UDI Implementation Reality – AIDC
How to identify/mark my medical device products?
UDI Implementation Reality

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

Moderator
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Global Regulatory Operations
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Siemens AG - Healthcare Sector

GS1 GO Staff
Chuck Biss
Senior Director, AIDC Healthcare
UDI Implementation Reality – AIDC

...UDI in a GS1 “AIDC” world... the “theory”...
UDI
Unique Device Identification
...enabled by...
GS1 Standards !!
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. FDA expects GS1 to play a major role
UDI system...
...AIDC components...

UDI/UDID - System

AIDC Identifiers
- DI (static data)
- PI (dynamic data)

UDID (database)
Static Data Elements
- DI = primary access key
  - ...
  - ...
  - ...

AIDC Data Carriers
Machine Readable
- 1D Bar Code
- 2D Bar Code
- RFID
  - ...

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

- **Device Identifier (DI)** – Meant to be the identification of the “generic” medical device – GS1 GTIN enables this.

- **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.

\[
\text{GTIN} + \text{AI(s)} = \text{UDI}
\]

**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.
# UDI in the GS1 system of standards

...UDI in GS1 terms...

<table>
<thead>
<tr>
<th>UDI</th>
<th>GS1 Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unique Device Identification</td>
<td>Product Identification</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DI</th>
<th>GTIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Identifier (DI)</td>
<td>Global Trade Item Number</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PI</th>
<th>AI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production Identifier (P)</td>
<td>Application Identifier (AI)</td>
</tr>
<tr>
<td>(if applicable)</td>
<td></td>
</tr>
</tbody>
</table>

- Expiration Date AI(17) - e.g. 141120
- Lot/Batch AI(10) - e.g. 1234AB
- 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
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 your 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, Kits & Placement

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

<table>
<thead>
<tr>
<th>Single Unit Package</th>
<th>Multiple Unit Package</th>
<th>Case or Shipper</th>
</tr>
</thead>
<tbody>
<tr>
<td>GTIN A</td>
<td>GTIN B</td>
<td>GTIN C</td>
</tr>
<tr>
<td>10857674002017</td>
<td>00857674002010</td>
<td>00857674002027</td>
</tr>
</tbody>
</table>

Kits – Medical Device “kits” have their own UDI.
(NOTE: Refer to the FDA Rule for details. Additional definition & allocation rules for Healthcare kits are being clarified through the GS1 GSMP.)

Placement – Bar code symbols are to be positioned to allow ready access for scanning when the product is stored or stocked on shelves.
UDI in the GS1 system of standards

...UDI in GS1 terms...

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 example - #1

16G Dual Lumen Oocyte Recovery Set

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)

© 2013 GS1
UDI example - #2

© 2013 GS1

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 - Unique Device Identification

Introduction

The U.S. Food and Drug Administration (FDA) and the European Commission have made safety and integrity of the global healthcare supply chain a strategic priority by preparing legislation for a Unique Device Identification (UDI).

UDI is expected to improve patient safety and healthcare business processes. A single, global system of standards is necessary to ensure an efficient and effective implementation of UDI by all healthcare stakeholders worldwide.

What is UDI?

UDI - Unique Device Identifier

UDI Leaflet

Are you ready for UDI? Click here to download the UDI Leaflet.
UDI leaflet: “Are you ready for UDI?”

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

www.gs1.org/healthcare/udi
UDI / GS1 AIDC - a snapshot...

Unique Device Identification in GS1 terms

<table>
<thead>
<tr>
<th>UDI</th>
<th>GS1 Standards</th>
<th>GTIN</th>
<th>GTIN or GTIN + Alpha = UDI</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDI</td>
<td>Package Identifications</td>
<td>GTIN</td>
<td>GTIN + Alpha = UDI</td>
</tr>
<tr>
<td>CI</td>
<td>Global Trade Item Numbers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PI</td>
<td>Application Identifiers (AI)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SI</td>
<td>Production Identification (PI)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Why GTINs change?

- Some common reasons for a CI/N or PI change are listed below. Refer to the appropriate UDI legislation and the GS1 Healthcare CI/N Allocation Rules for complete details/requirements. For GTIN: Check with your local GS1 Member Organization for GS1 Healthcare CI/N Allocation Rules.
- Change in quantity of a device package
- Change in package identity
- Change in product identifier or manufacturing device
- Change in certification mark, e.g., CE mark

Common industry practices

Packaging Levels - GTINs/GNs & AIIs should be in bar code & GS1 standards form on each applicable package level as defined by legislation. Each individual package level must have a GTIN (E)

Placement - For code symbols, are to be positioned to allow ready access for scanning when the product is stored or distributed.

A few examples of Data Carriers across the supply chain

- The Warehouse
  - GS-128 "Constrained" data
  - GS-128 "Non-Constrained" data
- The Hospital
  - GS-128 "Constrained" data
  - GS-128 "Non-Constrained" data
- The Point-of-Care
  - GS-128 "Constrained" data
  - GS1 DataMatrix
    - (01) 19450120400127
    - (1) 19450120400127
  - GS1 DataMatrix
    - (01) 19450120400127
    - 19450120400127
- The Retail POS
  - EAN-13
  - UPC-A

Data may be carried in a single GS1 standard, GS1 DataMatrix, or in two GS1 standards alternately.

GS1 DataMatrix is particularly suited to small spaces on Single Unit or Multiple Unit Packages.

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

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UDI Implementation Reality – AIDC

...our Panelists and the “reality”...
**Moderator**
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Cook Group Incorporated

Mr. Bodo Winkler  
Head of UDI Implementation, Sector Project Lead  
Siemens AG - Healthcare Sector
The UDI (Unique Device Identification) Challenge 2013
Timing
• Presentation 10 minutes
• Plus Q&A

Discussion Points
• Brief Teleflex Overview
• GS1 Specification & Rules
• AIDC Decision Process
• Symbology Format & Selection
• State of Readiness
• Quality Control
Leading global provider of medical devices with leading market positions

- Focused on critical care and surgical procedures
- Annual Revenues: $1.55 billion
- Serving healthcare providers in more than 140 countries
- Global operations: 25 countries
- Employees: ~11,500 organized into regions, divisions and global functions
- Established global sales and distribution network
- Well known brands in vascular access (including interventional access), anesthesia, respiratory care, urology, cardiac care and surgery
- Strong financial position
- NYSE: TFX
**TELEFLEX TODAY…**

<table>
<thead>
<tr>
<th>Vascular Access</th>
<th>Surgical</th>
<th>Specialty Markets</th>
<th>Cardiac Care</th>
<th>Anesthesia / Respiratory</th>
<th>OEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central, Peripheral and Arterial Vascular Access Catheters</td>
<td>Ligation Systems</td>
<td>Foley Catheters</td>
<td>Intra Aortic Balloon Pumps</td>
<td>Supraglottic Airways</td>
<td>Specialty Sutures</td>
</tr>
<tr>
<td>Catheter Tip Positioning Systems</td>
<td>Closure Devices</td>
<td>Intermittent Catheters</td>
<td>IAB Catheters</td>
<td>Atomization</td>
<td>Catheter Fabrication</td>
</tr>
<tr>
<td>Sheath Introducers</td>
<td>Laparoscopic Access Ports/Trocars</td>
<td>Dialysis Catheters</td>
<td>TransRadial Access</td>
<td>Epidurals</td>
<td>Performance Fibers</td>
</tr>
<tr>
<td>Vascular Access Accessories</td>
<td>General &amp; Specialty Instruments</td>
<td>PTA Balloons</td>
<td>Right Heart Products</td>
<td>Peripheral Nerve Blocks</td>
<td>Custom Engineered Precision Extrusion</td>
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<tr>
<td>Chest Drainage Systems</td>
<td>CV Sutures</td>
<td>Interventional Access</td>
<td>Percutaneous Sheath Introducers</td>
<td>Airway Management</td>
<td>Respiratory Therapy</td>
</tr>
</tbody>
</table>

- ~$375 million
- ~$291 million
- ~$260 million
- ~$79 million
- ~$406 million
- ~$140 million

**Note:** Figures represent 2012 revenues per Form 10K.
SYMBOLOGY, ALLOCATION RULES & INDICATOR DIGITS

Version 8

Symbol Placement Rules
Carrier Decision Tree
Human Readable Information Decision Tree
Product Marking GRIDS

Version 13

Healthcare GTIN Allocation Rules
GS1 Global Healthcare User Group

Teleflex
Data integrity is the light at the end of the tunnel, this will partly determine your company success!
Indicator Digit

GS1 Company Prefix  Item Reference

Check Digit

Retail Barcode Compatibility EAN / UPC

Can be shorter based on your GS1 Agreement

<table>
<thead>
<tr>
<th>A</th>
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<th>0</th>
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<th>2</th>
<th>3</th>
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<th>1</th>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Note: A, B, C & D Represent different levels of packaging in the hierarchy

Indicator Digits do **NOT** have any meaning, other than specific use cases for 0 and 9. **Indicator Digits are NOT package level indicators.**
The UDI for a large number of devices incorporates two parts, DI (Device Identification) & PI (Production Information)

- DI = GTIN (Global Trade Item Number)
- PI = Expiry Date, Lot Number, Serial Number, Manufacturing Date (or some part thereof).
  - Not all PI components apply to all Classes of Device, or all Levels of Packaging within the Hierarchy for a Product.
The variable component (PI) of the UDI may have huge impact on your manufacturing facility and their ability to apply.

Production speeds, print processes, in-line marking processes, data integration and validation all pose challenges and investment to enable.

Timelines could be significant for implementation.

QC must be managed, that is not the ability to read a code but the ability to measure the quality of the code to ISO / ANSI Standards.
It Beeped, it Must Be Good!
Unfortunately Not....

Standards to Meet
- ISO-15417
- ISO-15420
- ISO-16022
Contact Details

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Data Standards Implementation

Chuck Franz
Vice President & Chief Information Officer
Global GS1 Healthcare Conference
San Francisco, October 1, 2013
Cook Medical Overview

- Celebrating 50 years in business
- 8 manufacturing companies
- 10 clinical divisions
- Coverage in 135 countries
- 16,000 SKUs
Cook Medical Circa 1999

Cook Australia
Cook Ireland
Cook Denmark
Cook Incorporated
Cook Vascular
Cook Urological
Cook Biotech
Cook Endoscopy
How We Got To a Global Standard

- **1999**: Created global Cook product database
  - 376,000 SKUs representing 20,000 parts

- **2001**: Implemented GS1 standards on labels (GTIN-14 and other Al's)

- **2003**: Created Cook Americas customer service center (CMI)

- **2005**:
  - Validated and aligned packaging level indicators on labels
  - Published attributes to GDSN
  - Transacting with GTINs

- **2012**: Allows for one customer interface to do business with Cook
Cook Medical Today

- Cook Australia
- Cook Ireland
- Cook Denmark
- Cook Incorporated
- Cook Vascular
- Cook Urological
- Cook Biotech
- Cook Endoscopy

Cook Medical Incorporated

Hospital
Unique Device Identification – What are the Consequences for Manufacturers?

San Francisco, CA, USA
Unique Device Identification for Medical Devices – The rationale behind…

MORE
PATIENT SAFETY
THROUGH ENHANCED
DEVICE TRACEABILITY
IN POSTMARKET
SURVEILLANCE
What does UDI stand for?

**Unique Device Identifier**
Truly unique, manufacturer-independent identifier for listed medical devices

**Device Identifier (DI)**
- Type/Model-specific
- Human-readable on label
- Captured in AIDC (Optical Data Carrier)
- Transmitted to UDID

**Production Identifier (PI)**
- Device-specific (unit)
- Human-readable on label
- Captured in AIDC (Optical Data Carrier)
- NOT transmitted to UDID
Situation on UDI
Drivers, Consequences & Outlook

Drivers
Regulators see UDI as the core element for postmarket surveillance
Customers see in UDI prerequisite for optimizing procurement & inventory management

Situation
The deployment of UDIs will become mandatory in all major markets (USA, EU, CN, JAP etc.), starting in September 2014 with class III in USA.
Non-compliance will result in a lock-out from these markets.

No UDI – no business!

Goal & Challenge of a large medical device manufacturer
Create one UDI standard for the whole organization and in parallel accomplish UDI-compliance for Class III-Products by SEP 2014.

Outlook: This is just the starting point – UDI will open a new dimension of post market surveillance (EHR), hospital logistics/inventory management and performance controlling
All registered medical devices must carry a UDI.

The UDI on systems must be placed in a position that is accessible during routine use.

Components/Service parts do not require UDI's unless they are registered medical devices in their own right.

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Core Elements of the UDI System

XYZMedCompanyLabel

AIDC

DI: Device Identifier
=>Static data,
e.g. GS1 GTIN
GTIN (01)0123400100016

PI: Production Identifier
=>Dynamic data,
e.g. lot#, serial#, expiry date
SN (21)73667

Label

Databases

Static Data Elements
• DI = primary access key
• Issuing Agency
• DUNS#
• +~30 more (mandatory)/ +~30 facultative
check FDA regulations & IMDRF Guideline

HL7 SPL
(XML derivate)
manually/
avertomated

2015
0123

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UDI-Timelines (FDA)

**All Classes**
- Request exception or apply for alternative
- Adjust date format
- Implantables: DPM

**Immediately upon publication**
- DPM – Direct Part Marking
- UDID - UDI Data Base

**Time**
- +1yr (SEP 2014)
- +2yr (SEP 2015)
- +3yr (SEP 2016)
- +5yr (SEP 2018)
- +7yr (SEP 2020)

**Class III**
- UDI on label and package; Data in UDID
- DPM if 1) used >1x and sterilized before use 2) stand-alone SW

**Class II & I – Life-supporting, life-sustaining devices**
- UDI on label and package; Data in UDID
- DPM if 1) used >1x and sterilized before use 2) stand-alone SW

**Class I & devices that have not been classified into class I, class II, or class III**
- UDI on label and package; Data in GUDID
- DPM if 1) used >1x and sterilized before use 2) stand-alone SW
Challenges in UDI Implementation for Manufacturers

- High complexity
  - Heterogeneity of upcoming UDI regulations?
  - Risk classes in portfolio elements?
  - Existence of OEM business in/out?
  - Availability of mandatory data elements?
  - Regional distribution of customers & service?
  - Regional distribution of manufacturing?
  - Regional Warehousing and distribution?

- Low complexity
  - Few portfolio elements
  - Many portfolio elements

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Bodo Winkler / Siemens H QT PMO UDI
Process Impact Assessment

Development (All new & Maintenance) > Manufacturing & Production > Logistics > After Sales

UDI Data Elements
- Device Identifier
- Complete UDI Data Set?
- UDID Interface

Device History File/Engineering History File, Device Master Record & Device History Record

Internal IT Systems (esp. Material Master Data)

UDI Level Product
- Product Versions
- Maintenance Versioning

FCA’s
- Re-manufact.
- Options & Upgrade

Options & Upgrade
- Internal Guideline Fit

UDI’s
- Product Reg.
- Product Label
- AIDC Scanning
- Package Label
- Service Logistics

Issuing Agency(ies)
- Complete UDI Data Set?
- UDID Interface

GUDID

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Keep it simple: One common UDI Standard

One Common UDI

One Data Format
One AIDC Standard
One Data Pool
One GUDID Channel
UDI Project Workstreams

- **Labeling**
  - Project Management
  - DI- Standard
  - AIDC Standard
  - Date Format
  - Label Production

- **Data Repository & Transmission**
  - UDID(s)
  - Data Elements

- **‘Special’ Business Models**
  - OEM in & out
  - Service/Refurb
  - Information

- **Information Technology**
  - Information Privacy

**Project Set-up, government affairs, regulatory guidance**
- corporate governance, implementation control

**GS1 GTIN, HBICC**

**1D stacked Barcode, GS1 2D-Data Matrix, RFID?**

**CCYYMMDD**

**Label printers & scanners, design adaptions**

**Regulators side, centralization/standardization**

**Data Elements, Data Pool, Data Transmission & UDI in Regulatory Documentation along core processes**

**OEM in & out**

**Customer Services, Refurbishing Business**

**Any IT related aspects of UDI**
Contact Information

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UDI Glossary & Acronyms

- UDI – Unique Device Identifier
- DI – Device Identifier, e.g. GTIN, HBICC…
- PI – Production Identifier, e.g. serial#, lot#…
- HIBC - Health Industry Bar Code
- GTIN – Global Trade Item Number
- GLN – Global Location Number
- AIDC – Automatic Identification and Data Capture, e.g. 2D Data Matrix
- DPM – Direct Part Marking, e.g. laser, etch, engrave
- (G)UDIDs – (Global) UDI Data Base(s) with mandatory & facultative data elements
- Sellable Unit – Units intended to be sold, down to the lowest available level
- Unit of Use – Unit as applied by end user; 1 lancet; 1 test mixed from different bottles
- Configurable Medical Device - Group of Configurations represented by common DI
- Risk-based Approach – Start with highest Risk Class
- IMDRF – International Medical Device Regulators Forum, formerly GHTF
- EHR – Electronic Health Record
- ...
Legal Disclaimer

The information contained in this presentation is based on the FDA draft UDI regulations of July 2012, the EU Commission UDI Harmonised Framework of April 2013 and the IMDRF (formerly GHTF) UDI Guidance document published September 2011.

It is not intended to be used as a UDI implementation guide but only as a general information on what might be practical considerations when implementing UDI.

The reader must take the responsibility for the correct interpretation of the published final legislation, application and implementation of UDI in their own organisation.

Please note that some information in this document might become obsolete after the publication of the final legislation, Siemens AG can accept no responsibility for the validity of the information after the final legislation is published.
FDA Unique Device Identification (UDI)……… a Global Opportunity

Jackie Rae Elkin
Medtronic, Inc. Global Regulatory Affairs
Maximizing the UDI Investment

A strategic approach is necessary (vs. project) for an effective implementation

Consider holistic view of how this information will be used externally, and how industry can capitalize on the investment internally

- Supply Chain Efficiency
- Clinical Use Data Capture
- Regulatory Compliance
- Regulatory Master Data Foundation
Regulatory Benefits

- Enables healthcare providers to auto-capture device information consistently and accurately in systems and electronic medical records
- Provides for more efficiency, accuracy and automation of capturing product information in the global supply chain, i.e., traceability
- Provides better visibility of device supply and movement through the healthcare supply chain to the patient
- Provides better visibility to device adverse events
- Provides better global visibility to recalled devices
- Provides a better means to perform postmarket surveillance
## Global Device Identification Monitoring

<table>
<thead>
<tr>
<th>Country</th>
<th>Timeline</th>
<th>STD</th>
<th>AIDC / HRI Label Requirements</th>
<th>Data Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spain</td>
<td>2006</td>
<td>GS1</td>
<td>Device Identifier, Production Identifiers to Unit of Use Level</td>
<td>Reimbursement SAS - Department of Health Andaluz</td>
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<tr>
<td>Turkey</td>
<td>2009</td>
<td>GS1 HIBC</td>
<td>Device Identifier, Production Identifiers to Unit of Use Level</td>
<td>TITUBB: Reimbursement SGK – Social Security Institute</td>
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<td>Japan</td>
<td>2009 - Guideline</td>
<td>GS1</td>
<td>Device Identifier, Production Identifiers to Unit of Use Level</td>
<td>MEDIS: Reimbursement Ministry of Health, Labor and Welfare</td>
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<td>India</td>
<td>2012</td>
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<td>Device Identifier, Production Identifiers to Unit of Use Level</td>
<td>Procurement Ministry of Health and Family Welfare</td>
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<td>Device Identifier, Production Identifiers to Unit of Use Level</td>
<td>UDI - International Medical Device Regulators Forum (IMDRF)</td>
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“The UDI System is intended to provide a single, globally harmonized system for positive identification of medical devices”

- IMDRF UDI System for Medical Devices
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