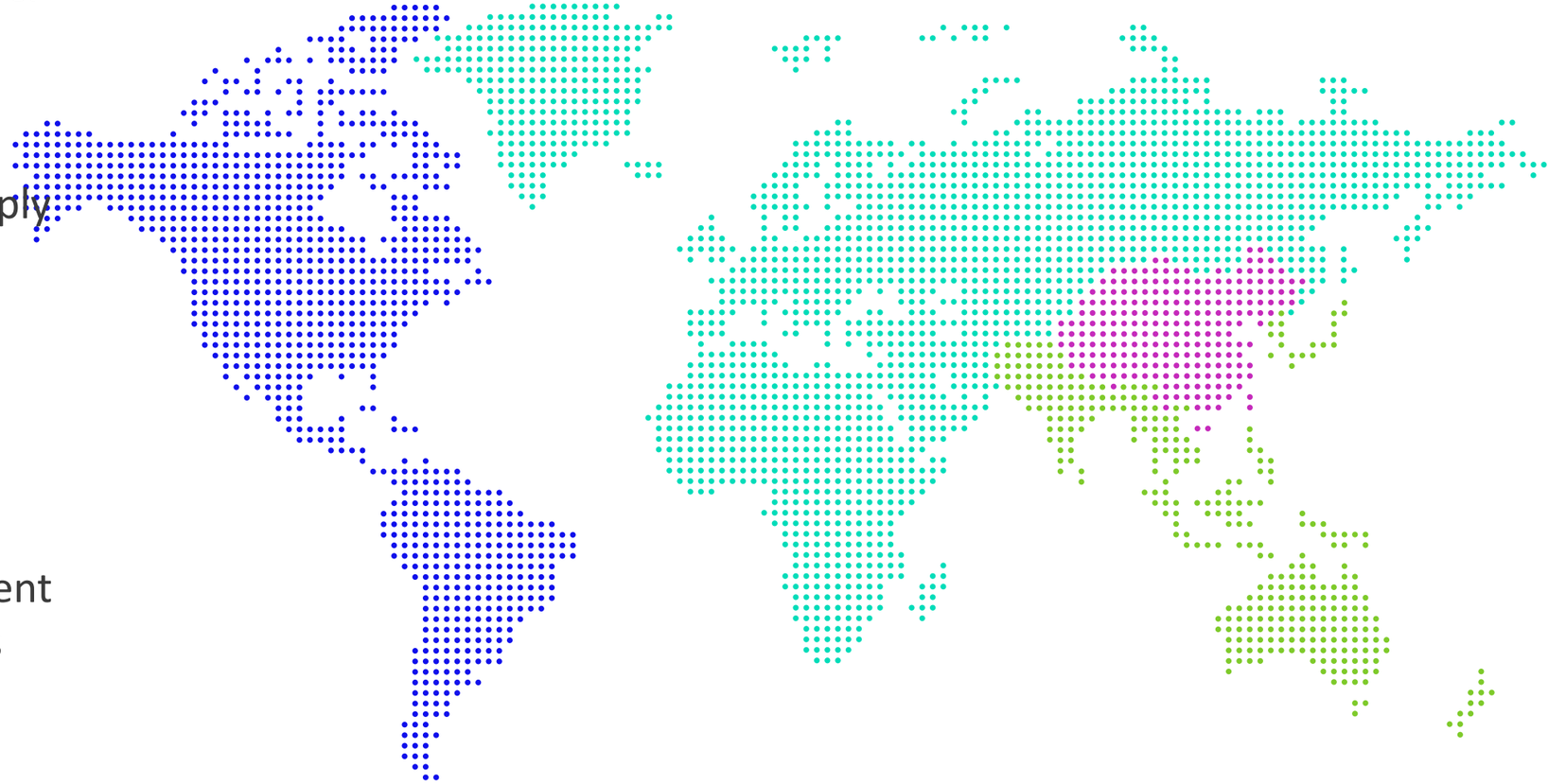
Benefits of UDI Global Alignment

World Class Advantages

- Provides for more efficiency, accuracy & automation of capturing product information in the global supply chain
- Provides global visibility of device supply & movement through the healthcare supply chain to patient
- Provides global visibility to device adverse events & recalled devices
- Enables capture of accurate & consistent device information in device registries globally



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Thank you

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Q&A

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