WelchAllyn

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Global Healthcare Data Standardization & Compliance
Frequently Asked Questions

Q: What is the difference between the terms Unique Device Identification (UDI) and Global Trade Identification Number (GTIN)?
A: UDI is the acronym established by the United States Food and Drug Administration (FDA) for the Unique Device Identification Rule. The GTIN is part of the UDI. According to the FDA, a UDI consists of two parts—first, a "Device Identifier," which is globally known as the GTIN, and, second, a "Production Identifier." The "Production Identifier" can be represented by a date code, lot code or serial number.

Q: Will each manufacturer of similar product use the same GTIN, or is the GTIN different for each manufacturer?
A: GTINs are unique for each manufacturer. At Welch Allyn, for example, using GS1 standards, our GTINs are 14-digit fully-numeric strings of numbers that all start with our GS1 assigned company prefix of 00732094.

Q: How will this impact our product labeling?
A: These new standards and regulations will require changes to every existing package label and device label. To begin, all Welch Allyn items that are sold to customers have been assigned a GTIN number in SAP. We have already started a multi-year activity schedule to remediate all devices, accessories and components to include the required labeling of the GTIN (a Device Identifier) and barcodes, as well as the Production Identifier where applicable. New development projects will have these requirements included in their label specifications. Once UDI it is required by the FDA, it is anticipated that any product that has already left the manufacturer and is in the supply chain will not be required to be called back or re-labeled.

Q: How will our supply chain partners get the GTIN numbers they need for the materials we sell to them?
A: Welch Allyn GTIN numbers have already been assigned; supply chain partners may request an extract of these assignments to start loading in their supply chain system at any time. Please contact lauri.ventresca@welchallyn.com to request an extract.

Q: Will sales catalogs change and will there be cross reference to my current device numbers in the future?
A: As more partners in the medical supply chain adopt these standards, we will consider updating our sales catalogs to represent both the existing Welch Allyn re-order number and the corresponding GTIN number. By 2015, each of our supply chain partners will also have the ability to "subscribe" to an electronic database called the Global Data Synchronization Network (GDSN).The GDSN includes these

GTIN numbers in addition to multiple other attributes about each material, such as the quantity in the package, the weight and dimensions of the packaging units and other key data about the trade item.

Q: Will suppliers be required to order product using the NEW GTIN numbers and stop using the current Welch Allyn Material numbers?
A: Our partners can continue to order product by *either* the existing Welch Allyn material number or the new GTIN. Once partners have contacted us and we verify the exchange of our GTIN extract information with them, they will be able to order product by *either* the Welch Allyn Material number or the GTIN. Getting all healthcare supply chain partners to comply with these standards will be a long journey. For this reason, our order entry and shipment methods are set up to be able to recognize both numbers.

Q: When will these changes happen and how will I know?
A: The first change that people will start to see will be on our package labeling. We will start to publish the GTIN on package labeling for select products by May 2013, even though compliance by law is still a few years in the future. Our partners are going through similar transformation to their business systems to support the changes. Once our partners are ready to support the new GTIN and Global Location Numbers, we will work with them individually on request to phase in Electronic Data Interchange (EDI) exchange of these new numbers. Partners, when you are ready, please contact robert.park@welchallyn.com to discuss and share your EDI readiness plan.

Q: Why are we going through all this effort before the UDI law is signed and we are required to comply?
A: Welch Allyn is voluntarily transforming our systems, labeling and attribute data sets to comply with these standards as soon as possible. In addition to the priority of improving the safety and efficiency of patient care, we understand that customers who purchase our product have many choices of who to buy from. It is our goal to make it easiest and most cost effective for our customers to choose Welch Allyn, than any competing brand.