Rimsys®

Reducing UDI confusion for RA teams

About Rimsys

Regulatory information management software designed specifically for medtech

About me

16 years MedTech regulatory & quality management with Class I, II, & III devices

What we'll talk about today

Agenda

- UDI 101 - Basics and components of unique device identification systems
- Country/region UDI requirements and implementation timelines
- Why managing UDI data is a regulatory concern
- Q&A

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Why UDI?

- Increases traceability of medical devices
- Provides unambiguous identification method throughout distribution and use, prevents counterfeiting
- Effective management of post-market safety-related activities (i.e., adverse event reporting and device recalls)
- Improves device documentation and reduces medical errors by healthcare professionals

Traditionally UDI has been handled separately from other regulatory information or processes

What's Changing?

United States

(01)04053213000004(17)270526(10)321TQS(21)6585HR7C08

European Union

(01)04053213000004(17)270526(10)321TQS(21)6585HR7C08

China

(01)04053213000004(17)270526(10)321TQS(21)6585HR7C08

Japan

(01)04053213000004(17)270526(10)321TQS(21)6585HR7C08

South Korea

(01)04053213000004(17)270526(10)321TQS(21)6585HR7C08

Saudi Arabia

(01)04053213000004(17)270526(10)321TQS(21)6585HR7C08

Singapore

(01)04053213000004(17)270526(10)321TQS(21)6585HR7C08

Australia

(01)04053213000004(17)270526(10)321TQS(21)6585HR7C08

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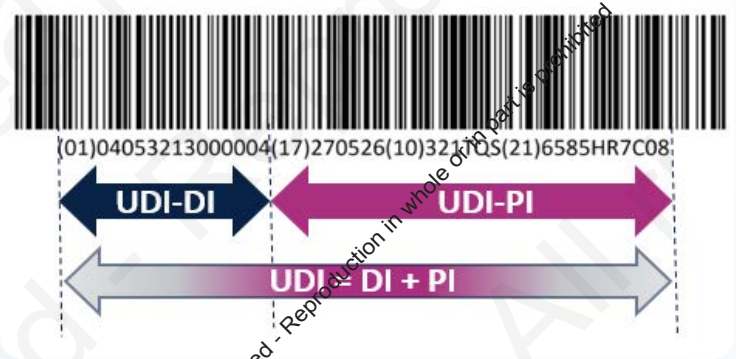
UDI 101 - What is UDI?

Unique device identifier (UDI): Is a unique numeric or alphanumeric code that consists of the following characteristics:

- Device identifier (DI)
- Production identifier (PI)
- *Basic UDI (BUDI) EU only*
- *Master UDI (MUDI) EU only*
- Human readable
- Machine readable

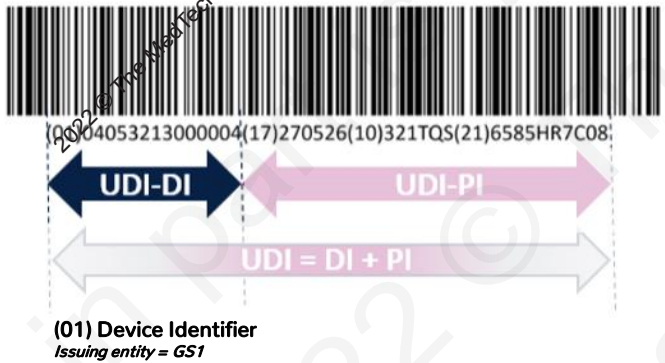
(Carrier)

- Accredited issuing entity
- Placed on devices, packages, or directly on the device (Direct Marking = DM)
- Data elements registered within a country specific database



UDI is more than just a bar code

UDI Components



(01) Device Identifier
Issuing entity = GS1

UDI Device Identifier (UDI-DI)

Static portion, identifies the labeler/ manufacturer and the specific device version of a device, contains:

- Device Identifier (a.k.a. Global Trade Item Number (GTIN) per GS1)
  - Company prefix
  - Manufacturers internal product code
  - Check character
- Primary identifier to look up device attributes in a country specific database
- Changes at different packaging levels
- Assigned prior to placing a device on the market

UDI Components

UDI Production Identifier (UDI-PI)

Dynamic portion that identifies one or more of the following:

- Manufacturing lot/batch
- Serial number
- Manufacturing date
- Expiration date
- Others, if defined by respective regulations

Actual UDI PI does not appear in country specific databases *(EU exception, only in case of vigilance)*

UDI Components – European Union

Basic UDI-DI/Global Model Number (GMN) per GS1			
405321300 GS1 Company Prefix	ProdFamily1REF Model Reference	05 Check characters	25-character max No bar code

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UDI-DI | UDI-PI

UDI = DI + PI

Basic UDI-DI (BUDI)

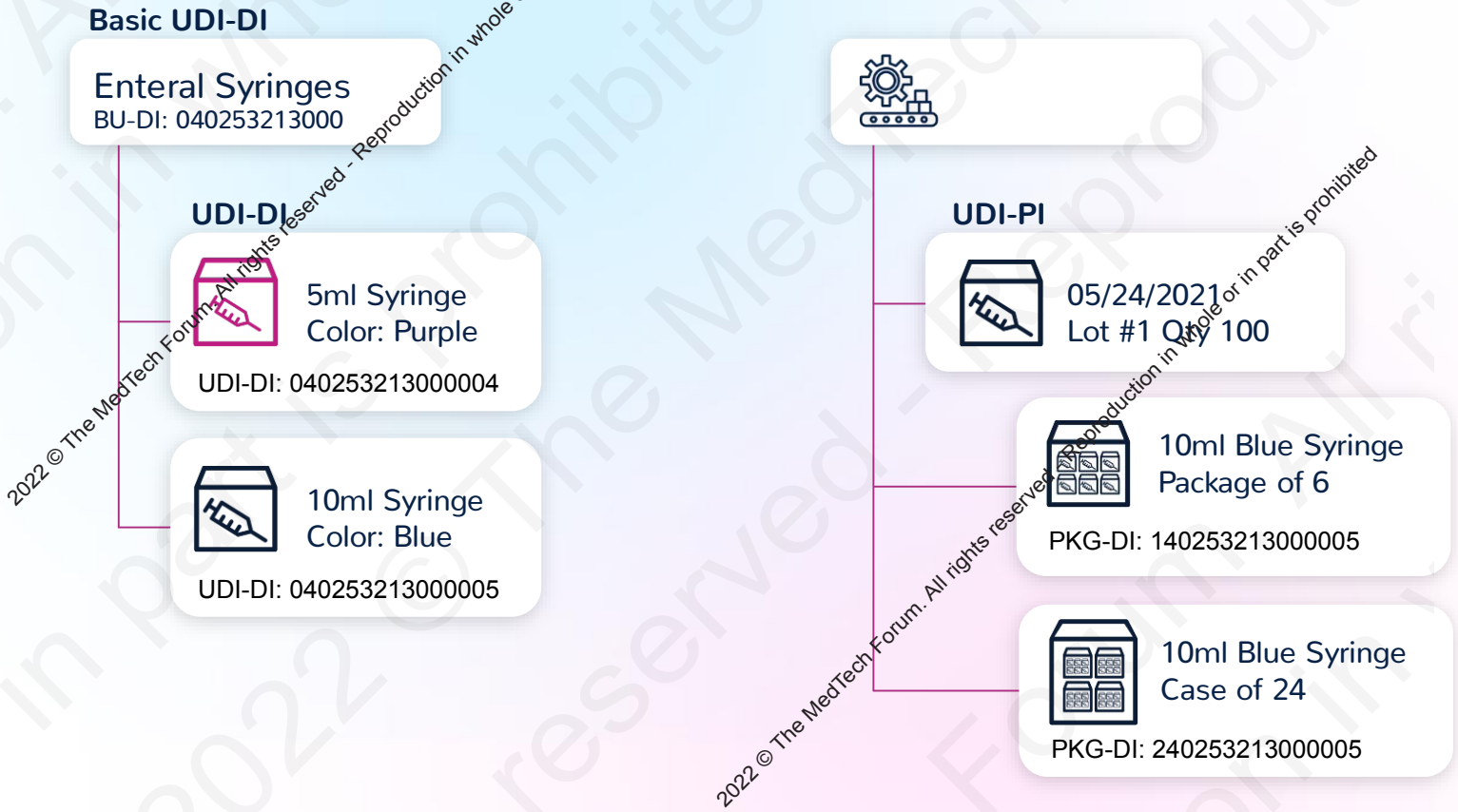
- Product family/group/model level
- Invisible to end users (not on packaging/labelling)
- For registration/administrative purposes only:
  - EC Certificate
  - Declaration of Conformity
  - Technical Documentation
  - Summary of Safety and Clinical Performance
  - Certificate of Free Sale
  - Vigilance and Post Market Surveillance Reports
- Part of the registration process
- One BUDI to many UDI-DI's, Not one DI to many BUDI's

Master UDI-DI (MUDI)

- Grouping of devices, high-level of individualization, reducing volume of data entries (e.g., contact lenses)
- Contained within the UDI-PI
- GS1 (8014) 14-character max
- Including clinical sizes in the carrier still undecided

Under development

A simplified example - Basic UDI-DI & UDI-DI packaging levels



UDI Labeling

Machine readable format

Automated Identification for Data Capture (AIDC)

Human readable format

Human Readable Information (HRI)

On the device

Direct marking

On packaging

Shipping carriers do not require UDI

Issuing entities

UDI codes must be issued by an approved organization for each market.
Large international organizations are approved across multiple regions.

IFA CODINGSYSTEM **EU authorized only** (issuing agency of both Pharmazentralnummer (PZN Code) and Pharmacy Product Number (PPN))

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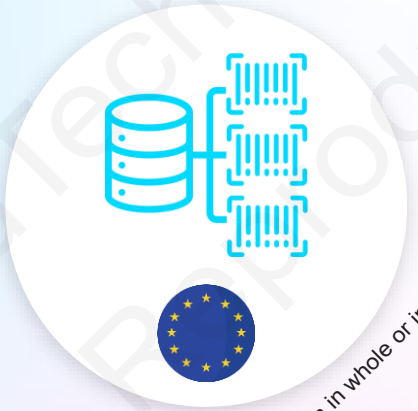
UDI databases

Core data elements based on IMDRF

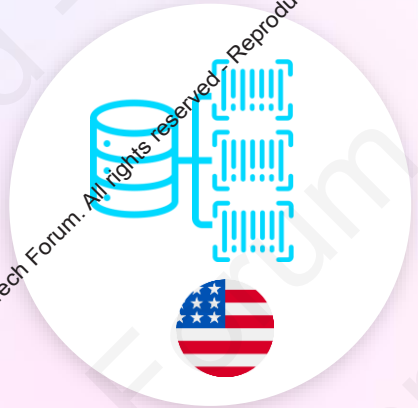
- Device Identification
- Manufacturer/Labeler
- Regulatory
- Packaging
- Production Control
- Device Characteristics
- Country specific attributes

Country specified:

- Data elements/rules
- Submission upload: Manual, spreadsheet, or automated
- Submission timing: During registration and/or prior to placing on the market
- Maintenance: Periodic review and change management



EUDAMED UDI



GUDID

Global UDI adoption

Sep 2014

Jul 2019

Jan 2021

Jun 2021

Aug 2021

May 2022

Nov 2022

2023?

Jul 2024?

Pending

Pending

Pending

Pending

2014

2024

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US UDI requirements

Device risk class	Compliance date
Class III	Sep 24, 2014
Class II	Sep 24, 2016
Class II - reusable	Sep 24, 2018
Class I	Sep 24, 2018
Class I - reusable	Sep 24, 2022

	United States
UDI Database	GUDID
Data elements	64
Nomenclature	GMDN
Issuing entities	GS1, HIBCC, ICCBA
Unique fact	Requires entry of Labeler DUNS number

EU UDI requirements

Device risk class	Compliance date*
Class III	May 26, 2022
Class IIa and IIb	May 26, 2023
Class I	May 26, 2025
Class III - reusable	May 26, 2023
Class IIa and IIb - reusable	May 26, 2025
Class I - reusable	May 26, 2027
Class D (IVD)	May 26, 2023
Class B&C (IVD)	May 26, 2025
Class A (IVD)	May 26, 2027

*Implementation data for UDI carrier on the device label
- EUDAMED – UDI voluntary registration since Oct 2021
- EUDAMED – UDI mandatory registration Q2 2025

	European Union
UDI Database	EUDAMED-UDI
Data elements	130 (BUDI-DI & UDI-DI)
Nomenclature	EMDN
Issuing entities	GS1, HIBCC, ICCBA, IFA
Unique fact	Requires a Basic-UDI

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China UDI requirements

Device risk class	Compliance date*
Class III (subgroup)	Jan 2021
Class III (remaining devices)	Jun 2022
Class II	Oct 2024 (Estimated)
Class I	Oct 2026 (Estimated)

* Implementation data for UDI carrier on device label & UDI Registered

	China
UDI Database	CUDID
Data elements	51
Nomenclature	NMPA
Issuing entities	GS1 China, ZIIOT, Ali Health
Unique fact	UDI required as part of device registration

South Korea UDI requirements

Device risk class	Compliance date*
Class IV	Jul 2019
Class III	Jul 2020
Class II	Jul 2021
Class I	Jul 2022

* Implementation data for UDI carrier on device label & UDI Registered

	South Korea
UDI Database	IMDIS UDID
Data elements	40
Nomenclature	Not required
Issuing entities	GS1, HIBCC, ICCBA
Unique fact	Requires a monthly supply history report, + 1 year from compliance date

Saudi Arabia UDI requirements

Device risk class	Compliance date
Class D (high risk)	Sep 1, 2022
Class B & C (medium risk)	Sep 1, 2022
Class A (low risk)	Sep 1, 2023

Voluntary UDI registration since Oct 1, 2020

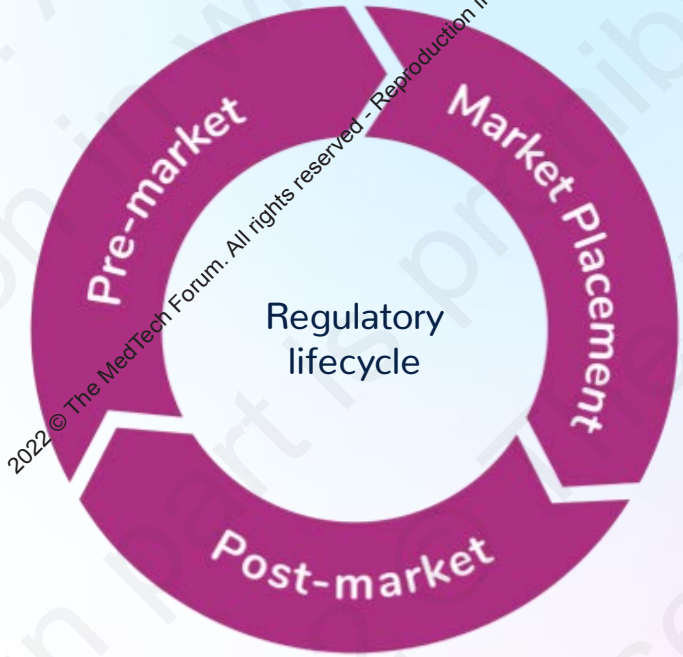
	Saudi Arabia
UDI Database	Saudi-DI
Data elements	35
Nomenclature	GMDN
Issuing entities	GS1, HIBCC, ICCBA
Unique fact	If linear barcode, must be single barcode

Singapore UDI requirements

Device risk class	Compliance date
High risk implantable	Nov 2022
Class D	Nov 2024
Class C	Nov 2026
Class B	Nov 2028
Class A	Not required, voluntary

	Singapore
UDI Database	MEDICS
Data elements	13
Nomenclature	None required
Issuing entities	GS1, HIBCC, ICCBA
Unique fact	If device is marketed in US and EU accepts UDI Label. If not need to use HSA issuing agency.

Why is UDI a regulatory concern?



Pre-market

UDI is part of design controls, and regulatory submissions. Products cannot be registered without it

Market Placement

Manufacturers are responsible to ensure that all submitted UDI information is current and up to date

Post-market

UDI is contained in Vigilance and Post Market Surveillance Reports

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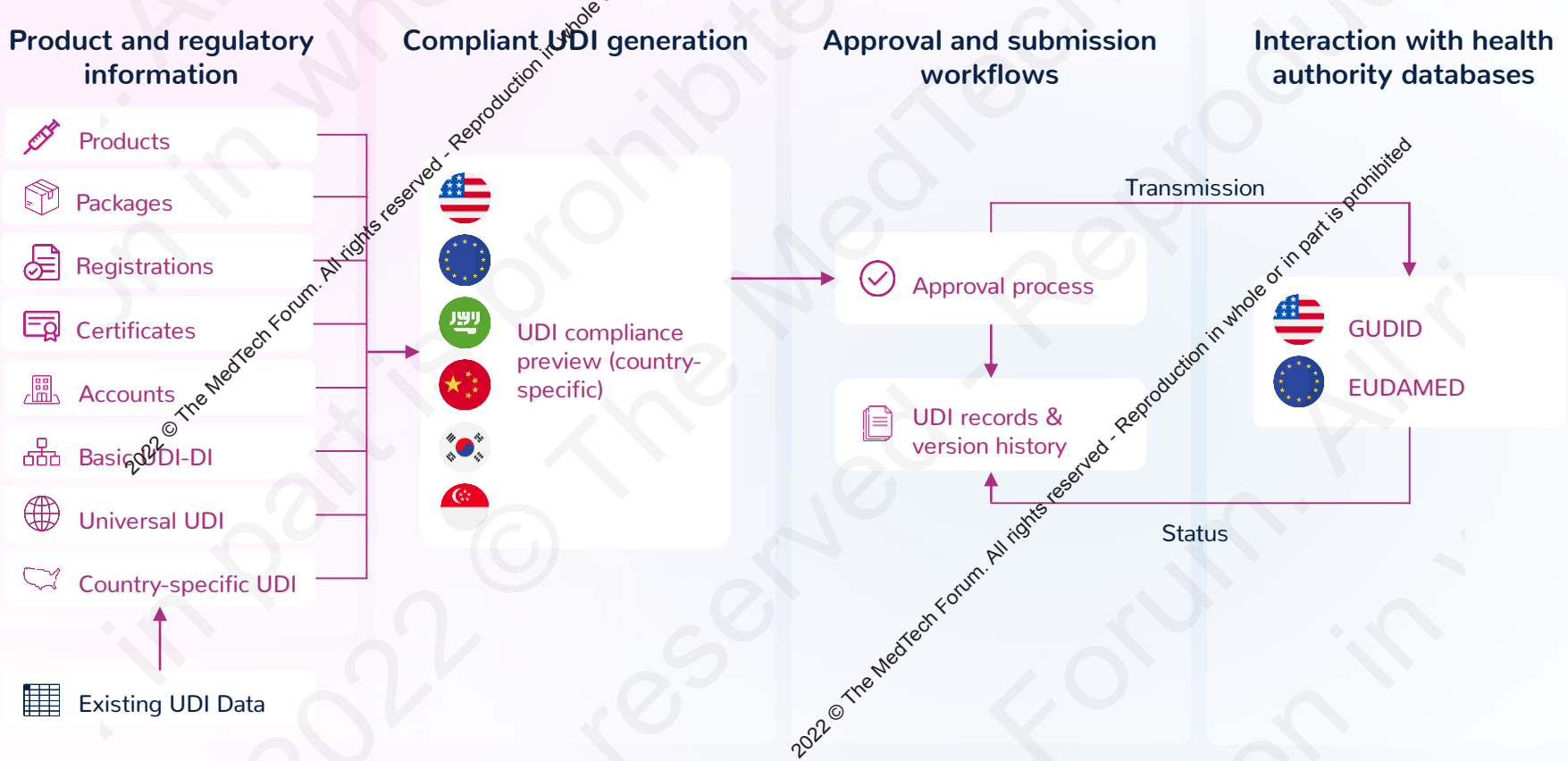
What's at stake?

- Proliferation of UDI data increases complexity
- Incorrect or out of date submissions can lead to fines and impact product selling status

Compliant UDI auto-generation and submission



Universal UDI approach

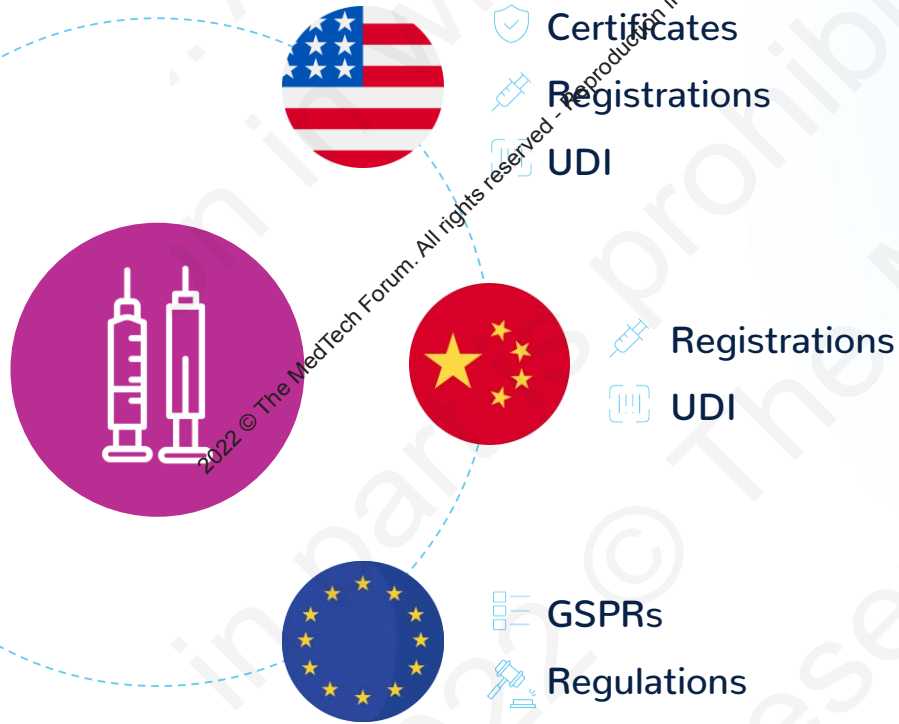





Identification	UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute
	UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute
Characteristics	UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute
	UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute
Packaging		UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute
		UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute
Production			UDI Attribute	UDI Attribute	UDI Attribute	UDI Attribute
				UDI Attribute	UDI Attribute	UDI Attribute
				UDI Attribute	UDI Attribute	UDI Attribute
						UDI Attribute
						UDI Attribute

Common attributes are stored centrally making UDI data easier to manage

A better approach



Product-centric RIM

Centralized UDI, registration, certificate, and other regulatory data stored together and associated directly with product records

Universal UDI data structure

Common UDI

FDA UDI

MDR/IVDR

NMPA

UDI Inanna™ Stent

On the Market

Issuing Entity
GS1

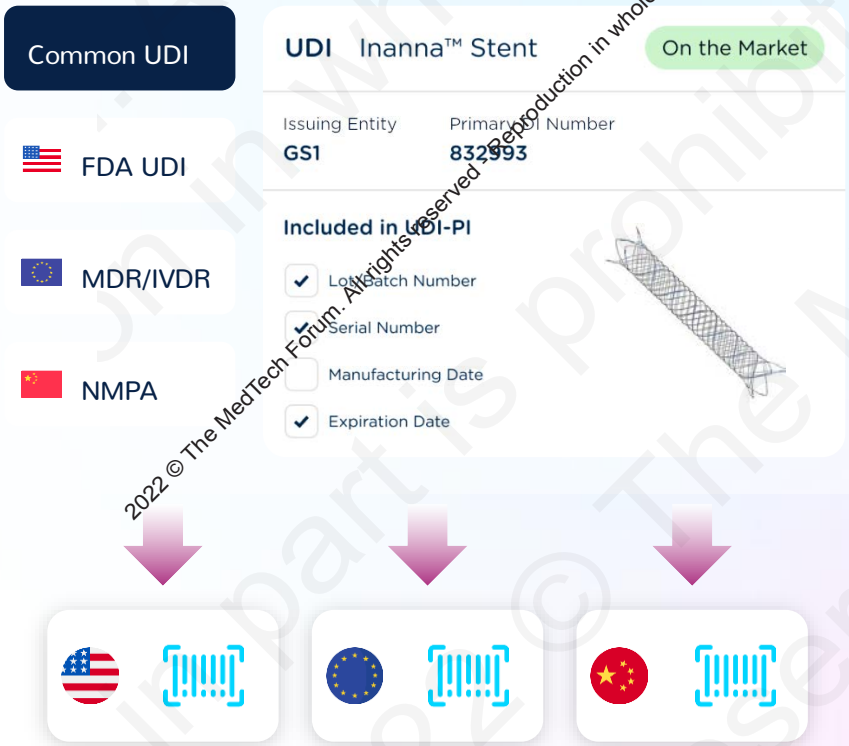
Primary DI Number
832993

Included in UDI-PI

- Lot/Batch Number
- Serial Number
- Manufacturing Date
- Expiration Date

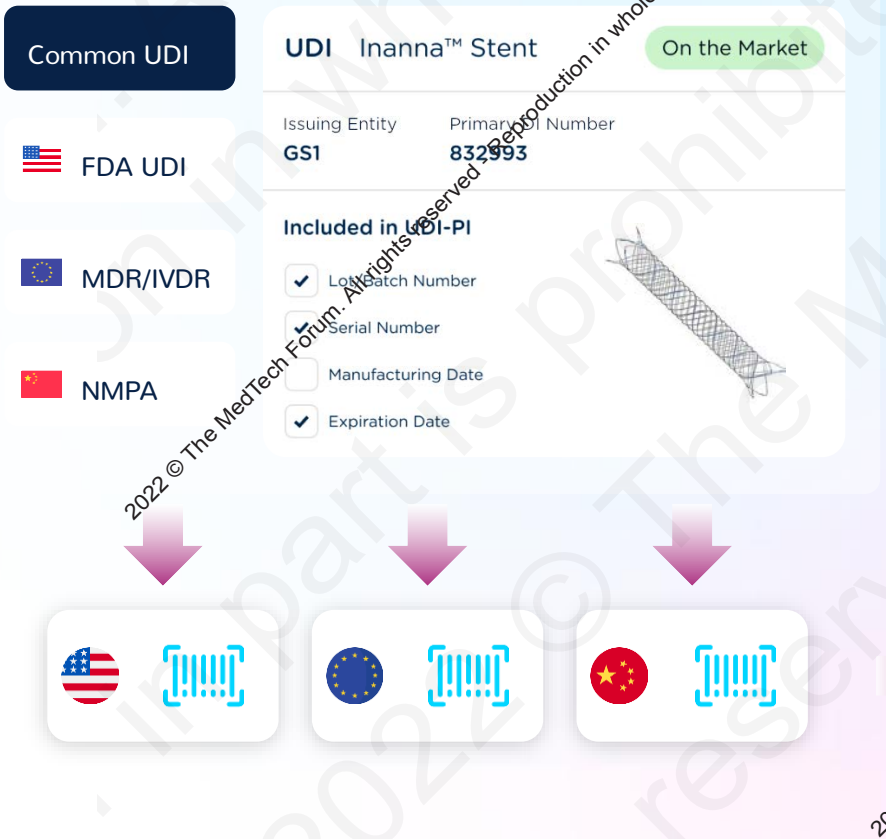
- Top-level (universal) information remains consistent and is associated with individual products

Auto-populated to region-specific records



- Top-level (universal) information remains consistent and is associated with individual products
- Compliant data is generated for different regions

Auto-populated to region-specific records



- Top-level (universal) information remains consistent and is associated with individual products
- Compliant data is generated for different regions
- Electronic UDI records submitted to government databases

Q&A

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