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Unique Device Identification (UDI) Regulations and GS1[R] Standards

Frequently Asked Questions

Why is the Food and Drug Administration (FDA) requiring the UDI initiative?

The FDA issued a 'final rule' to establish a system to adequately identify medical devices through distribution and use. This rule requires the label of medical devices to include a unique device identifier (UDI), except where the rule provides for an exception or alternative placement.

Under the UDI system, the health care community and the public will be able to identify a device through a UDI that will appear on the label and package of a device. The UDI system will make it possible to rapidly and definitively identify a device and key attributes that affect its safe and effective use, and will subsequently facilitate a reduction in medical errors that result from misidentification of a device or confusion concerning its appropriate use.

Additionally, the UDI system will also facilitate healthcare product data synchronization and accurate reporting of adverse events by making it easier to identify the device prior to submitting a report. Synchronizing healthcare product data globally allows the healthcare industry to know when and where products are produced and to manage recall and adverse event reporting to a global standard.

Why GS1?

Zimmer has elected to utilize GS1 standards in order to meet our business and customer supply chain requirements. GS1 standards also fulfill requirements for the new FDA UDI (Unique Device Identifier) rule.

What are GS1, GUDID, GDSN[R], GLN and GTIN?

GS1: A Global Standards Organization responsible for establishing uniform supply chain protocols for company and product identification facilitating e-commerce through barcoding and data synchronization.

GUDID: Global Unique Device Identification Database – Publically searchable database administered by the FDA that will serve as a reference catalog for every medical device with an identifier.

GDSN: Global Data Synchronization Network - GS1 endorsed global database to maintain key descriptive elements for parts assigned GTIN numbers.

GTIN: Global Trade Identification Number - GS1 endorsed method for uniquely identifying a part at its various saleable units.

GLN: Global Location Number - GS1 endorsed method for identifying a company in e-commerce transaction.

When does Zimmer need to be compliant with UDI requirements and have evidence to support compliance during an FDA audit?

Class III devices – 12 months after publication of final rule – September 24, 2014

- Direct part marking due September 24, 2016

Implants & life sustaining/supporting devices – 24 months after publication of final rule – September 24, 2015

- Direct part marking due September 24, 2016, if applicable.
- For devices delivered non-sterile in sets that are sterilized by the hospital before use, providing UDI information to the point of final use is due September 24, 2016 (per FDA communication on 11/19/2014 entitled, "Dear Non-sterile Ortho Set Labelers 11-18-2014 FINAL.pdf").

Class II devices – 36 months after publication of final rule – September 24, 2016

- Direct part marking due September 24, 2018

Class I devices – 60 months after publication of final rule – September 24, 2018

- Direct part marking due September 24, 2020

Existing Inventory – The FDA provides a period of three (3) years for devices that have been manufactured and labeled prior to the compliance date that applies to that device.

What happens with products already produced and distributed once the UDI rule is in place? Would there be a need to re-label the products?

Devices distributed in interstate commerce prior to their compliance dates and held for sale by potential purchasers are not under the control of the manufacturer. These devices exceed the scope of the UDI final rule.

What is Direct Part Mark (DPM) and what products require this?

A Direct Part Mark is a UDI put directly on the device. It is used on devices that are intended to be used more than once and reprocessed between or before each use.

Why GHX?

GHX does business electronically through their trading exchange with 4,100 healthcare providers and 400 manufacturer divisions in North America, the largest community in the healthcare industry. This community collectively has cut more than $5.3 billion from the cost of healthcare since 2010 and is on track to cut even more.

How do customers access the data in the GDSN?

1) Establish a GDSN trading partner relationship with a GS1 certified GDSN data pool provider.

2) Submit a subscription request using GLN (0885836000000)

3) Email the provider GLN to zimmerstandards@zimmer.com to ensure the subscription request is processed as quickly as possible. Data will be returned via an xml format for each product to accept or reject prior to the data going into the MMIS system.

When a customer places an order (paper or EDI), will anything change?

No change at this time. Zimmer will make available the use of GTIN numbers in EDI transactions in 2015.

Will the GTIN number be on customer pricing documents? If so, when?

GTIN's will be available on all customer pricing documents as they become available for each product classification.

Visit zimmer.com/UDI for timeline details.

Can a customer send a GLN on a paper or EDI purchase order?

Yes, but the GLN needs to be registered with GHX or the EDI PO will fail.

How do I obtain a cross reference between the current Zimmer part number and the GTIN number?

A cross reference of the GTIN number to Zimmer part number will be available, in an excel format, located on zimmer.com/UDI. Otherwise, the list must be obtained through a GDSN service provider.

Why are there two bar codes on the product? Which one should I tell the customer to scan?

In the global healthcare industry, there is a movement toward the use of both GS1-128 and GS1 Data Matrix as a best practice. The GS1-128 can be scanned using linear barcode scanners while the GS1 Data Matrix can be scanned using a camera or image scanner as long as the GS1 General Specifications are followed.

The vast majority of Zimmer products will use the GS1 Data Matrix for the UDI information. The linear barcode that was previously on the package label will remain in place for internal company usage. There may be deviations from this arrangement in situations where Zimmer distributes products from a third party manufacturer. In those instances the original manufacturer is often considered the "labeler" by the FDA and must meet the UDI rule independent of Zimmer's involvement.

Is there an official customer letter that is being used to communicate Zimmer's commitment to the FDA UDI/initiative?

Yes, there is a letter that the ZUDI (Zimmer Unique Device Identification) and Sales Operations team is using as a formal response regarding Zimmer's position on UDI implementation, which is accessible for download on Zimmer.com/UDI.

Where can I find additional information?

GHX Blog: www.thehealthcarehub.com

Medical Device Supply Chain Council: www.mdiscc.org

FDA Medical Device/UDI website: www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

GS1 website: www.GS1US.org/Healthcare

Zimmer.com

- Project Timeline
- Item master cross reference to GTIN
- Labeling

- Customer Communication Letter

Who can I contact if I have questions?

If you have a question, concern or a general comment, please email us at zimmerstandards@zimmer.com.