GS1 Standards for Medical Device Identification
Global UDI AIDC Harmonization & GS1 Standards
Global GS1 Healthcare Conference 2018
Bogotá, Colombia

Tuesday - 10 April 2018
Global UDI AIDC Harmonization & GS1

Our Panel:

• **Mark Hoyle** (Session Chair)
  Technical Director, UDI - Teleflex

• **Jackie Elkin**
  Global Process Owner - Standard Product Identification - Medtronic

• **Tom Jones**
  Unique Device Identification (UDI) Program Director - Johnson & Johnson

• **Volker Zeinar**
  Global Coordinator Auto-ID Affairs - B. Braun
Mark Hoyle
Technical Director, UDI
Teleflex
Global Harmonization and GS1 Standards for Medical Device Identification

2018 - GS1 Healthcare Conference, Bogota, Colombia. | Mark Hoyle
Today’s Presentations

Global UDI Regulation
Harmonisation Benefits & Risks
Technical Challenges
What is UDI?

Unique Device Identification
The UDI Barcode – What’s on the Label?

The UDI Barcode contains various degrees of product data, Harmonising the requirement:

- **(01) GTIN-Global Trade Item No.**
- **(10) Batch/Lot**
- **(11) Production Date (YYMMDD)**
- **(17) Expiration Date (YYMMDD)**
- **(21) Serial Number**
UDI Data Sharing

• What is the Ask?
  • Populate a National Database
  • Share with Customers

• Share What?
  • A Common Set of Data Attributes
UDI Labeling & UDI Data Sharing

Ease of Implementation and Early Adoption is Enabled by Global Harmonisation
We Like Questions!
Are you scratching your head?

Why are there different barcode symbologies?
Do GTINs Change on a Product?
Can you share UDI information electronically?
Why GS1?
Where can I go to get more UDI information?
Thank You

Mark Hoyle, Technical Director
Global UDI Implementation
Mark.hoyle@Teleflex.com
Jackie Elkin
Global Process Owner - Standard Product Identification
Medtronic
Global UDI Regulations
Developments & Differences
GS1 as a Global Issuing Agency

GS1 Global Conference – Bogota, Colombia
April 11, 2018

JACKIE RAE ELKIN
MEDTRONIC GLOBAL REGULATORY AFFAIRS
PRESENTATION SCOPE

- UDI Published Rules
- Focus on Aligned AIDC Rules
- Comparison of UDI Requirements in Publications
- Draft UDI Rules and Announcements
- Non-UDI Healthcare Ministry Implementations with a focus on GS1
Unique Device Identifier (UDI): An identifier that unambiguously identifies a device through its distribution and use. Comprised of Two Parts:

1. **A 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); and

2. **A 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*;
   - For an HCT/P regulated as a device, the distinct identification code required aka *Donor Code.*
UNIQUE DEVICE IDENTIFICATION REGULATION CONCEPTS

Combination of 3 Distinct Concepts

1. Development of a standardized system of Unique Device Identifiers (UDI)
2. Placing UDI in Human Readable and AutoID Formats on Package, Label or on the Device
3. Register UDI Data in a Public Database
   - GUDID (US)
   - EUDAMED (EU)
Choose an **Issuing Agency** to develop the UDI and assign the **Device Identifier**.
Marking of **UDI in human readable and auto-identification formats on product package, label or device.** AIDC technology requirements (linear bar code, 2D bar code, RFID) will remain **technology neutral** and based on **ISO standards.** Must be adequate to identify the device through distribution and use.

Questions to Consider:

- Is package label space an issue?
- Can all supply chain stakeholders read it?
- What type of auto-identification is appropriate for your application?
THE WORLD VIEW OF UDI
2. Introduction

This guidance provides a framework for those regulatory authorities that intend to develop their own UDI Systems—such that, when implemented, it achieves a globally harmonized approach to UDI. It is expected that the regulatory authorities will follow the guidance when developing their own UDI requirements. The framework can be used at a local, national, or global level. In order to reach the goal of a globally harmonized UDI System, it is critical that these systems are implemented without regional or national differences.


**IMDRF Guidance**

**UDI for Medical Devices**

**Final Version,**

**December 9, 2013**

http://www.imdrf.org/documents/documents.asp
New Work Item Proposal (NWIP) for Harmonized UDI Application Guide presented to IMDRF Management Committee (MC) - March 2017

IMDRF MC instructed GMTA to prepare first draft of IMDRF UDI Application Guide. Draft submitted to IMDRF - July 7, 2017

IMDRF MC Approved NWIP (w/ revisions), "Harmonized Unique Device Identifier Application Guide." - September 2017

IMDRF UDI WG kick-off - December 2017

Draft for Public Consultation - May 2018
DIFFERENCES BETWEEN IMDRF, US FDA & EU MDR

ADAPT EXISTING STRATEGIES AND SYSTEMS
## IMDRF / US FDA / EU COMM COMPARISON

<table>
<thead>
<tr>
<th>REQUIREMENT</th>
<th>IMDRF</th>
<th>US</th>
<th>EU</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI of UDI not required</td>
<td>Only applies to retail POS devices</td>
<td>Applies to Class I devices</td>
<td>Only applies to retail POS devices</td>
</tr>
<tr>
<td>Manufacturing Date PI exception provided</td>
<td>Unless it is the only PI on the label</td>
<td>Unless it is the only PI on the label</td>
<td>Unless it is the only PI on the label</td>
</tr>
<tr>
<td>UDI required on label of Unit of Use (individual packaged units w/in a multipack)</td>
<td>Excludes Class A &amp; B</td>
<td>Only required for implants</td>
<td>Excludes Class I &amp; IIa</td>
</tr>
<tr>
<td>Labeling exception when constraints limiting both AIDC and HRI on Label</td>
<td>AIDC format shall be favored</td>
<td>No exception</td>
<td>Only AIDC required</td>
</tr>
<tr>
<td>Use of RFID as AIDC</td>
<td>Also requires 2D bar code on label</td>
<td>No requirement</td>
<td>Also requires 2D bar code on label</td>
</tr>
</tbody>
</table>
## IMDRF / US FDA / EU COMM COMPARISON

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</thead>
<tbody>
<tr>
<td>UDI Carrier</td>
<td>Readily identifiable</td>
<td>AIDC must be evident or disclose its presence</td>
<td>Readily identifiable</td>
</tr>
<tr>
<td>Software as a Medical Device (SaMD) - Version</td>
<td>Software Version included in the PI</td>
<td>Software Version included in the PI</td>
<td>Software Version included in the PI</td>
</tr>
<tr>
<td>Human Readable Format of UDI GS1 – Include AIs</td>
<td>HRI format following the issuing agency /entity</td>
<td>HRI format following the issuing agency /entity</td>
<td>HRI format following the issuing agency /entity</td>
</tr>
<tr>
<td>Mechanism for evaluating and adjudicating requests for UDI exemptions and alternative placement of UDI</td>
<td>Provides for process to be included</td>
<td>Extensive processes developed</td>
<td>Does not provide</td>
</tr>
<tr>
<td>Direct Marking Scope</td>
<td>Devices that are reusable and require reprocessing between patients</td>
<td>Devices that are reusable and require reprocessing between patients</td>
<td>All devices that are reusable</td>
</tr>
</tbody>
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<tbody>
<tr>
<td>The Direct Mark Format</td>
<td>“Data Carrier” requires both AIDC and HRI</td>
<td>Allows AIDC or HRI or both AIDC and HRI</td>
<td>“Data Carrier” requires both AIDC and HRI</td>
</tr>
<tr>
<td>Direct Mark UDI Content</td>
<td>Not addressed</td>
<td>• Identical to UDI on the label of the device, or</td>
<td>Not addressed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Different UDI used to distinguish unpackaged device from package</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>containing the device</td>
<td></td>
</tr>
<tr>
<td>Direct Marking Exceptions</td>
<td>Not possible due to size, design, materials, processing, or</td>
<td>• Interfere with the safety or effectiveness;</td>
<td>• Interfere with the safety or performance of the device</td>
</tr>
<tr>
<td></td>
<td>performance issues</td>
<td>• Not technologically feasible;</td>
<td>• Not technologically feasible</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Device is a single-use;</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Device has been previously marked w/UDI</td>
<td></td>
</tr>
<tr>
<td>Direct Marking Compliance</td>
<td>Two years after label compliance date</td>
<td>Two years after label compliance date</td>
<td>Two years after label compliance date</td>
</tr>
<tr>
<td>Timelines</td>
<td></td>
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</table>
INDIVIDUAL REGION IMPLEMENTATIONS
Public Consultation of 2017

Resolution has the objective of instituting the mandatory inclusion of a standard bar code of UDI / IMDRF on cardiological stents, hip and knee implants.

Bar code to include Device Identifier (DI) and Expiry Date and Lot or Serial Number Production Identifier (PI) on the traceability label of the device package.
CHINA FDA UDI REGULATION

Draft Rule March 2018

- Accepts International Coding and reserves right for National Code
- Bar Code - Linear, 2 Dimensional, RFID (must have bar code back-up)
  - Device Identifier
  - Production Identifier
    - Lot or Serial Number
    - Production date
    - Expiry date
- All package levels
- Direct Marking for reusable devices
TAIWAN FDA UDI

Issuing Agencies / Entities - GS1, HIBCC, ICCBBA
Bar Code - Linear, 2 Dimensional, also accepts RFID
  ➢ Device Identifier
  ➢ Production Identifier
    ▪ Lot or Serial Number
    ▪ Production date
    ▪ Expiry date

All package levels
Direct Marking for reusable devices requiring reprocessing between use
- Mandatory 2020
SAUDI ARABIA  SFDA

UDI Regulation
Issuing Agencies / Entities - GS1, HIBCC, ICCBBA
Bar Code - Linear, 2 Dimensional, also accepts RFID
  ➢ Device Identifier
  ➢ Production Identifier
    ▪ Lot or Serial Number
    ▪ Production date
    ▪ Expiry date
All package levels
Direct Marking for reusable devices requiring reprocessing between use
- Begin Enforcement 2020
The Ministry of Food and Drug Safety will introduce the UDI system, which will manage all information from production to distribution and final use of medical devices, in 2019

- Project has phase approach starting in 2017
  - Device Identifier
  - Production Identifier
ENGLAND NATIONAL HEALTH SERVICE (NHS)
eProcurement Strategy

Issuing Agencies / Entities - GS1
Bar Code - Linear, 2 Dimensional, also accepts RFID
- Device Identifier
- Production Identifier
  - Lot or Serial Number
  - Production date
  - Expiry date

Implementation 2015 - 2016
Registration and Tracking System

Issuing Agencies / Entities - GS1 & HIBCC
Bar Code - Linear & 2 Dimensional

- Device Identifier
- Production Identifier
  - Lot or Serial Number
  - Expiry date

All package levels
- Enforcement since 2012
ARGENTINA – ANMAT TRACEABILITY PROJECT

- Issuing Agency / Entity - GS1
- Bar Code - Linear, 2 Dimensional, also accepts RFID
  - Device Identifier
  - Production Identifier
- Lot
- Serial Number
- Expiry date

Enforcement February 2015 - Defibrillators/cardioverters, electric stimulators for cochlear hearing, intraocular lenses, cardiac pacemaker, breast internal prosthesis;
Enforcement August 2015 - Vascular coronary stent, hip prosthesis, and spine prosthesis
JAPAN - MINISTRY OF HEALTH, LABOUR AND WELFARE (MHLW)

Issuing Agency / Entity - GS1
Bar Code - Linear & 2 Dimensional
  - Device Identifier
  - Production Identifier
    - Lot or Serial Number (not required for consumable supplies)
    - Expiry date (not required for consumable supplies)

All package levels
- Enforcement since 2009
- JFMDA Voluntary Guidelines in place since 1999
ANDALUSIAN MINISTRY OF PUBLIC HEALTH

Issuing Agency / Entity - GS1

Bar Code - Linear & 2 Dimensional
- Device Identifier
- Production Identifier
  - Lot or Serial Number
  - Expiry date

All package levels
- Enforcement since 2006
Jackie Rae Elkin
Global Process Owner - Standard Product Identification | Corporate Regulatory Operations

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LET'S TAKE HEALTHCARE FURTHER, TOGETHER
Tom Jones
Unique Device Identification (UDI) Program Director
Johnson & Johnson
Benefits of UDI Harmonization

Impact to Patients and Supply Chain Stakeholders

Tom Jones
UDI Program Director, Supply Chain Visibility
Johnson & Johnson Supply Chain
April 10, 2018
Johnson & Johnson

- Global science & technology company focused solely on healthcare
- More than 275 operating companies in 60 countries
- Selling products in more than 175 countries
- Approximately 128,000 employees worldwide
Johnson & Johnson Portfolio

Consumer

Baby Care • Body Care • Facial Skin Care • Sun Care • Feminine Personal Care • Allergy Care • Compromised Skin Care • Cough and Cold Care • Digestive Health • Oral Care • Pain Care

Medical Devices

Wound Closure & Surgical Devices • Minimally Invasive Surgery • Joint Replacement • Sterilization • Eye Health • Diabetes Care

Pharmaceuticals

Oncology • Infectious Diseases & Vaccines • Immunology • Cardiovascular & Metabolism • Neuroscience & Pain • Pulmonary Hypertension
Our Credo

We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality.

We must constantly strive to reduce our costs in order to maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our suppliers and distributors must have an opportunity to make a fair profit.

We are responsible to our employees, the men and women who work with us throughout the world. Everyone must be considered as an individual. We must respect their dignity and recognize their merit. They must have a sense of security in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe.

We must be mindful of ways to help our employees fulfill their family responsibilities. Employees must feel free to make suggestions and complaints. They must be equal opportunity for employment, development and advancement for those qualified. We must provide competent management and their actions must be just and ethical.

We are responsible to the communities in which we live and work and in the world community as well. We must be good citizens—support good works and charities and bear our fair share of taxes. We must encourage civic improvements and better health and education.

We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed and mistakes paid for.

New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.

Johnson & Johnson
Presentation Overview

- Common regulatory components
- UDI has evolved into a global requirement
- Key challenges for global alignment
- Benefits of global alignment

We’ll discuss the challenges and opportunities with gaining alignment across the global UDI requirements
Elements of Harmonization
Common components of UDI Regulations

These three components are commonly found in the published and draft UDI regulations, representing key opportunities for harmonization.
## UDI Benefits

Patient benefits before, during, and after their surgical procedure

<table>
<thead>
<tr>
<th>Pre-Surgery</th>
<th>Authentication</th>
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<tr>
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<td>Improve supply chain efficiencies</td>
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<tr>
<th>During Surgery</th>
<th>Safety</th>
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UDI Benefits

- **Authentication**: Identify counterfeits and ensure only genuine products are used.
- **Product Availability**: Improve supply chain efficiencies.
- **Safety**: Only appropriate devices are used for the procedure.
- **Knowledge**: Accurate identification of devices for performance analysis.

 UDIs benefits patient benefits before, during, and after their surgical procedure.

UDI: Unique Device Identifier.

**Pre-Surgery**

- **Authentication**: Identify counterfeits and ensure only genuine products are used.
- **Product Availability**: Improve supply chain efficiencies.

**During Surgery**

- **Safety**: Only appropriate devices are used for the procedure.

**Post-Surgery**

- **Knowledge**: Accurate identification of devices for performance analysis.
Moving to a Global Perspective
Regulations and Customer Requirements

- Regulations
- Customer Requirements

Many regulatory bodies have either published or have signaled that they will be publishing UDI Regulations.
Moving to a Global Perspective
Regulations and Customer Requirements

• Regulations

• Customer Requirements

Many customers are requesting GS1 compliant barcodes

Major customers within a given region are also driving requirements similar to UDI, often with requirements associated with data pools and labeling.
Challenges to Alignment
Examples of key differences

Direct marking
• FDA: May use plain text or barcode
• EU MDR: Requires 2D Barcode

Data Fields: MRI Compatibility
• FDA: List of Values
• Turkey: Yes / No

Device Class
• FDA: III, Implantable / Life Sustaining / Life Supporting, II, and I
• UK NHS: III, IIa, IIb, and I

Differences in regulations require manufacturers to continually evaluate their strategies and can create additional transformation efforts when trying to leverage work from previously published regulations
Imagine – Sharing data globally
Opportunities with alignment in UDI regulations

Given compatible device identifications across regions, practitioners, researchers and manufacturers may consolidate data for a global, rather than a regional, view.

- Easier sharing of Outcomes data
- Adverse events / recalls
- Global vs. regional analysis
Imagine – Global rather than Regional Inventory
Opportunities with alignment in UDI regulations

Global Inventory

versus

Region A Inventory
Region B Inventory
Region C Inventory
Region D Inventory

• Improved response to global surgery demands
• Overall increase to product availability
• Supply Chain efficiencies

Global alignment on labeling and direct marking standards will help mitigate the need for inventory dedicated solely for a specific region, driving improved availability for patient procedures.
Imagine – Benefits for Patients and Hospitals
Opportunities with alignment in UDI regulations

**Common Data Elements**

**Patient Outcomes**
Analysis based on global rather than regional data

**Easier Identification**
Common definitions and data elements allow patients to search multiple repositories for additional information on their device

**Common Labels and Direct Marking**

**Product Availability**
Easier to share inventory across regions if regional differences minimized

**Supply Chain Integrity**
Global awareness to counterfeits is easier if fewer label varieties exist

**Patient Safety**
Commonality in DM could reduce misinterpretations if HCP serves multiple regions
Volker Zeinar
Global Coordinator Auto-ID Affairs
B. Braun
GS1 STANDARDS FOR MEDICAL DEVICE IDENTIFICATION

GS1 HEALTHCARE CONFERENCE, BOGOTA

April, 10th 2018
Medical Devices are extremely diverse in size, material, processing, use and criticality!
Multi-market Labeling

- >20 languages on the label
- Country / regional groups
- Supply Chain efficiency

Multi-market presentation of medical devices is the standard (and not the exception)!
Device Packaging

- Which information need to be in AIDC format on the different packaging levels?
  - static data (GTIN) – dynamic data (Exp.Date, Lot/Batch, Serial No, …)
- AIDC printing 'on the fly'
  - pre-printed codes (like in FMC) are no option
- What is really necessary from HC provider point of view?
- Differentiation between Risk Classes?
  - (high/medium risk → EHR/patient docu., prim pack = static + dyn. data)
- Differentiation due to the value of the device?
  - (high/medium cost → reimbursement, prim pack = only static data)
- Other aspects

Requirements from UDI regulations are focused on ‘patient safety’ aspects!
Do they meet the HC provider expectations?
Production Environment
Disposables

Print on the fly (speed) – print equipm. – print head width/fixed/moving – sterilization
Data Carriers

- Preferences on data carriers?
  - Past / Current → linear BC (in particular on second./tertiary pack)
  - Current / Trend → 2D code (GS1 Data Matrix)
  - Future → RFID? (+2D code as Backup)

- Risk to change from linear to 2D ( {?)
- Choice of data carrier to be made by manufacturers
- Best practice → just one data carrier on the label (1 scan to capture all data)
- HC providers should be able
  - to capture all AIDC formats as established by GS1 (image scanners)
  - to interpret its content (data parsing)

Keep in mind → global Standards also have ‘Family Members’!
Technical Challenges / Limitations

**technical framework**
- limited space means → small carriers + high data density
  - e.g. DM size: 6x6 - 10x10 mm
- production/packaging line speed
- packaging material
- printing technology (inkjet, thermal transfer, laser, …)
- only validated ink

**quality issues**
- quality verification (ISO)
- translucent paper
- impact on contrast

ISO required = C (1.5 – 2.5)

100 % AIDC marking is impossible – exceptions need to be accepted!
AIDC application is an end-to-end process!

GS1 General Specifications + Best Practice Guidelines help to design and implement a proper AIDC use case.
Summary

- Diversity
  - Products
  - Packaging

- Technical Aspects
  - Impact factors
  - Production environment
  - Quality

- Regulatory Requirements
  - Jurisdictions
  - Deviations

- User Requirements
  - different preferences & use cases

- GS1 Standards Toolbox
  - Data Carrier
  - Data Content
  - Data Sharing

Harmonization!
- Simplification
- Acceleration
THANK YOU VERY MUCH
FOR YOUR TIME

Volker Zeinar
Global Coordinator Auto-ID Affairs
volker.zeinar@bbraun.com
And now... Audience Q&A
Welcome Reception in Circo Restaurant

• **17:15 – 18:15**
• **MEET REMARKABLE PEOPLE**
• **AN AMAZING COLOMBIAN EXPERIENCE**