Benefits of Data Standardization

- Increased cost efficiencies by reducing the need to maintain duplicate information across multiple databases
- Common data definitions and standardized robust data for all BARD products
- Improved clarity of product information that is disseminated to and used by customers
- Facilitates unique identification of products used in clinical settings, allowing for improved analysis of product outcomes

FDA UDI REQUIREMENT

In 2007, Congress passed a law requiring that all medical devices sold in the U.S. would need a Unique Device Identifier (UDI) in which the FDA provided guidance on the application of required UDI components. BARD has chosen the GS1 Standards, which use the Global Trade Identification Number (GTIN) as the UDI.

COMPONENTS OF UDI

<table>
<thead>
<tr>
<th>FDA Requirement</th>
<th>UDI:</th>
<th>UDI Attributes:</th>
<th>UDI Labeling:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>A unique identifier must be assigned to every medical device sold in the U.S. at every level of packaging.</td>
<td>The FDA defined product attributes related to UDI. This data must be submitted to the FDA for all products and all levels of packaging.</td>
<td>The FDA requires that all products be labeled with the UDI number, expiration date and serial number (where applicable) in both human readable and barcode formats.</td>
</tr>
<tr>
<td><strong>BARD Status</strong></td>
<td><strong>BARD has assigned a UDI for all medical devices sold in the U.S.</strong></td>
<td><strong>BARD is completing the collection of all required UDI attributes. Similar data is also available in the GS1 Global Data Synchronization Network (GDSN) according to the timeline below.</strong></td>
<td><strong>BARD is adding a UDI compliant barcode to all U.S. medical devices at all levels of packaging according to the timeline below.</strong></td>
</tr>
</tbody>
</table>

IMPLEMENTATION TIMELINE

BARD is in the process of applying GS1 (GTIN) barcodes on all products sold in the U.S. down to the unit of use according to the timeline outlined below. BARD is using the GS1 Code 128 format.

BARCODE FORMAT

The GS1 (GTIN) barcode is made up of a BARD specific Company Prefix or GLN (seven digits) combined with the assignment of a non-intelligent 5 character number. The combination of these two pieces creates a unique number. BARD uses a GTIN-14 format.

<table>
<thead>
<tr>
<th>Packaging Level Indicator</th>
<th>Check Sum Digit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leading Indicator Digit</td>
<td>GS1 Company Prefix</td>
</tr>
<tr>
<td>GS1 Company Prefix</td>
<td>Item Reference</td>
</tr>
<tr>
<td>Item Reference</td>
<td>Check Digit</td>
</tr>
</tbody>
</table>

NOTE: BARD is ahead of the FDA schedule towards meeting these compliance dates
UDI DATA STANDARDS

FREQUENTLY ASKED QUESTIONS

What is a UDI vs. a GTIN?
A UDI is a unique identifier that the FDA requires to be assigned to every medical device sold in the U.S. A GTIN is the standard that BARD and most manufacturers have chosen as the UDI to comply with FDA regulations.

Where will GTINs be used?
GTINs will be used on product packaging labels, invoices, packing slips, other Electronic Data Interchange (EDI) transactions and various business documents and reports.

What are the components of GTIN implementation?
1. Assignment of a unique device number (UDI/GTIN) for every BARD medical device sold in the U.S.
2. Collection, posting, and maintenance of certain required product attributes for all medical devices sold in the U.S.
3. Application of GTIN company bar codes on all products down to the unit of measure.

Do I have to use GTINs to order products from BARD?
No. BARD products do not need to be ordered with a GTIN. However, BARD does have the ability to accept GTINs as product identifiers on all EDI transactions.

What are the GS1 Standards?
GS1 standards are the most widely used supply chain systems in the world, spanning many industries. They drive supply chain efficiency, traceability, and accuracy. Examples of GS1 supply chain applications include Global Trade Item Numbers (GTIN), Global Location Numbers (GLN), and the Global Data Synchronization Network (GDSN). To learn more about GS1 Healthcare, please visit: www.gs1.org/healthcare.

What is GDSN?
The GDSN (Global Data Synchronization Network) is a cloud based repository of pre-defined product data (attributes) as defined by GS1.

How do you access the GDSN Data?
Contact BARD at UDI.Info@crbard.com and we will walk you through the process.

GLOSSARY OF TERMS

UDI (Unique Device Identifier)
A UDI is a unique numeric or alphanumeric code required by the FDA for all medical devices sold in the U.S. This identifier consists of two parts: a device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and a production identifier (PI), a conditional, variable portion of a UDI.

GTINs (Global Trade Item Numbers)
GTINs are unique, global product identification numbers. GTINs are located on product packaging. They identify the manufacturer, the product, and the packaging level. BARD uses a 14-digit GTIN.

GS1
GS1 is an international, not-for-profit association that creates and implements standards to bring efficiency and visibility to supply chains across a variety of industries.

GLNs (Global Location Numbers)
GLNs are unique, 13-digit global numbers that identify physical locations and legal entities of all trading partners.

GDSN (Global Data Synchronization Network)
The GDSN is a subscription-based warehouse of certified data that enables subscribers to access and share information, including GLNs and GTINs.

GUDID (Global Unique Device Identification Database)
The GUDID is a database created and managed by the FDA to store and track specified attributes for all medical devices sold in the U.S.