# UDI Implementation Reality – AIDC

## How to identify/mark my medical device products?

# UDI Implementation Reality

## …How to identify/mark my medical device products?…

Moderator

Ms. Jackie Rae Elkin
Global Process Owner - Standard Product Identification
Global Regulatory Operations
Medtronic, Inc.

Panelists

Mr. Dennis Black
Director, e-Business
BD - Becton, Dickinson and Company

Mr. Jithendra Nair
Director Information Technology, Asia Pacific
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Global Process Owner - Auto ID Technology and Data Standards
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GS1 GO Staff

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Senior Director, AIDC Healthcare

# UDI Implementation Reality – AIDC

## …UDI in a GS1 "AIDC" world… the "theory"…

# UDI
# Unique Device Identification

## ...is enabled by…

## GS1 Standards !!

**NOTE:** At the time of this presentation the US FDA Ruling has been published. As it is a detailed and in-depth document, it is recommended that you always refer to the final US FDA Ruling for all details specific to it at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

# Unique Device Identification

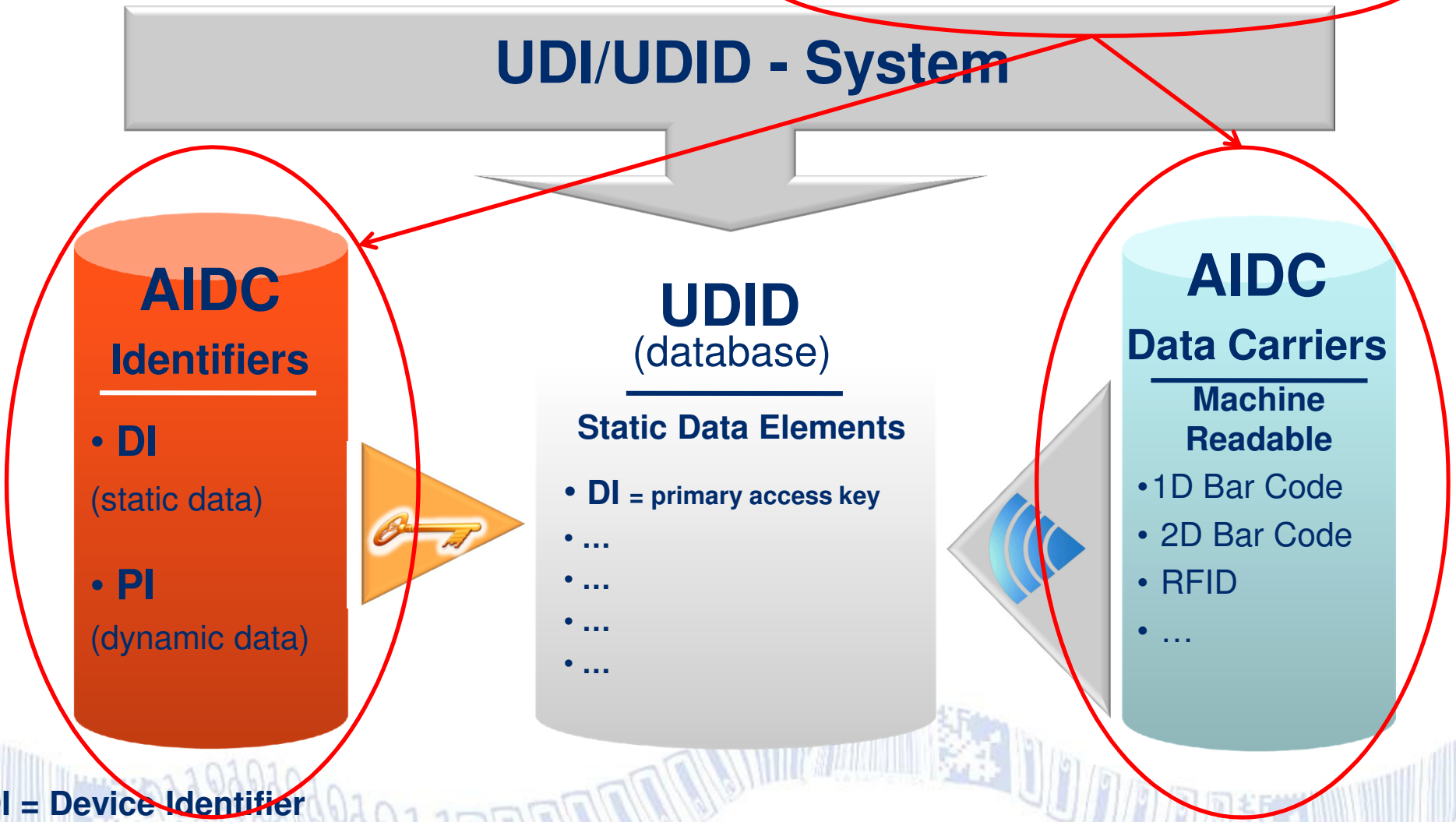
1. A standardized system to develop **Unique Device Identification numbers** (UDI)
2. **UDI** in human readable and/or **bar code/RFID** on a device, its label, or both
3. **UDI Database** will be created and will need to be maintained
4. **Users** need your help to implement. The FDA expects GS1 as an "Issuing Agency" to play a major role

**…the AIDC "bits" of UDI…**

# UDI system…

…AIDC “bits”…

…the AIDC “bits”…



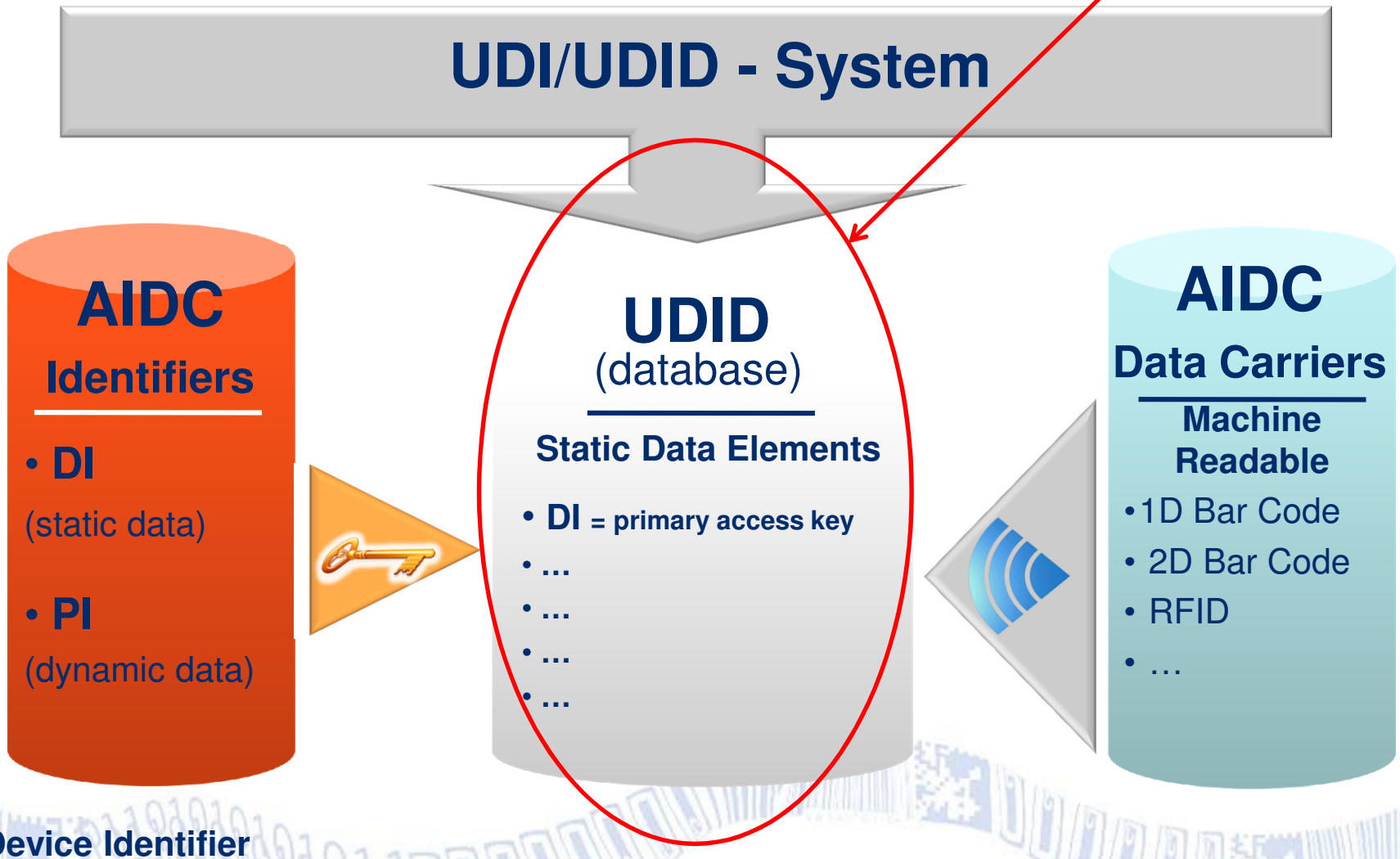

**DI = Device Identifier**

**PI = Production Identifiers** (i.e. lot/batch no., serial no., expiry *[use by]* date, date of manufacture)

# UDI system…

## …and some non-AIDC "bits"…

**GDSN discussed NOW in a parallel breakout session!!**




**DI = Device Identifier**

**PI = Production Identifiers** (i.e. lot/batch no., serial no., expiry *[use by]* date, date of manufacture)

# UDI in the GS1 system of standards

## …UDI in GS1 terms…

## AIDC – Unique Device Identification (UDI)

Goal of unambiguous identification of a specific medical device. From an AIDC standpoint this identification has two (2) parts:

- The **Device Identifier (DI)** – Meant to be the identification of the "generic" medical device – GS1 **GTIN** enables this.
- The **Production Identifier (PI)** – Meant to be whatever "control" numbers or data a manufacturer uses in their process – GS1 **Application Identifiers** (**AI's** such as lot/batch number, serial number, expiry, in any combination with a GTIN) enable this aspect.

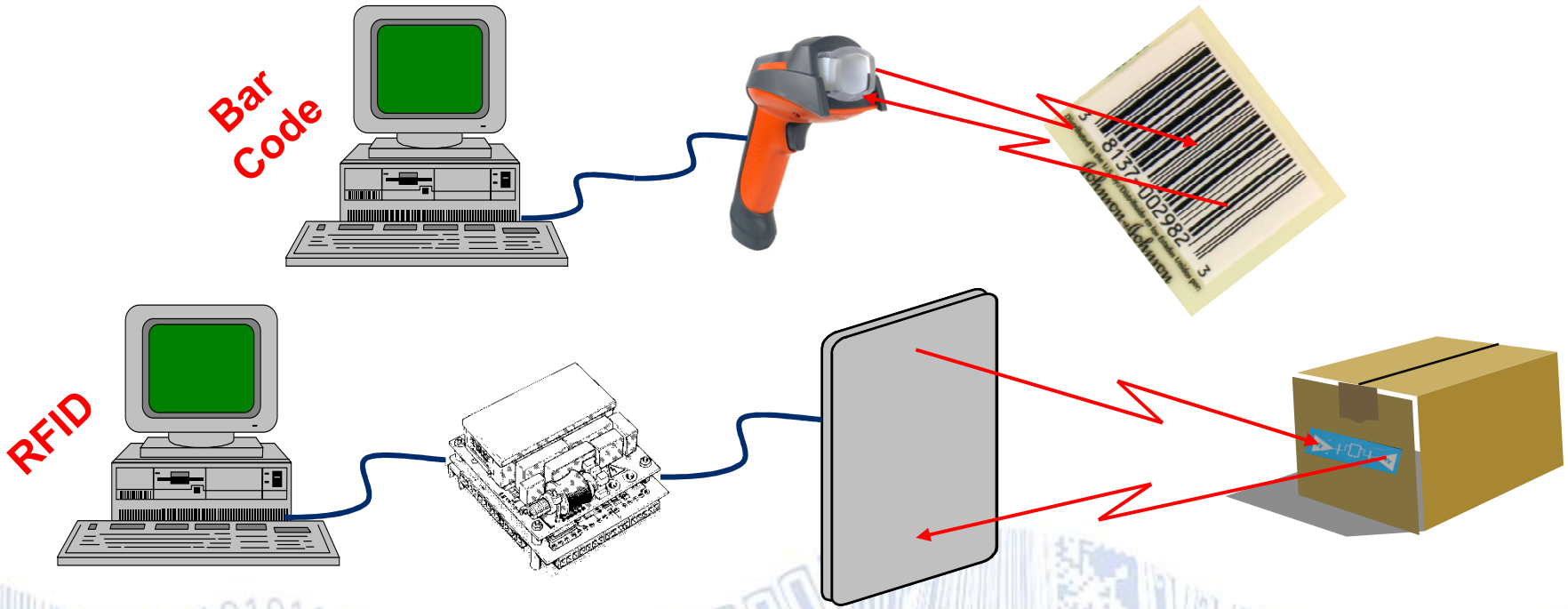
**GTIN + AI(s) = UDI**

# UDI in the GS1 system of standards

## …UDI in GS1 terms…

# AIDC - Data Carriers

ISO compliant machine-readable **Data Carriers** on the product (via label or DPM… Direct Part Marking) or it's packaging, which contain the UDI – 1D / Linear & 2D / Matrix bar code symbols, RFID.



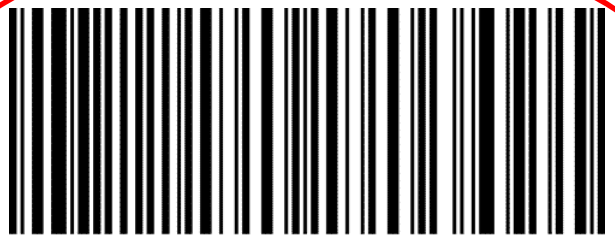

**NOTE:** Though "any" ISO compliant machine-readable Data Carrier is applicable… GS1 Healthcare members have agreed to focus at this time on the use of bar code technology before considering other data carriers…

# UDI in the GS1 system of standards

## …Bar Code Data Carriers "most" typically seen in UDI…


EAN/UPC


GS1 DataBar


GS1-128

Composite Component


GS1 DataMatrix


ITF-14

# UDI in the GS1 system of standards

## …UDI in GS1 terms…

| | | |
|---|---|---|
| **UDI**<br>Unique Device Identification | → | **GS1 Standards**<br>Product Identification |
| **DI**<br>Device Identifier (DI) | → | **GTIN**<br>Global Trade Item Number |
| **PI**<br>Production Identifier (PI)<br>(if applicable) | → | **AI**<br>Application Identifier (AI)<br>• Expiration Date AI(17) - e.g. 141120<br>• Lot/Batch AI(10) - e.g. 1234AB<br>• 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** |

# UDI in the GS1 system of standards

## …UDI in GS1 terms…

## Device Identifier / GTIN Allocation

Some (but not all) common reasons for a Device Identifier (DI = GTIN) to change are:

- Change in quantity of a device package
- Change to package sterility
- Re-labeling of the original labeler's (mfg.) device
- Change labeling languages for different global markets
- Change in certification mark, e.g., CE Mark

Refer to the appropriate UDI regulation in you area and the GS1 GTIN Allocation Rules for complete details on any regional influence for DI / GTIN change.

# UDI in the GS1 system of standards

## …UDI in GS1 terms…

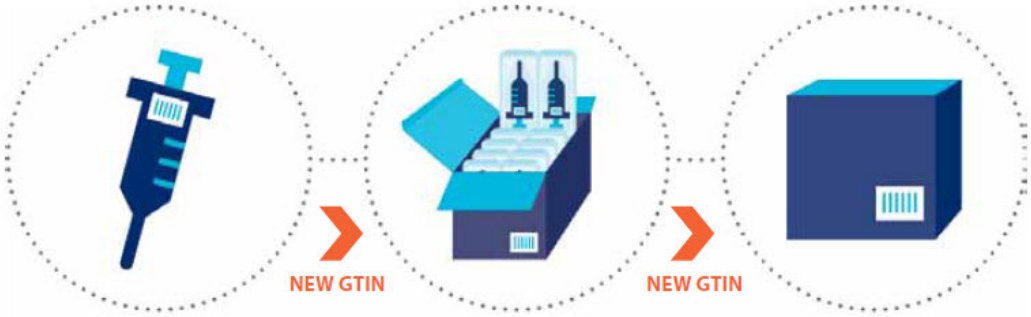
## Package Levels/Hierarchy

Packaging Levels –The UDI (a 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 items are exempt.

### Common industry practices

**Packaging Levels** - The GTIN (DI) & AIs (PIs) should be in bar code & in human-readable form on each applicable package level as defined by regulation. Each designated package level must have its own GTIN (DI).

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




*NOTE: GTINs below for illustration only*

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

# UDI in the GS1 system of standards

## …UDI in GS1 terms…

## Kits

Medical Device “kits” have there own UDI. The general rule is that only the packaged kit/combination product needs a UDI on its label, and that the individual devices contained within do not.

(NOTE: Refer to the FDA Rule for details and/or refer members to their compliance team for guidance specific to their products. Within GS1 additional definition & allocation rules for Healthcare kits are presently being clarified through the GSMP AIDC Healthcare Application Standard Updates Mission Specific Work Group.)

## Data Carrier Placement

As with any AIDC data carrier in any sector overall placement is important. Bar code symbols, with their associated HRI, should be positioned to allow ready access for scanning when the product is stored, stocked on shelves or handled for PoC use.

# UDI in the GS1 system of standards

## …UDI in GS1 terms, carriers you might see at…

### The Warehouse

GS1-128
"Concatenated" data


GS1-128
"Non-Concatenated" data



ITF-14


### The Hospital

GS1-128
"Concatenated" data


GS1-128
"Non-Concatenated" data



GS1 DataMatrix

(01)10857674002017
(17)141120
(10)1234AB

All data carriers are for illustration only, not to scale and not in proportional size to one another.
Please refer to GS1 General Specifications for detailed & up-to-date GS1 System information.
UDI requirements may vary by geography -please refer to regional UDI regulations.

# UDI in the GS1 system of standards

## …UDI in GS1 terms, carriers you might see at…

**The Point-of-Care**

**The Retail POS**

GS1-128
"Concatenated" data


EAN 13


UPC-A


GS1 DataMatrix

(01)10857674002017
(17)141120
(10)1234AB

ITF-14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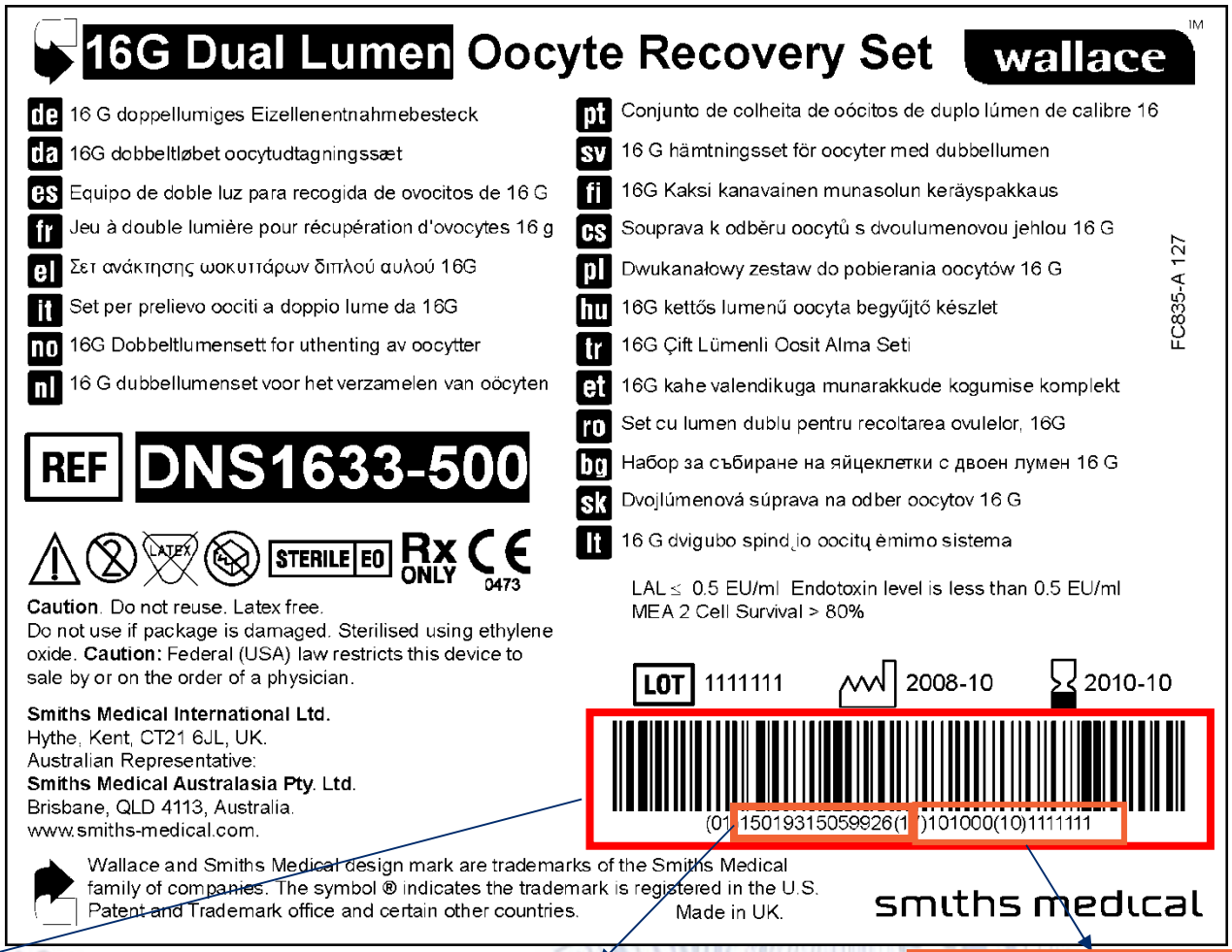
# UDI example - #1




**UDI Bar Code symbol**

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

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

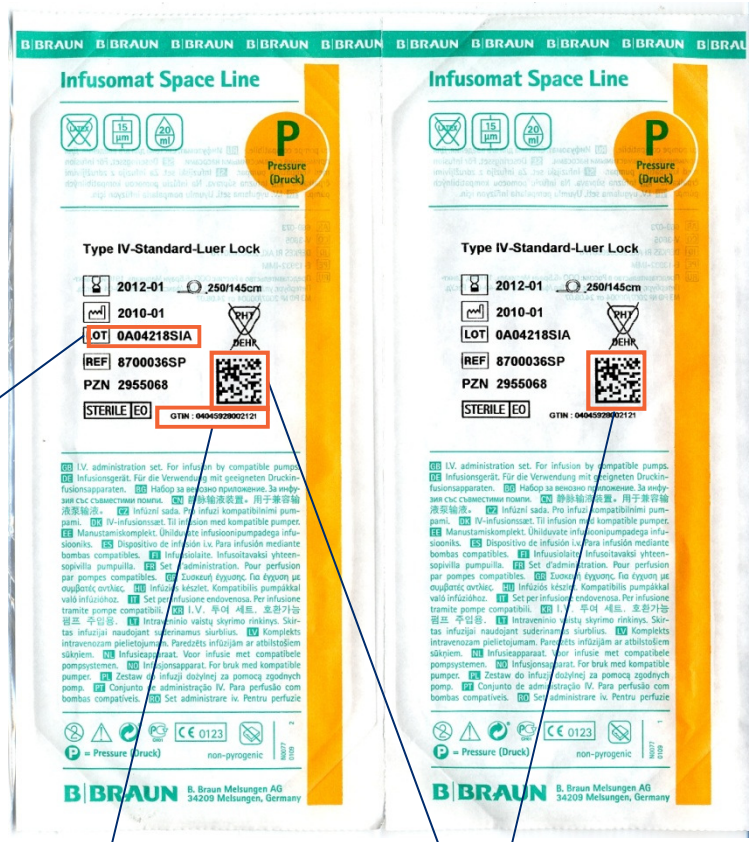
# UDI example - #2

**UDI Bar Code symbol**

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

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

# UDI example - #3



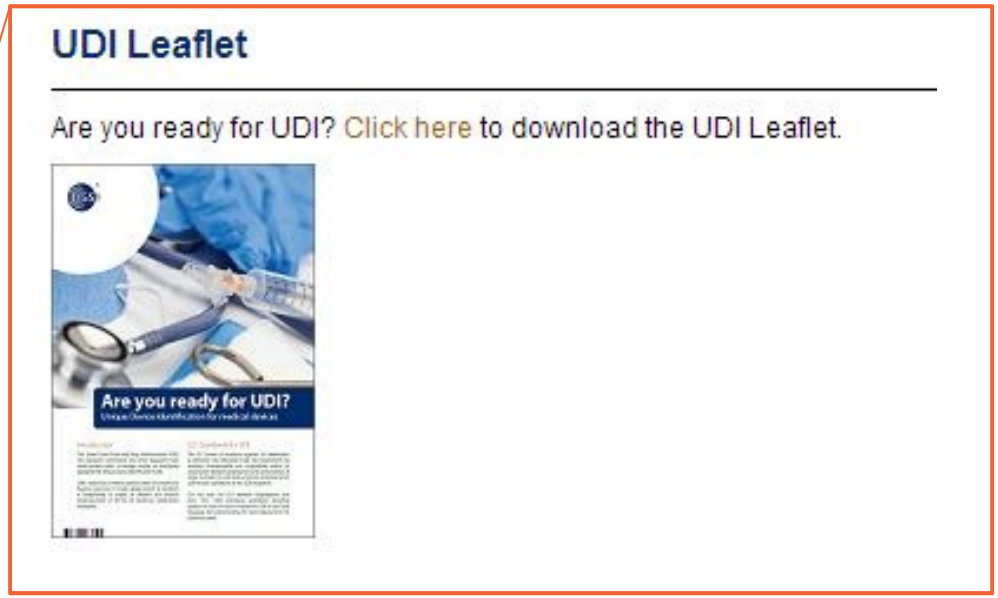

**Production Identifier (PI)**
**"Dynamic" portion**
Application Identifiers (e.g. serial, lot number & expiry date)

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

**UDI Bar Code symbol**

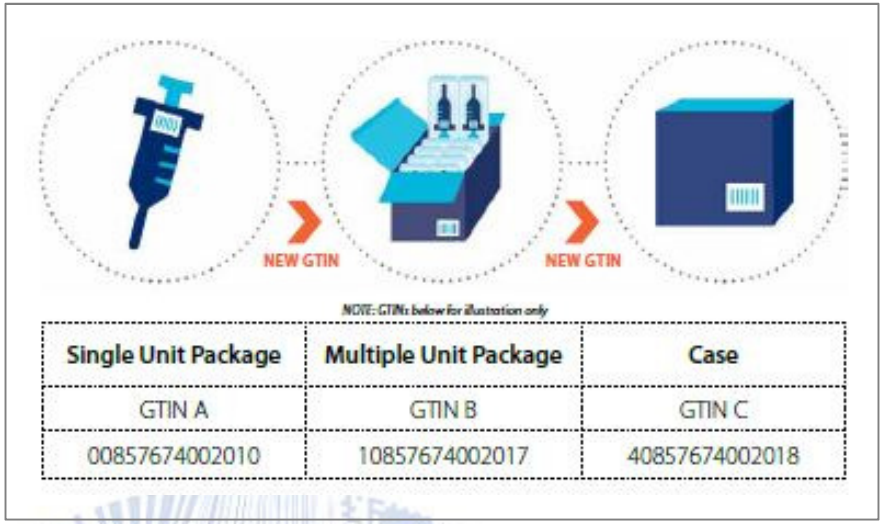
# UDI webpage

www.gs1.org/healthcare/udi

# UDI Support: “Are you ready for UDI?”

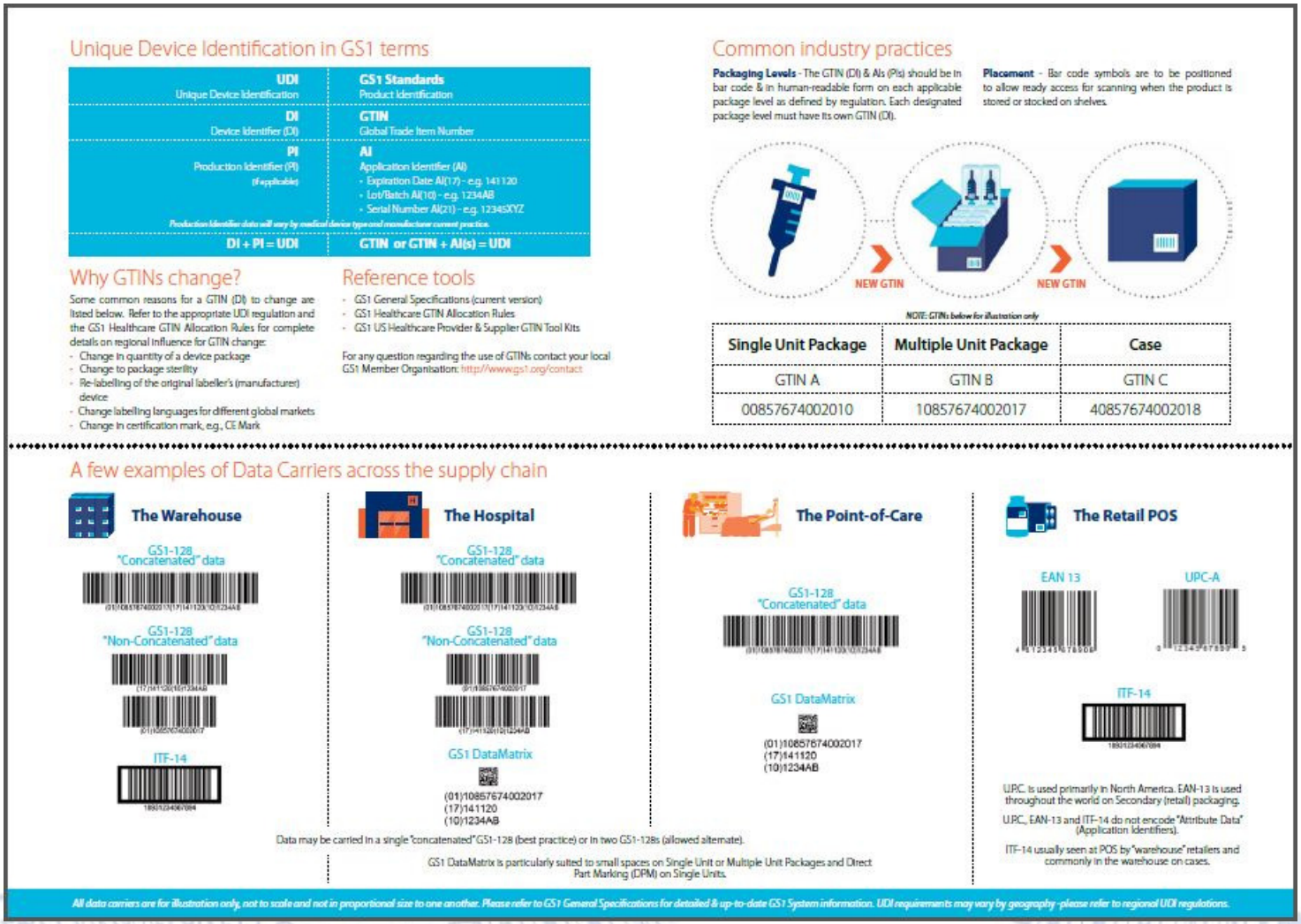

- Introduction to UDI
- UDI in GS1 terms
- Presentation of industry practices
- Benefits of UDI




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

***www.gs1.org/healthcare/udi***

# UDI / GS1 AIDC - the "snapshot"…



## Unique Device Identification in GS1 terms

| | GS1 Standards |
|---|---|
| UDI<br>Unique Device Identification | Product Identification |
| DI<br>Device Identifier (DI) | GTIN<br>Global Trade Item Number |
| PI<br>Production Identifier (PI)<br>(If applicable) | AI<br>Application Identifier (AI)<br>• Expiration Date AI(17) - e.g. 141120<br>• Lot/Batch AI(10) - e.g. 1234AB<br>• Serial Number AI(21) - e.g. 1234SXYZ |
| *Production Identifier data will vary by medical device type and manufacturer current practice.* | |
| DI + PI = UDI | GTIN or GTIN + AI(s) = UDI |

## Why GTINs change?

Some common reasons for a GTIN (DI) to change are listed below. Refer to the appropriate UDI regulation and the GS1 Healthcare GTIN Allocation Rules for complete details on regional influence for GTIN change:

- Change in quantity of a device package
- Change to package sterility
- Re-labelling of the original labeller's (manufacturer) device
- Change labelling languages for different global markets
- Change in certification mark, e.g., CE Mark

## Reference tools

- GS1 General Specifications (current version)
- GS1 Healthcare GTIN Allocation Rules
- GS1 US Healthcare Provider & Supplier GTIN Tool Kits

For any question regarding the use of GTINs contact your local GS1 Member Organisation: http://www.gs1.org/contact

## Common industry practices

**Packaging Levels** - The GTIN (DI) & AIs (PIs) should be in bar code & in human-readable form on each applicable package level as defined by regulation. Each designated package level must have its own GTIN (DI).

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




NOTE: GTINs below for illustration only

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

## A few examples of Data Carriers across the supply chain

### The Warehouse

GS1-128 "Concatenated" data

GS1-128 "Non-Concatenated" data

ITF-14

### The Hospital

GS1-128 "Concatenated" data

GS1-128 "Non-Concatenated" data

GS1 DataMatrix

(01)10857674002017
(17)141120
(10)1234AB

### The Point-of-Care

GS1-128 "Concatenated" data

GS1 DataMatrix

(01)10857674002017
(17)141120
(10)1234AB

### The Retail POS

EAN 13

UPC-A

ITF-14

U.P.C. is used primarily in North America. EAN-13 is used throughout the world on Secondary (retail) packaging.

U.P.C., EAN-13 and ITF-14 do not encode "Attribute Data" (Application Identifiers).

ITF-14 usually seen at POS by "warehouse" retailers and commonly in the warehouse on cases.

Data may be carried in a single "concatenated" GS1-128 (best practice) or in two GS1-128s (allowed alternate).

GS1 DataMatrix is particularly suited to small spaces on Single Unit or Multiple Unit Packages and Direct Part Marking (DPM) on Single Units.

*All data carriers are for illustration only, not to scale and not in proportional size to one another. Please refer to GS1 General Specifications for detailed & up-to-date GS1 System information. UDI requirements may vary by geography - please refer to regional UDI regulations.*

**NOTE:** Check out the GS1 Healthcare UDI web page at: http://www.gs1.org/healthcare/udi

# UDI Implementation Reality – AIDC

## …our Panelists and the "reality"…

# UDI Implementation Reality

## …How to identify/mark my medical device products?…

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Mr. Dennis Black
Director, e-Business
BD - Becton, Dickinson and Company

Mr. Jithendra Nair
Director Information Technology, Asia Pacific
Cook Medical

Mr. Tom Werthwine
Global Process Owner - Auto ID Technology and Data Standards
Johnson & Johnson

Moderator

Ms. Jackie Rae Elkin
Global Process Owner - Standard Product Identification
Global Regulatory Operations
Medtronic, Inc.

# IMPLEMENTATION REALITY

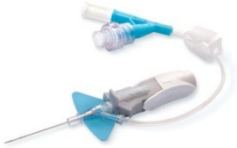
## “Medical Devices: How to identify/mark my products?”

Dennis Black
BD - Becton, Dickinson and Company

GS1 Global Meeting
01 April 2014 - Seoul

# BD (Becton, Dickinson and Company)

- FORTUNE 500 company (#332)
- Locations in more than 50 countries
- Nearly 30,000 associates worldwide
- Serves healthcare institutions, life science researchers, clinical laboratories and the general public
- Sells a broad range of medical supplies and services, devices, laboratory equipment, diagnostic products, and pharmaceuticals



**BD Nexiva™ Closed IV Catheter System**

**BD Influx™ Flow Cytometry System**

**BD SurePath™ PAP Collection System**

**BD Vacutainer® Push Button Blood Collection Set & Blood Collection Tubes**

**BD PosiFlush™ Flush Syringe**

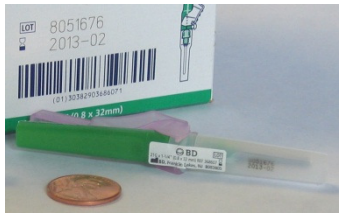
**BD™ Insulin Syringes**

**BD Viper™ System with XTR Technology**

**BD RX**

# Current UDI Efforts Include:

- Reviewing <u>all</u> applicable UDI data, GTIN assignment, and labels to conduct a gap analysis
- Internal Education on UDI Requirements
- Confirming Nuances in FDA UDI Rule
- Verifying Non-US Requirements & IMDRF Guidance
- Revising ERP and Other System to Store UDI Data
- Retooling/Printing Processes/Reassigning GTINs if Necessary
- Revising Policies, Procedures and Processes to Comply with UDI
- Label Revision Process
- Populating UDID
- Revising Commercial Processes







***Moving from voluntary adoption of data standards to compliance with a regulation.***

# Are We There Yet?

## Driving data standards within the healthcare supply chain


Jithendra Nair

UDI & Traceability for Medical Devices

Seoul, Korea 1-3 April, 2014

# Improved Patient Safety – using global standards


- Identifies: Right product, right patient, right time
- Is scanned at the bedside
- Helps prevent medication errors
- Combats counterfeit products
- Facilitates recalls

Image source: http://www.gs1eg.org/Sectors-Healthcare-100.htm

# What is a data standard & What does it all mean?

- Data standard: A common language for trading partners to use about products that pass through the supply chain.

| SAME DATA. DIFFERENT NAMES. | |
|---|---|
| UDI<br>Unique Device Identification | GS1 Standards<br>Product Identification |
| DI<br>Device Identifier | GTIN<br>Global Trade Item Number |
| PI<br>Product Identifier<br>*(if applicable)* | AI<br>Application Identifier<br>• Expiration Date AI(17) – e.g. 141120<br>• Lot/Batch AI(10) – e.g. 1234AB<br>• Serial Number A(21) – e.g. 12345XYZ |
| *Product identifier data will vary by medical device type and manufacturer current practice.* | |
| **DI + PI = UDI** | **GTIN *or* GTIN + AI(s) = UDI** |

## Labeling challenges

### Date format

- YYYY-MM-DD for all dates displayed in the labeling
- Cook will start using day within the date

### For Cook product, must include DI + PI (at least one)

- UDI does not dictate which PI is used
- Exceptions for retail and some Class I devices

### AIDC portion of the UDI

- DI + PI (include all PI information shown on the label)
- Can request FDA exception for some PIs
- Must be human and machine readable

## Labeling challenges

UDI is technology-neutral

- Linear barcodes, 2D data matrices, RFID, etc.
- As technologies evolve, supply chain will drive changes to the standards;

Standards are internationally recognized; GS1 is Cook's Issuing Agency

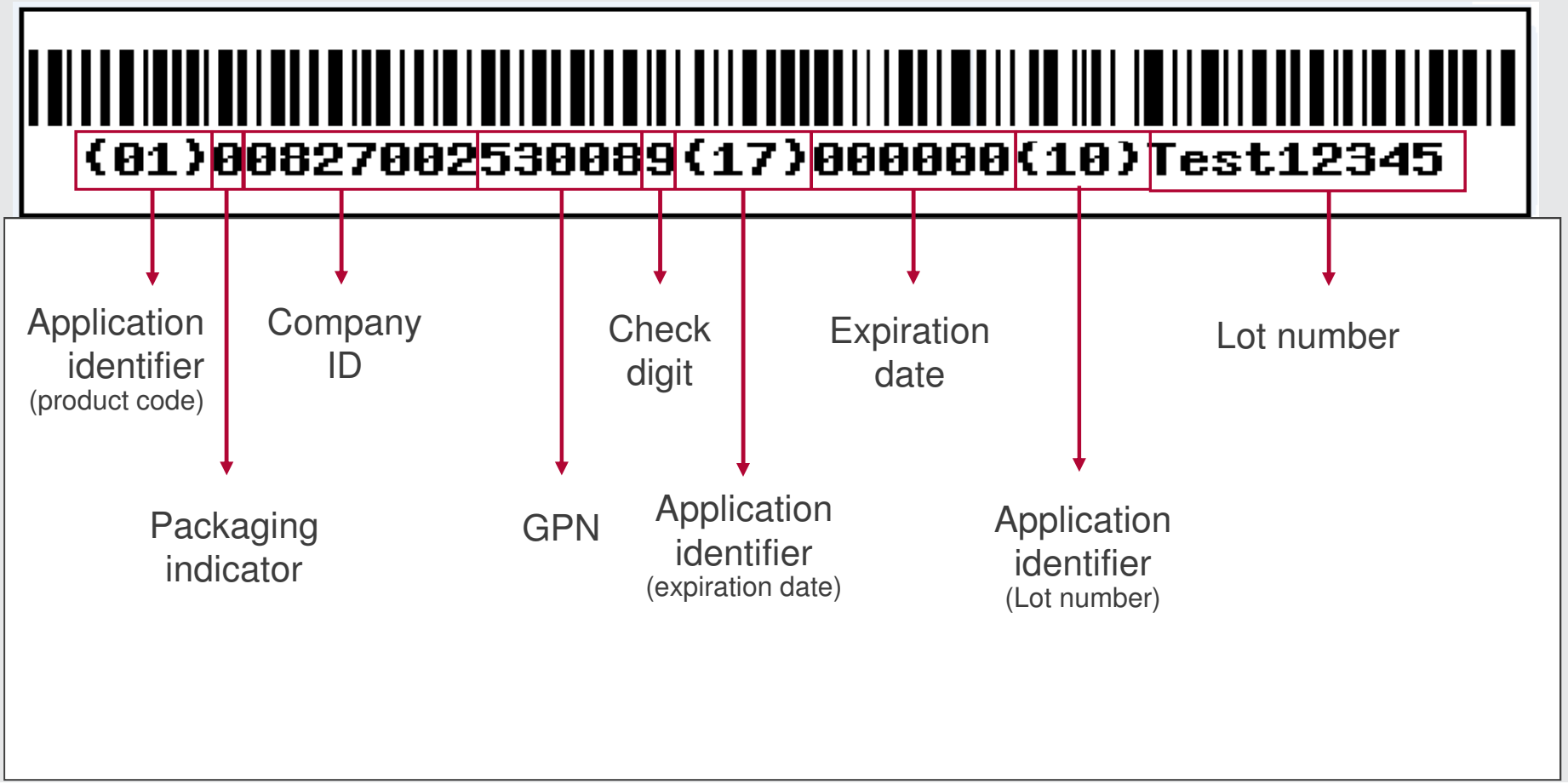
**GTIN-14 linear barcode is Cook's AIDC format**

# Labels – Current Cook Label

# Labels – GTIN-14 Requirements

***By complying with GS1 and the GTIN-14 requirements, Cook is already complying, at least in part, with UDI!!!***

# Labels – GTIN-14 Format



# Labels – GTIN-14 Format

- Additional changes moving forward:
  - AI (30) – Box quantity
  - AI (21) – Serial number
  - Which AIDC method(s) is best for customers?
    - Single, linear barcode (current)
    - Split, linear barcodes
    - 2D data matrices
    - RFID
    - Combination

# GTIN-14 Challenges


- Create a global product database
- Manufacturers had to change barcode labeling logic
- Cook distribution systems had to change
- EDI systems had to be altered to pass data through all systems
- Packaging changed, resulting in going from a 1-to-1 relationship to a 1-to-many relationship between product number and packaging
- UOM changed, requiring inventory conversions

# Cook Medical's approach to implementing GS1 Standards


- Identify current systems' capabilities
- Establish core business implementation team

- *GLN*
- *GTIN*
- *GDSN*
- *E-commerce*

- Use GS1 Standards in all transactions
- Work to achieve perfect order

- *GTIN use at bedside*
- *Integration into electronic health records*

# Start by building a plan and forming a team

***Milestones***

1. Scope project
2. Assess systems
3. Form implementation team
4. Timelines

# Setting up Global Location Numbers (GLNs)

***Milestone***

1. ***GLN***
2. GTIN
3. GDSN
4. E-commerce

***Milestone Steps***

1. Identify GLN location(s) / entity(ies)

2. Request and assign GLNs from your GPO or GS1

   GS1 GLN Quick Start Guide

   GS1 Healthcare Provider GLN Tool Kit

3. Exchange and upload GLN(s) with supplier

# Setting Up Global Trade Item Numbers (GTINs)

***Milestone***

1. GLN
2. ***GTIN***
3. GDSN
4. E-commerce

***Milestone Steps***

1. Perform an item master cleanup.
2. Upload cleansed item master into the NPC/GS1 Catalogue
3. ***Optional:*** Request supplier GTIN information through GDSN

# Setting Up Global Data Synchronization Network (GDSN)

***Milestone***

1. GLN
2. GTIN
3. ***GDSN***
4. E-commerce

***Milestone Steps***

1. Choose data pool provider
2. Request Cook publish GTIN attributes from GDSN

# Setting Up E-commerce

***Milestone***

1. GLN
2. GTIN
3. GDSN
4. ***E-commerce***

***Milestone Steps***

1. Choose e-commerce option
2. Setup e-commerce

## Thank You

Jithendra Nair
Director Information Technology (Asia Pacific)
Cook Medical

Johnson & Johnson CUSTOMER & LOGISTICS SERVICES

# Unique Device Identification (UDI) Use Case

Tom Werthwine
GS1 Global Healthcare Conference Spring 2014

# UDI - Objectives

- Develop a clear understanding of the rule
- Establish a common framework to drive consistency, standardization and clear ownership
- Develop an initial comprehensive view of resources, requirements and investments across all work streams – including: UDI data & database, labeling, direct part marking, conforming amendments, steady state organization, etc.


# Required Components for FDA Compliance

| Requirement | Description | Challenge |
|---|---|---|
| Bar Coding | GTIN and appropriate Application Identifiers | Migrating from HIBCC bar codes to GS1 bar codes |
| Date Format | YYYY-MM-DD | Many products carry month and year |
| GUDID Date Submission | GTIN, regulatory and labeling data | Need to associate “primary UDI” with other levels of packaging<br>May need GTINS for unpackaged and DPM units<br>US only product lack Global Medical Device Nomenclature<br>RA data decentralized |
| Direct Part Marking | Bar code and/or human readable | Technology and space constraints |
| Conforming Amendments | Usage in Adverse Event Reports, Device Hx files | Change management |

# UDI Bar Coding

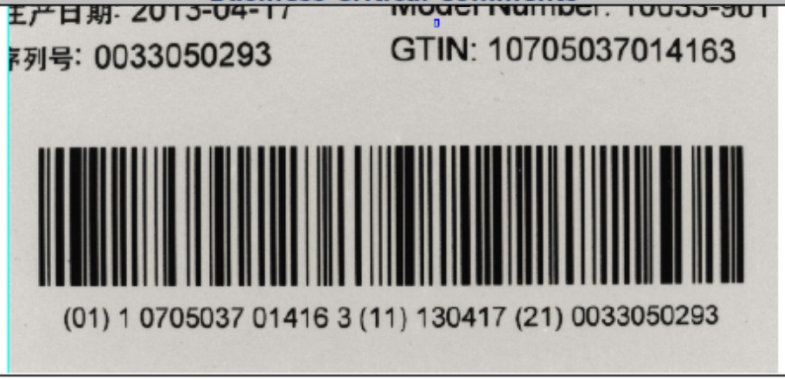

GS1 Linear 128 and Datamatrix

**Testing Summary**

| GS1 General Specifications for Linear Symbols tested environments: |
|---|
| Not Assessed for Retail, Point of Sale Scanning |
| Not Assessed for General Distribution and Logistics scanning |
| Approved for Other Scanning Applications - Regulated Healthcare Non-Retail |
| Consumer Trade Items Not Scanned in General Distribution |

| | |
|---|---|
| Complies to GS1 Symbol Location Recommendations | In/Out of Spec - Not Assessed (Comment on Business Critical Issue) |
| GS1 System Grade | PASS |
| ISO Symbol Grade | ISO 3.1/10/660 (B) - PASS<br>Example: ISO 4.00/06/660<br>(0.00 – 4.00) PASS/FAIL |

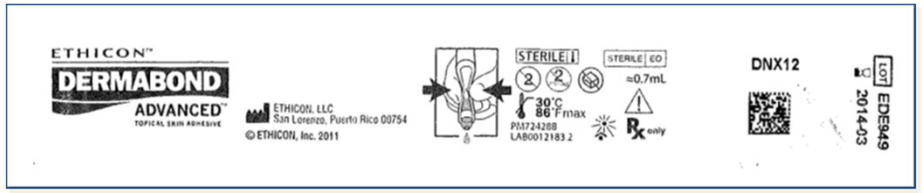
**Business Critical Comments**




GS1 US Verification Report

# GUDID Database Support

| Field | Example |
|---|---|
| Submitter DUNS | TBD |
| Labeler DUNS | 002144145 (ETHICON) |
| RA Contact | TBD |
| Customer Contact | 1-877-384-4266 |
| UDI Issuing Agency | GS1 |
| Primary UDI | 10705031203532 |
| Primary UDI Count | 1 EA |
| Secondary UDI IA | HIBCC |
| Secondary Primary UDI | H206DNX121 |
| FDA Authorization | K100423 |
| FDA PROCODE | MPN |
| FDA PROCODE Name | Tissue adhesive |




| Field | Example |
|---|---|
| FDA Listing | From FURLS |
| GMDN Code | TBD |
| GMDN Term | TBD |
| Brand Name | DERMABOND ADV |
| Model/REF | DNX12 |
| Description | Topical Skin Adhesive |
| Market Status | Active |
| Combination Product | No |
| Contains Human Tissue | No |

# Sample 2D Bar Code Etches for DePuy Synthes



DePuy Synthes
COMPANIES OF Johnson & Johnson

# UDI and Conforming Amendments

| Part | Name |
|---|---|
| 803 | Medical Device Reporting |
| 806 | Reports of Corrections and Removals |
| 810 | Medical Device Recall Authority |
| 814 | Premarket Approvals |
| 820 | Quality System Regulations |
| 821 | Medical Device Tracking Requirements |
| 822 | Post market Surveillance |

Impacts Device History Records, Complaint Files, and Tracking Records.

# UDI in Medical Device Reporting

§ 803.32 If I am a user facility, importer or manufacturer, what information must I submit in my individual adverse event reports?

* * * * *

(c) * * *

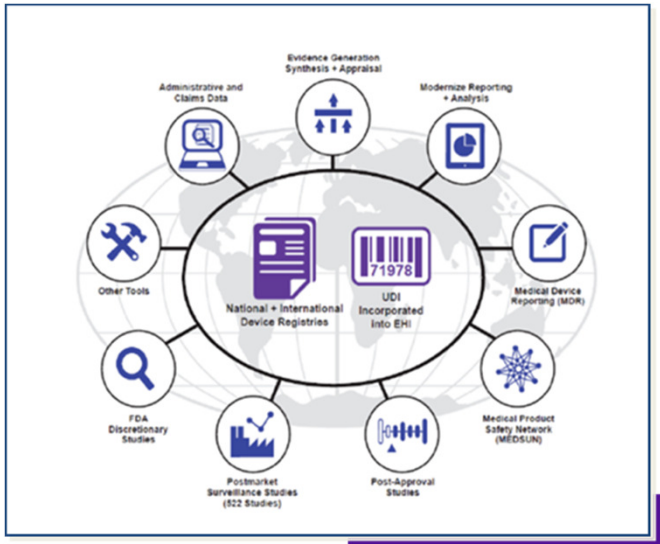
(6) The unique device identifier (UDI) that appears on the device label or on the device package;

* * * * *

# UDI Opportunities

For manufacturers:

- Supporting customer need for data
- Globally unique product identification versus product selection by color, package size, etc.
- Support “perfect order”
- Support implant registries
- Support electronic health records
- Increase efficiencies for evidenced-based medicine




# US FDA UDI

## Compliance …….. some important things to think about

Jackie Rae Elkin, Medtronic, Inc. Global Regulatory Affairs

# Unique Device Identification

Combination of 4 Distinct Ideas

1. Development of a standardized system of Unique Device Identifiers (UDI)
2. Place UDI in human readable and AutoID formats on package label and in some cases, on the device
3. Register UDI data in FDA GUDID public database
4. Implementation

# 1 Development of a standardized system of Unique Device Identifiers (UDI)

*Can you use more than one?*

*You might need to ……..*

The global language of business

International Council for Commonality in Blood Banking Automation, Inc.

Health Industry Business Communication Council

## 2 Place UDI in human readable and AutoID formats on package label and in some cases, on the device

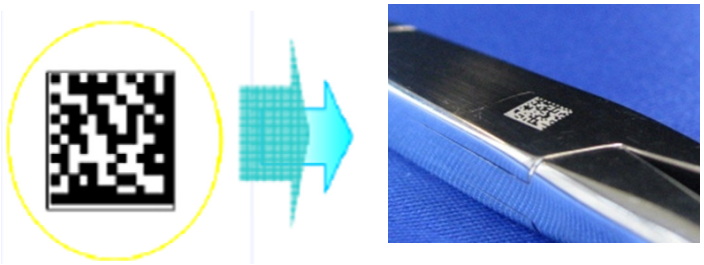
- The Date Format applies to **All** medical devices (not just those subject to UDI). Compliance timelines follow the classification of the product.
- Bar code quality **must be verified**. Simply scanning for readability is not verification, nor is it sufficient. You must measure and verify the quality of the code to ISO/ANSI standards.
- Medical device **software version** should be captured in the Lot or Batch Production Identifier (AI 10 for GS1).
- **Manufacturing date** on the label. If you want an exception from FDA, the **labeler** needs to request it (industry groups cannot) or wait for the outcome of another labeler to be posted.
- GUDID concept of **"should" match** what appears on the product label. UDI and GUDID do not have requirements for the label beyond date format and the UDI itself. But remember the intent to accommodate description to your customer. Should give the customer the "sense" that this is the same product.

# Take the Opportunity to Fix Other Issues ……

What is wrong with this picture?


If you must make label changes to be UDI compliant, e.g., date format, take the opportunity to fix other issues that may cause you problems in the future.

# Direct Marking on the Device



Reusable devices that require reprocessing (sterilization, cleaning) before reuse must have the UDI directly marked on the device.

- Remember the **exceptions** in the rule:
  - ✓ Interfere with safety and efficacy
  - ✓ Not technically feasible
  - ✓ SUD
  - ✓ Previously marked
- **Self exempt** and document in Design History File.
- Consider legacy products placed on market in consignment and remember the 3 years to deplete inventory begins to toll with the classification level for label and direct marking timelines

# 3 Register UDI data in FDA GUDID public database

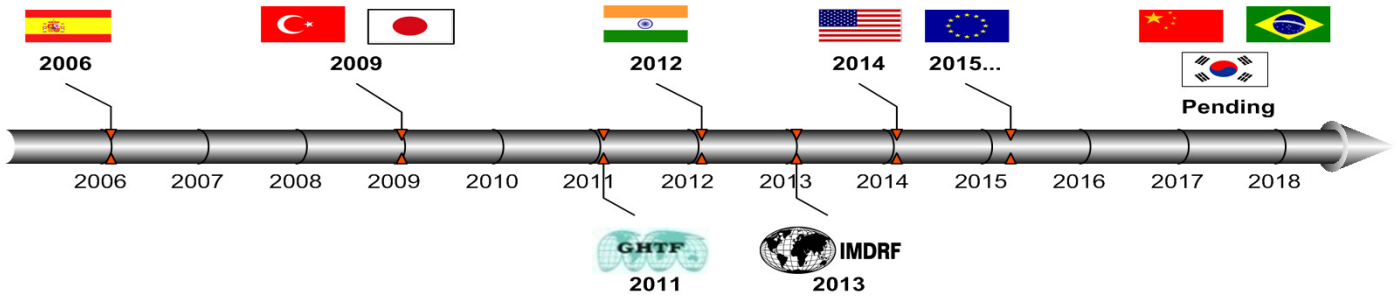
- Who will be **responsible for UDI submission** to FDA?
  - ✓ Using a solution provider to assist?
- **Data Governance** needed - roles and responsibilities to be defined.
  - ✓ Shared responsibility for data maintenance (business units, global/local)
- All UDI data for a medical devices must be submitted to the GUDID **before commercialization** of the product – where is product release trigger?
- **FDA pushing for labelers to publish data now** in order to provide insight to potential issues not anticipated. You can submit your data and push the publish date out 30 – 60 days which will allow you ample time to fix it before actual go–live or compliance dates.
  - * FDA highly recommend labelers "test the waters" before finishing system and process designs.
- **DUNs conundrum -** it is up to the labeler to determine the responsible entity on the label, s/b the person responsible for interpretation of the rule. Primarily used to provide consistency of the responsible labeler name (trying avoid errors in manual entry).

# Interpretation Required !


The **objective** of UDI is to **establish a system to adequately identify devices through distribution and use.** The **purpose** is to **rapidly and definitively identify a device** and it is intended to lead to more **accurate reporting** of adverse events by **making it easier to identify the device** prior to submitting a report.

- Be able to identify a device through a UDI that will appear on the label and package of the device
- UDI, when provided through AIDC technology will allow rapid and accurate data acquisition, recording and retrieval.
- Eliminating the uncertainty concerning the identity of the device subject of an adverse report
- More effective FDA safety communication
- To be used in EHR of a patient implanted with device to strengthen the ability to identify a specific device and improve response to postmarket surveillance activities including adverse event reporting and recalls.

# Global Device Identification Monitoring

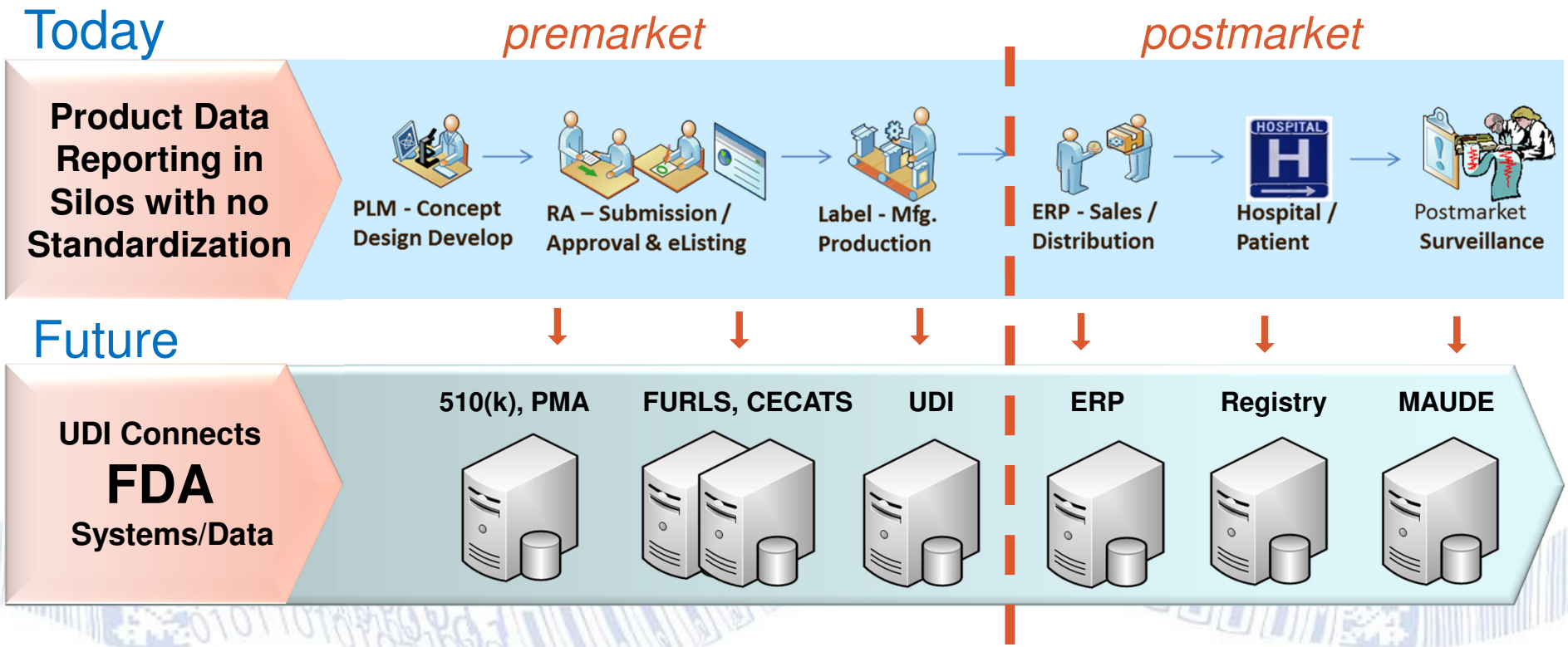



| Country | Timeline | STD | Label Requirements | Data Reporting |
|---|---|---|---|---|
| *Spain* | *2006* | *GS1* | *Device Identifier, Production Identifiers to Unit of Use Level* | *Reimbursement SAS - Department of Health Andaluz* |
| *Turkey* | *2009* | *GS1 HIBC* | *Device Identifier, Production Identifiers to Unit of Use Level* | *TITUBB: Reimbursement SGK – Social Security Institute* |
| *Japan* | *2009 - Guideline* | *GS1* | *Device Identifier, Production Identifiers to Unit of Use Level* | *MEDIS: Reimbursement Ministry of Health, Labor and Wellfare* |
| *India* | *2012* | *GS1* | *Device Identifier, Production Identifiers to Unit of Use Level* | *Procurement Ministry of Health & Family Welfare* |
| IMDRF | Release 2013 | GS1 HIBC | Device Identifier, Production Identifiers to Unit of Use Level | **UDI -** International Medical Device Regulators Forum (IMDRF) |
| USA | Implementation Timeline<br>Class III: 2014<br>LS / LS Implants: 2015<br>Class II: 2016<br>Class I: 2018 | GS1 HIBC ISBT | Device Identifier, Production Identifiers to Unit of Use Level Class II & III | **UDI** Database – US FDA |
| EU | Recommendation Release 2013 | GS1 HIBC | Will Align with IMDRF | **EUDAMED -** European Commission |
| China | TBD | TBD | TBD | **TBD - CFDA** |
| Brazil | TBD | GS1 | Will Align with IMDRF | **TBD - ANVISA** |
| S. Korea | TBD | GS1 | TBD | **TBD - KFDA** |

# External Trends Affecting RIM

## Regulators are Developing Master Data Strategies

- UDI requirements include electronic data about products.
- Regulated Product Submissions (RPS): standards for electronic submissions and electronic data about documents, common data elements for products.



# Contact Details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# More questions afterwards… ??

## Check out more FAQ's at:

http://helpdesk.gs1.org/ArticlesBySubject.aspx?UDI%20-%20Unique%20Device%20Identifier&id=3a55268a-c05a-e311-ba24-00155d644240

## Or if you have additional questions:

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GS1 Healthcare UDI web page at:
http://www.gs1.org/healthcare/udi
GS1 US Healthcare UDI web page:
http://www.gs1us.org/industries/healthcare/gs1-healthcare-us/fda-udi
FDA Helpdesk Direct
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm

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**REMEMBER TO CHECK OUT:**

…GS1 Healthcare UDI web page at: http://www.gs1.org/healthcare/udi
…GS1 US Healthcare UDI web page at: http://www.gs1us.org/industries/healthcare/gs1-healthcare-us/fda-udi
…U.S. FDA UDI general web page at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm