GS1 Ireland Healthcare User Group (HUG) Information Day

The impact of the US and EU UDI Regulation from a Manufacturing/Distributor perspective

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What we do

Pharmaceuticals

- Manufacture
- Contract Manufacturers
- Distributor

Medical Devices

- Logistics Provider
- Managed Services Provider

3rd party brand owners

- Own brand/licence products

Hospitals

- Pharma retailers and wholesalers
- Primary Care
UDI for USA
3 years after publication of the final rule (September 24, 2016)

<table>
<thead>
<tr>
<th>Section</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class III devices</td>
<td>Class III devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.</td>
</tr>
<tr>
<td>Class II devices</td>
<td>The labels and packages of class II medical devices must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. Class II stand-alone software must provide its UDI as required by § 801.50(b).</td>
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<tr>
<td>Class II devices</td>
<td>Data for class II devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.</td>
</tr>
</tbody>
</table>
UDI Barcode

GS1 Code-128

2D Data matrix

(01) 05060358122101 (17) 210331 (10) 1234
GTIN

- Member of GS1
- Entitled to 1000 numbers in our database
- 13 digits
These barcodes will comprise a Device Identifier (GTIN number) and the Product identifiers (expiry date and lot number), which will also be in human readable format.

This is an example of the human readable data from the barcodes:
Packaging levels

- We have created different GTIN numbers for different packaging levels
- Below example shows a single unit of EMP70ECO and its GTIN in a 20 pack

<table>
<thead>
<tr>
<th>GTIN</th>
<th>Description</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>5060358121616</td>
<td>EMP70ECO-1</td>
<td>25/08/2016</td>
<td>13:50:02</td>
</tr>
<tr>
<td>5060358120831</td>
<td>EMP70ECO-20</td>
<td>18/04/2016</td>
<td>13:59:50</td>
</tr>
</tbody>
</table>
Packaging levels

Each different packaging configuration must be assigned a different Global Trade Item Number (GTIN)

- **SAME GTIN**
  - Single unit of EMP180Eco
  - 5 unit pack (Standard box)
  - 10 unit pack (Economy pack)

- **DIFFERENT GTIN**
  - Each pack has a different GTIN

GTINs:
- 5060358121739
- 5060358120179
- 5060358120879
Espiner Label

Espiner Tissue Retrieval System
Master E-Sac
Trocar: 10mm Vol: 200ml

REF: EMP100WG-6
LOT: 1114

Distributor: Espiner Medical
Yeo Bank 3
Kern Road
Clevedon
BS21 6TH

05/16

QR Code links to www.espinermedical.com

GS1 Code-128 detailing single unit GTIN, expiry date & Lot

2D Data Matrix detailing single unit GTIN, expiry date & Lot

GS1 Code-128 & 2D Data matrix detailing GTIN for pack configuration, expiry date & Lot
Final step - GUDID

- Create and manage all DI numbers (GTIN part of UDI)
- Allows you to put in packaging DI as well as single DI
- Labeller account and Management accounts