

C. R. Bard, Inc.
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June 20, 2014

Dear Valued Customer:

The Food and Drug Administration (FDA) released a final rule in September 2013 requiring that medical devices distributed in the United States carry a Unique Device Identifier, or UDI. The rule makes it possible to rapidly and definitively identify a device and key attributes that affect its safe and effective use.

The UDI is required to be in both human readable and machine readable form (e.g.: barcode) on all levels of packaging. Device manufacturers must follow a prescribed schedule over the next several years to bring all affected products into compliance.

Key items you should be aware of:

Effective July 1, 2014,

- **BARD has completed assignment of GS1 Global Trade Identification Numbers (GTINs) to all products sold in the U.S.**
- **GTIN information for BARD devices and a nominal set of product attributes will be available through the Global Data Synchronization Network (GDSN) database.**
- **BARD products can be ordered using GTINs and Global Locator Numbers (GLNs).**

BARD will be transitioning to the use of GS1 formatted bar codes for all products sold in the U.S. on a rollout basis beginning September 24, 2014 and continuing through September 2018. **See attached schedule.**

Ordering BARD Products Using GTINs & GLNs

Starting July 1, 2014, BARD will be able to accept electronic orders that use the GTIN to identify the product, and we will return the GTIN information on the order acknowledgement, invoice, and advance ship notice.

Initially, you will need to send BOTH the BARD vendor catalog number AND GTIN on the Purchase Order (850).

Product Labeling Timeline

The transition to GTINs and bar codes will begin in September 2014 and continue in phases with completion targeted by the end of 2018.

BARD will be completing the label changes by FDA designated product class:

- Class III first by September 24, 2014
- Class II products (Life sustaining, life supporting products) by September 24, 2015
- Remainder of the Class II products by September 24, 2016
- Class 1– by September 24, 2018.

See attached schedule.

As these label changes are complete, BARD will also publish all required product attribute data to the FDA Government Unique Device Identifier Database (GUDID).

BARD will be providing more detailed communications as we move forward with more of our UDI implementation online at http://www.crbard.com/About_Bard/Data_Standards.html.

Regards,



Rich Spano
UDI Project Director
C. R. Bard, Inc.

P.S. Please share this communication with the appropriate individuals in your organization. For the latest information on BARD's UDI implementation visit http://www.crbard.com/About_Bard/Data_Standards.html. Please direct all inquiries to UDI.Info@crbard.com.