ZEBRA UNIQUE DEVICE
IDENTIFICATION (UDI) OFFERING

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Food and Drug Administration (FDA) rule requires most medical devices distributed in the United States to carry a unique device identifier, or UDI. This rule applies to certain combination products that contain devices and to devices licensed under the Public Health Service (PHS) Act (e.g., donor screening assays).

Under this system, all medical devices, such as cardiac stents and implanted hips, will be assigned codes corresponding to their manufacturers and model types.

HOW DOES IT WORK?

FDA DATABASE

The FDA's database is referred to as the Global Unique Device Identification Database (GUDID) and the rules requires that Medical Device manufactures UDI (unique numeric or alphanumeric code) are stored in this database prior to products going on the market.

The manufacturer is required to submit product information into Global Unique Device Identification Database (GUDID) so that users of a medical device can easily look up information about the respective device.
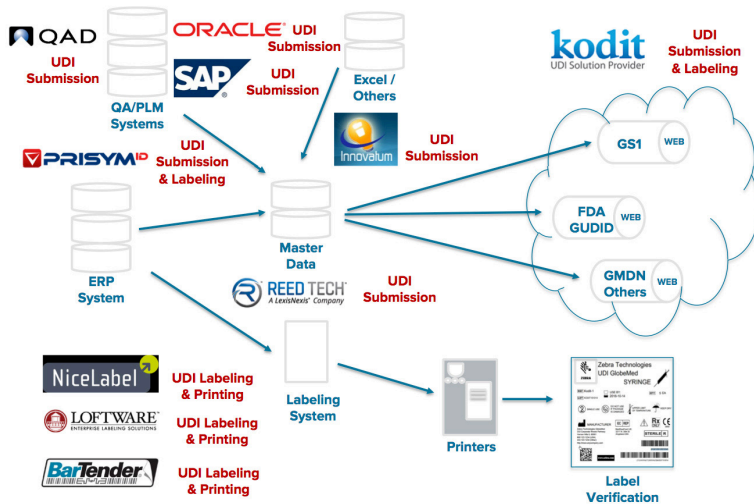
A UDI CONSISTS OF TWO PARTS:

A device identifier (DI), a mandatory, fixed portion that identifies the labeler and the specific version or model of a device, and a production identifier (PI) which is a conditional, variable portion that identifies one or more of the following when included on the label of a device.

With this in place, users of medical devices can easily look up information about the device.

UDI SOFTWARE

SOFTWARE SOLUTION PROVIDERS

UDI software providers offer on-premise or cloud base solutions. The offering may consist of master data management, GUDID data submission, ERP database connection, barcode label designs, supplies and RFID printing. The figure below shows a few of Zebra's software partners who provide solutions for UDI.

Organizations have differing data attributes, compliance timelines and business rules as how to achieve, and then maintain, compliance over time.

Gaining an understanding of these various rules can be a daunting and time consuming task for any size organization so together with our global partners, Zebra provides a detailed understanding of the steps required to both achieve, and maintain compliance, in the easiest and most cost effective method possible.

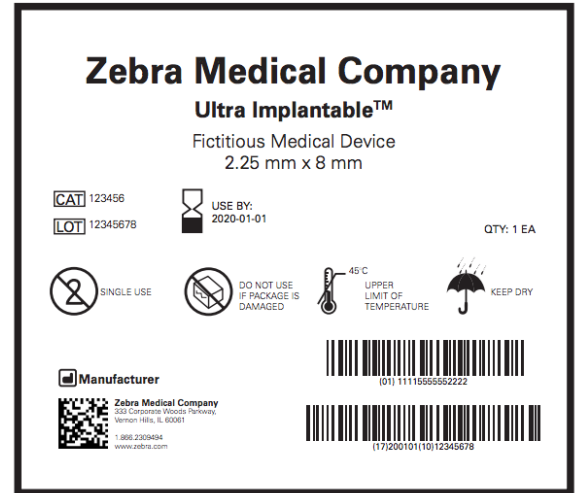# ZEBRA UNIQUE DEVICE
IDENTIFICATION (UDI) OFFERING

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LABELING FOR UDI

Medical device labels are now viewed as a critical mechanism for maintaining compliance, ensuring brand consistency, improving operational efficiency, and supporting business growth. They are the final link between your company and key stakeholders including customers, care givers, patients and regulators.

HIGH QUALITY. PRE-TESTED. RELIABLE.
GENUINE ZEBRA® SUPPLIES

Not all thermal labels are created equal. It is critical that labels you utilize are not only readable and scannable when they leave your operation, but throughout the products safe and appropriate use and disposal. Purchasing genuine Zebra supplies means you have access to a large selection of quality, pre-tested, supplies manufactured by a thermal industry expert, reducing your risk of non-compliance.

PRODUCT PACKAGING AND CARTON LABELING

LABEL MATERIALS	KEY FEATURES	STERILIZATION RESISTANCE	CHEMICAL RESISTANCE	USE WITH APPLICATOR (Y/N)
Z-Select™ 4000T	Paper label with a high-tack permanent acrylic adhesive. Temperature exposure up to 200°F.	Gamma Radiation Ethylene Oxide	Minimal resistance to moisture and chemicals.	Y

DIRECT MEDICAL DEVICE LABELING

LABEL MATERIALS	KEY FEATURES	STERILIZATION RESISTANCE	CHEMICAL RESISTANCE	USE WITH APPLICA-TOR (Y/N)	UL RECOGNITION
PolyPro™ 4000T	Matte Kimdura polypropylene label with a permanent acrylic adhesive. Offers some flexibility for labeling curved surfaces. Temperature exposure up to 250°F.	Steam Autoclave Gamma Radiation Ethylene Oxide	Excellent resistance to moisture and chemicals, such as isopropyl alcohol, bleach and additional healthcare cleaning agents.	Y	
Z-Ultimate® 4000T	Gloss polyester label with a high performance permanent acrylic adhesive. Temperature exposure up to 302°F.	Steam Autoclave Gamma Radiation Ethylene Oxide	Excellent resistance to moisture and chemicals, such as isopropyl alcohol, bleach and additional healthcare cleaning agents.	Y	UL 969 and UL/IEC 60601-1 3rd edition marking and durability rub tests when paired with 5100 resin ribbon
Z-Xtreme™ 4000T	Matte polyester label with a high performance acrylic adhesive. Temperature exposure up to 300°F.	Steam Autoclave Gamma Radiation Ethylene Oxide	Provides unparalleled resistance to moisture and harsh chemicals. Provides excellent resistance to isopropyl alcohol, bleach and additional healthcare cleaning agents.	Y	UL 969 when paired with 5095 resin ribbon

ZEBRA PRINTERS FOR UDI

Medical device labels are now viewed as a critical mechanism for maintaining compliance, ensuring brand consistency, improving operational efficiency, and supporting business growth. They are the final link between your company and key stakeholders including customers, care givers, patients and regulators.

300 & 600DPI PRINTER
Xi4™, ZT™ & G-SERIES™ PRINTER

The **Xi printers** are industrial grade printers that are built for high-volume applications and harsh environments, these label printers deliver superior print quality and reliability for UDI labeling. It boost productivity with faster print and connection speeds, and reduce downtime with early warning.

The long-proven Xi series platform is designed and built to work nonstop, all day, every day for mission-critical and 24/7 operations, every minute down means money out the window.

These qualities translate into low total cost of ownership as you comply with the FDA UDI ruling—making a smart investment for organizations with high-volume, missioncritical or specialty labeling applications.

Xi SERIES

The **Z-Series printer** is by far one of the easies printer to operate with dynamic QR codes for on-demand, web-based support. Its built in Near Field Communication (NFC) is used to launch web-pages making it easy to access Zebra's extensive knowledge base of how-to videos and product support.

Its designed to run a 2 shift operation, printing multiple label types for Manufacturing: work-in-process, product ID/serial numbers, packaging labels, receiving/putaway and UDI labeling.

The **G-Series printers** are ideal for Ideal for UDI labeling in small to light manufacturing; printing of text, graphics and 2D barcodes. Its 300 DPI version is high-resolution is available in thermal transfer (ribbon and label combination delivering outstanding quality and fast printing speeds for UDI product labeling.

Z-SERIES

G-SERIES

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ZEBRA

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