Johnson & Johnson SUPPLY CHAIN

430 US Highway 22 E
Bridgewater, NJ 08807
United States of America

August 11, 2016

Dear Valued Customer,

The Johnson & Johnson Family of Companies are focused on ensuring the integrity and safety of our supply chain. We embrace product identification and traceability because of its benefits to industry, our customers and to patients.

In late 2013, the U.S. Food and Drug Administration (FDA) released a final rule requiring manufacturers to uniquely identify medical devices. According to the FDA, this rule, which is called Unique Device Identification or UDI, requires uniform product labeling of medical devices and the submission of data elements describing each device to an FDA created database called the Global Unique Device Identification Database (GUDID).

The Johnson & Johnson Family of Companies are complying with the UDI mandate. We have established a UDI program focused on meeting the key implementation milestones set by the FDA and have selected the GS1 Global Trade Identification Number (GTIN) as our standard device identifier (DI).

We submitted the required Class III device records to the GUDID in September, 2014 and in September, 2015 successfully met the compliance date for "Implantable/Life Sustaining/Life Supporting" devices as well. The FDA has granted extensions for specific Class III devices, including contact and intraocular lenses and we intend to meet these compliance dates when announced. We have begun to submit records to the FDA's GUDID to meet the September 24, 2016 compliance dates for Class II devices.

We realize that you may have more specific questions, so we've prepared a selection of Frequently Asked Questions (FAQs) which follow. However, if you have other questions beyond these, please forward your questions to the J&J UDI email address JNJUDIFAQ@its.jnj.com.

Sincerely,

Mike Rose

Vice President, Supply Chain Visibility
Johnson & Johnson Supply Chain
Johnson & Johnson Services, Inc.

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Frequently Asked Questions

1. Which Johnson & Johnson Family of Companies are involved in UDI Compliance?

All Johnson & Johnson Family of Companies with UDI-eligible products either have already complied or are actively working towards UDI compliance by the required dates. This includes the Johnson & Johnson Medical Device companies as well as Janssen Diagnostics and the Johnson & Johnson Consumer companies.

2. What is Unique Device Identification (UDI) and how does it impact healthcare providers?

According to the U.S. Food and Drug Administration (FDA) ruling, UDI is a system to mark and identify medical devices through distribution and use within the healthcare supply chain. It creates a common vocabulary for reporting and it enhances electronic tracking capabilities.

A UDI is a unique numeric or alphanumeric code that consists of two parts: a device identifier (DI) that identifies the labeler and the specific version or model of a device, and a production identifier (PI), that identifies lot, batch and serial number. The UDI rule also specifies that dates on medical device labels conform to a standard format of YYYY-MM-DD.

The UDI rule requires the submission of specific device "data elements" to the FDA created database called the Global Unique Device Identification Database (GUDID). The FDA has created a specific timetable by which medical devices must comply (see Q4). Products that do not meet their UDI compliance dates cannot be distributed in the U.S.

With the UDI system in place, healthcare providers will now have the ability to more accurately identify medical devices that they receive, dispense and record in patient records.

3. How can I obtain more information about the UDI rule?

The U.S. FDA website (www.FDA.gov) has information that explains the UDI rule, the GUDID data elements and other relevant information. The following link is to the FDA's UDI website:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

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The FDA published a set of FAQs that may also be helpful.

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM410439.pdf

4. What are key FDA regulatory milestones for UDI?

The U.S. FDA has established a specific timetable by which medical devices must be compliant. Class III devices were the first group of devices that had to comply, followed by Class II and Class I. If these dates are not met, the product cannot be distributed in the U.S.

To view the FDA's table of compliance dates, click on this link.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm#compliancedates

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5. **Which classes of medical devices does the Johnson & Johnson Family of Companies produce?**

We produce medical devices in all of the U.S. FDA device classes. Our Consumer and Pharmaceutical companies also sell products that are classified as medical devices by the FDA.

6. **What is the standard for device identification for the Johnson & Johnson Family of Companies?**

Our standard for device identification is GS1. The GS1 GTIN or Global Trade Item Number is our device identifier (DI).

7. **How can customers obtain additional "identification" data for UDI-eligible products marketed by the Johnson & Johnson Family of Companies?**

We recognize the value that results when our customers use our product data in their systems and processes. We are committed to ensuring accurate product data to our customers through the GS1 Global Data Synchronization Network (GDSN®.) To inquire about using GDSN® to obtain relevant product data, please contact us through GDSN_External_Users_@ITS.JNJ.Com.

Another option to access product-specific data is to go directly to the FDA's publically accessible database at AccessGUDID. Here you will find product data for all UDI compliant products that our companies have submitted to date to the FDA's Global UDI database. Use the Basic Search capability to search by any device attribute, such as: Device Identifier (DI), Company Name, Device Brand Name, Device Common Name or Device Version or Model.

8. **What will change on the product labels as a result of UDI?**

Our product labels will carry GS1 GTINs for the device identifier (DI) and the appropriate application identifiers for the production identifier (PI). If the product label carries an expiration or manufacturing date, then this date will be expressed in the format: YYYY-MM-DD to comply with the UDI rule.

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9. As a customer, what changes do I need to make as a result of UDI?

Universal adoption of UDI will allow healthcare providers to use UDI data in their procurement systems, inventory management systems, electronic health record systems and implant registries. These systems may need to be modified to accept certain UDI fields such as the 14-digit GTIN device identifier (DI), and new date format (YYYY- MM-DD).

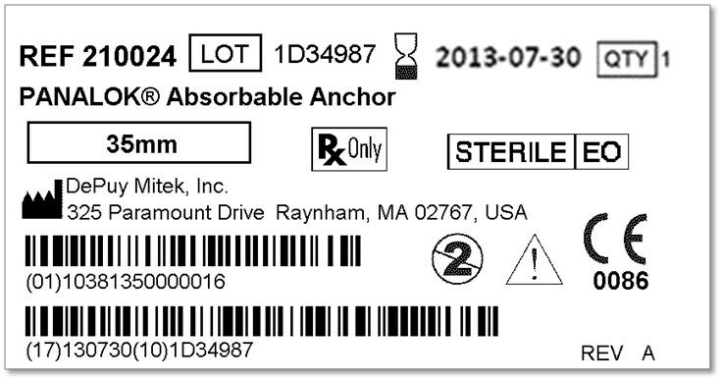
10. Will product numbers change with UDI labeling?

No. We will continue to display model numbers and/or catalog numbers on product labels.

11. Will UDI drive any changes with the barcodes on product labels?

The U.S. FDA stated in the final UDI rule: "FDA does not require the use of specific forms of AIDC or specific AIDC technologies." The Johnson & Johnson Family of Companies will select the GS1 bar code symbol appropriate to the size of the package and the scanning environment (for instance, bedside scanning versus scanning in a warehouse). 2D Datamatrix symbols may be used on small packages. Larger packages may use GS1-128 linear bar codes.

GS1 128 Linear Bar Codes



GS1 2D Datamatrix

12. When a customer places an order, will anything change?

No. Customers can continue to use product catalog numbers to place orders, and can also use the GTIN to order products.

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13. Will the invoice or packing slip look any different with UDI?

No. The look of the invoice and packing slip will remain the same.

14. When will customers receive UDI compliant product labeling from the Johnson & Johnson Family of Companies?

The Johnson & Johnson Family of Companies is actively updating labels of UDI-eligible products to meet the compliance deadlines set by the U.S. FDA. Customers are already receiving some devices with UDI compliant product labeling, and we will have 100% UDI compliant products once finished goods inventory is depleted according to the FDA's rule:

> *"UDI requirements apply to devices placed into commercial distribution after the compliance date that applies to the device.* ***A finished device manufactured and labeled prior to its compliance date and held in inventory is exempted from UDI requirements for three years after the compliance date.*** *This exception applies to both products held in inventory by the labeler and those consigned to a hospital or other potential purchaser and held in inventory, but not yet purchased, by the potential purchaser. This exception applies to all UDI requirements."*

The Johnson & Johnson Family of Companies will follow the FDA's ruling for compliance of finished devices in inventory for our products which sell slowly or have a long shelf life. These devices may be sold without UDI compliant labels during a three year period after the product's compliance date.