Are you ready for UDI?

The Unique Device Identification Regulation means that the label of EVERY medical device, including all IVDs, must have a UDI.

Introduction

The United States Food and Drug Administration (FDA), the European Commission and other regulators have made patient safety a strategic priority by developing legislation for Unique Device Identification (UDI).

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

GS1 standards for UDI

The GS1 System of Standards supports all stakeholders to efficiently and effectively meet UDI requirements by enabling interoperability within an organisation, between organisations and across borders. A single standard can ultimately accelerate implementation and increase compliance to the UDI regulations.

UDI training and advice

Interested in learning more about UDI implementation? We have a range of guides and resources that can be accessed via our website www.GS1ie.org/Healthcare/UDI.

- Do you require advice and staff training in preparation for compliance with US FDA UDI requirements?
- Do you understand how to correctly implement GS1 identification numbers on your production lines?
- Are you aware of the specifications for creating and printing barcode labels?

GS1 experts are on hand to provide you with the help needed. We offer both private, company specific tailored courses on your site or optionally you can choose to participate in one of our online webinars to learn about implementing GS1 identification standards such as GTINs and barcodes.

In December 2013, GS1 was accredited as an Issuing Agency by U.S. Food and Drug Administration (FDA) for Unique Device Identification (UDI) of Medical Devices to meet new patient safety, traceability and supply chain security regulations.

GS1 has over 110 member offices and more than 2,000 employees worldwide providing UDI implementation support to users in their own language combined with an understanding of local requirements.

Connect With Us

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Overview of Unique Device Identification

Unique Device Identification in GS1 terms

<table>
<thead>
<tr>
<th>UDI</th>
<th>Unique Device Identification</th>
</tr>
</thead>
<tbody>
<tr>
<td>DI</td>
<td>Device Identifier (DI)</td>
</tr>
<tr>
<td>PI</td>
<td>Production Identifier (PI)</td>
</tr>
</tbody>
</table>

GS1 Standards

<table>
<thead>
<tr>
<th>GTIN</th>
<th>Global Trade Item Number</th>
</tr>
</thead>
</table>

AI

<table>
<thead>
<tr>
<th>Application Identifier (AI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiration Date AI(17) - e.g. 141120</td>
</tr>
<tr>
<td>Lot/Batch AI(10) - e.g. 1234AB</td>
</tr>
<tr>
<td>Serial Number AI(21) - e.g. 12345XYZ</td>
</tr>
</tbody>
</table>

DI + PI = UDI

GUDID (Global UDI Database)

Data Elements linked to the DI (Device Identifier) element

GTIN or GTIN + AI(s) = UDI

GS1 Certified Datapool

Attributes (product data) mapped to each GUDID data element

The Unique Identifier

<table>
<thead>
<tr>
<th>UDI</th>
</tr>
</thead>
<tbody>
<tr>
<td>DI (Device Identifier) Static Data</td>
</tr>
<tr>
<td>PI (Product Identifier) Dynamic Data</td>
</tr>
</tbody>
</table>

The Barcode

<table>
<thead>
<tr>
<th>AIDC</th>
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</thead>
<tbody>
<tr>
<td>Machine Readable Data Carrier</td>
</tr>
<tr>
<td>Linear barcode</td>
</tr>
<tr>
<td>GS1 DataMatrix</td>
</tr>
<tr>
<td>RFID</td>
</tr>
</tbody>
</table>

Product Data

<table>
<thead>
<tr>
<th>GUDID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Static Data Elements only</td>
</tr>
<tr>
<td>Primary Keys</td>
</tr>
<tr>
<td>DI/GTIN</td>
</tr>
</tbody>
</table>

Examples of some of the data required: (See FDA website for full list.)

- Manufacturer Name
- Address
- Brand Name
- Packaging Hierarchy
- Nomenclature + Term
- Device Model or Version
- Reference Number
- Clinical Size
- ... etc.

COMMON INDUSTRIES PRACTICES

WHEN THE UDI (DI) IS A GTIN

- GTIN encoded in an EAN 13 barcode
- GTIN encoded in a GS1-128 barcode
- GTIN encoded in a GS1 DataMatrix

WHEN UDI HAS DYNAMIC DATA

- GTIN with Lot Number encoded in a GS1-128 barcode
- GTIN with Batch, Expiry and Serial Number encoded in a GS1 DataMatrix
- GTIN encoded in an EAN 13 barcode
- GTIN encoded in a GS1-128 barcode
- GTIN encoded in a GS1 DataMatrix

US FDA REQUIREMENTS FOR PRODUCT DATA

- Manufacturer/Supplier
- Web based tool
- Bulk upload (peer to peer)
- GS1 Certified Datapool (NPC)
- FDA Global UDI Database
- GUDID
- EU UDI Database (Eudamed)
- Other UDI Databases
- Irish Healthcare Providers
- Other catalogues (eg: NHS)
- Key Benefit: Information uploaded once to the NPC can be shared to many locations (FDA, EU, Healthcare providers).

There are different options for registering data in the US FDA Global UDI Database (GUDID).

GS1 certified data pools (called the NPC in Ireland) can register data on behalf of the manufacturers using the HL7 Structured Product Labeling (SPL) standard.

Note: It is expected that the EU requirements for UDI will be similar to those of the FDA with a compliance date of 2017 (phased approach based on risk class of medical device).