Sales Guide

ZEBRA

COMPLYING WITH FDA REGULATIONS

DO YOU HAVE CUSTOMERS WHO MANUFACTURE MEDICAL DEVICES? THEY NEED UNIQUE DEVICE IDENTIFIERS...

NO UDIS? NO US BUSINESS...

In 2013 the Food and Drug Administration announced that most medical devices would need to carry a Unique Device Identifier, or UDI. Devices were divided into three categories and the introduction of UDIs for these different classes has been taking place in stages – not just in the USA but across EMEA and the rest of the world.

UDIs are important. They tell healthcare professionals what devices are, what the model numbers are and who made them. They also provide supply chain traceability information for each specific device, including its serial number, batch number, date of manufacture and expiration date.

Medical device manufacturers worldwide need to comply with this legislation – which means they need a reliable approach to labeling.

Here at Zebra we have a comprehensive portfolio of printers, scanners, mobile computing devices and ancillary products and services – all of which can help your customers meet regulatory requirements like these.

The Zebra ZT410 and Xi4 labeling printers, for instance, provide an ideal solution to the FDA requirement – and a solution is absolutely necessary. Without one, medical device manufacturers won't be able to sell into the US market.

And you can boost your own business at the same time. It's a great new channel of opportunity...

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For Device Manufacturers:

WHAT DOES THE LEGISLATION MEAN FOR MEDICAL DEVICE MANUFACTURERS?

The FDA regulations stipulate three UDI categories for medical devices:

- **Class III devices:** able to support or sustain human life and/or to prevent impairment of human health – eg. pacemakers, automated external defibrillators
- **Class II devices:** requiring higher-than-normal checks to ensure safety and effectiveness eg. powered wheelchairs, infusion pumps
- **Class I devices:** not intended to support or sustain human life nor to prevent impairment of human health – eg. elastic bandages, examination gloves

UDI requirements are already in place for many Class III and Class II devices, and regulations covering all remaining devices will become law in the US, EMEA and the rest of world in stages between now and 2020.

Compliance for all medical device manufacturers is mandatory. If they haven't acted on it yet they're going to need to do so soon. If they don't, they won't be able to sell into the US market.

NB. This information is only a summary and is purely for your guidance. It is the responsibility of medical device manufacturers to understand the regulations, and compliance is a legal requirement. For further information you should direct your customers to the following sources of information:

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

USEFUL HINT:

If your customer is already using Zebra products, introduce them to compatible Zebra solutions. If they are not, ask about the different technologies they are currently using and whether managing products from multiple vendors is too time-consuming.

For you:

WHAT DOES THE LEGISLATION MEAN FOR YOU?

The FDA legislation requires device manufacturers to provide a UDI on every device label and on every device package.

This represents a huge opportunity for you. You'll be able to:

- **Enter new markets:** even if you already have customers who manufacture medical devices, there are many, many more of them in markets at home and abroad – and they all need to comply with the regulations
- **Upsell in existing markets:** as each new legislation stage is reached the needs of your current device manufacturer customers will grow
- **Deepen your customer relationships:** you'll be helping customers meet a real and pressing requirement with a straightforward but high-quality solution
- **Cross-sell to your installed base:** the FDA requirement broadens the range of products you can sell to your medical device manufacturer customers
- **Broaden your reach:** Zebra's wide portfolio of products and services can bring the right technology to all your client's key processes
- **Help everyone in healthcare meet regulatory standards:** with a great UDI printing process in place, your medical device manufacturer customers will pass FDA checks – and so will their healthcare sector clients
- **Sell Professional Services and other support services from Zebra and its ISVs:** if the legislation has specific implications for some of your customers, you'll be able to point them to the help they need
- **Sell more labels and supplies:** each new customer and each new device represents an opportunity to sell more consumables
- **Help your customers beat their rivals:** with a comprehensive and reliable approach in place for UDIs they'll be able to show they're protecting patients and their own reputations.
- **Enable your customers to demonstrate good corporate citizenship:** with a comprehensive and reliable approach in place for UDIs they'll be able to show they're protecting patients and their own reputations

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Key Benefits:

FOR MEDICAL DEVICE MANUFACTURERS

PEACE OF MIND	A Zebra solution means they'll be compliant now and at each new legislative stage that follows
INSIGHT AND UNDERSTANDING	Zebra knows the healthcare market and understands the impact this legislation will have
HIGH QUALITY	Zebra consistently delivers high-quality and highly reliable products and services to its customers – and with a great (TCO) Total Cost of Ownership too
COMPREHENSIVE RANGE	Zebra scanners, printers and mobile computing products are ideal for medical device UDIs. RFID label stock, product packaging and carton labels are available in sterilisation-resistant paper, polypropylene and polyester with a range of chemical resistance properties
REPUTATION	Zebra is known and respected for its integrity, innovation, and value
KNOWLEDGE	A clear UDI from Zebra provides unambiguous evidence of the device's lifetime. Great for your customer – and great for you as the supplier

USEFUL HINT:

Zebra can also offer unique IQ Color labels that enable a colour to be printed on demand in a pre-specified zone of the label. This helps medical manufacturers work smarter and highlight key information about a device for healthcare practitioners.

KEY CONVERSATION STARTERS

" Have you heard of the FDA legislation on medical device labeling? Every manufacturer needs to comply – and not just in the US, either."

" Did you know each new stage of the FDA regulations means more kinds of medical devices need to carry ID labels? It's even going to cover things like elastic bandages."

" Did you know the new FDA regulations on medical device labeling are being introduced in phases? The next stage is 2016, then 2018, then 2020 – and each time more devices and products are going to be covered."

" The FDA regulations cover all kinds of medical devices and their packaging. This means manufacturers are going to need all kinds of labels depending on the products they make, using different label materials and adhesives. Zebra has a great range of label types, and a great range of scanners, printers and mobile computing products too. We've got the whole thing covered end to end so we're bound to be able to help with a solution to meet your customers' needs."

" Do you currently sell into the US? Are you planning to? Either way, you need to know about new regulations from the FDA. Under the legislation, if medical devices don't carry detailed ID labels you won't be allowed to sell them in the USA."

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Objection Handling:

We already have label printers. These FDA rules won't change anything.

Are you sure? The legislation is pretty specific about what the UDI labels should say, and the label type and print quality are important too. Whatever printers you have are going to have to be flexible enough to deal with the rules laid down in your case. We can check whether you're going to be able to comply – and if your printers aren't up to it, we can help.

The next stage of legislation doesn't come in for a long time yet. There's no rush.

For one thing, are you sure you already comply with the current stage? And for another, this is too important an issue to leave to the last minute – especially if your case turns out not to be straightforward. We'd be happy to look into it for you, so you can see what you're going to need and when you're going to have to take action.

This is just a bit of red tape, and you're using it as a sales opportunity.

I'm afraid not. This isn't just red tape – it's the law. If you break it your organisation will be held to account. You do need to do something about it, even if that just means checking you're already compliant. Or we can do that check for you?

We already have Zebra printers, and we buy our consumables elsewhere because they're cheaper.

Print quality and label quality are always important – and with these FDA regulations they're even more so. You need to be sure the UDI labels you produce are going to be acceptable, and with Zebra consumables they will be. What's more, Zebra tests all its materials in its own printers – so yes, you'll be able to rely on the quality, but also you'll also be saving on printer wear and tear.

Good consumables are cheaper than new printers, and ours are great. Our supplies are pre-tested and high quality, and there's a huge range – from barcode labels to card printer supplies to RFID tags and more.

KEY COMPLIANCE DATES

Sept 24, 2014 Class III & licensed under PHS (Public Health Service) Act

- Labels and packages must bear a UDI

Sept 24, 2015 Class II – Implantable devices and life-supporting and life-sustaining devices and software

- Labels and packages must bear a UDI
- Devices intended to be used more than once and reprocessed before each use must a bear UDI as a permanent marking on the device itself

Sept 24, 2016 Class III Remaining devices

- Devices intended to be used more than once and reprocessed before each use must a bear UDI as a permanent marking on the device itself

Class II

- Labels and packages must bear a UDI

Sept 24, 2018 Class II

- Devices intended to be used more than once and reprocessed before each use must a bear UDI as a permanent marking on the device itself

Class I & Non Classified Devices and Software

- • Labels and packages must bear a UDI

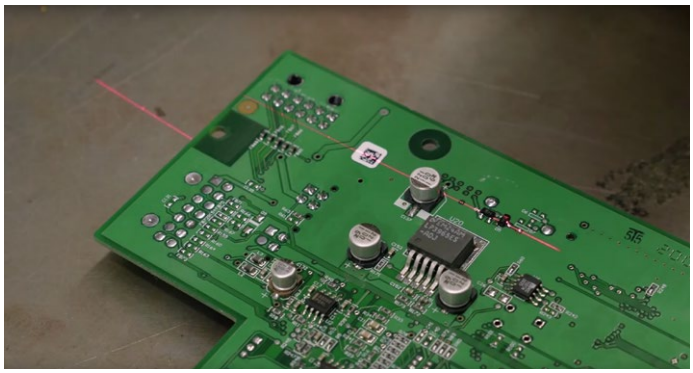
Sept 24, 2020 Class I & Non Classified Devices and Software

- Devices intended to be used more than once must a bear UDI as a permanent marking on the device itself

ZEBRA – WHY WE'RE RIGHT FOR YOU AND YOUR CUSTOMERS

Zebra has been providing products and services to the medical manufacturing market for many years. Our services team can provide support in:

- Planning and designing an appropriate strategy
- Implementing new networks, devices, and applications
- Training people so as to increase the return on your customers' investment
- Running operations on your customers' behalf so as to reduce downtime and improve value and productivity



I ♥ RULES

TURN COMPLIANCE INTO OPPORTUNITY

The FDA's UDI requirements for medical device manufacturers give you a sales great sales opportunity. Upsell and cross-sell Zebra printers, scanners, consumables and services – and enter new markets too.

FIND OUT MORE

DON'T FORGET...

ZebraCare Services

Help your customers increase printer uptime and reduce lost productivity by offering them a ZebraCare service agreement. This is a cost-effective means of planning and budgeting for annual maintenance costs, so that companies can minimise unexpected financial outlay. Customers who have ZebraCare are guaranteed trained Zebra technical support that will bring their printer back to factory specifications. Visit **www.zebra.com/services**

ZEBRA PRINTER WARRANTY

All Zebra Printers come with a 12-month warranty as standard.

ZEBRA SUPPLIES

Get the most out of your Zebra Supplies. Finding the right supplies is simple with the ZipShip online selector tool. A full range of labels and ribbons is available from stock with a minimum order of just 1 box! Visit **www.zebrazipship.com** and answer 4 simple questions to find the Supplies you need!

ZEBRA

About Zebra Technologies

Zebra (NASDAQ: ZBRA) makes businesses as smart and connected as the world we live in. Zebra tracking and visibility solutions transform the physical to digital, creating the data streams enterprises need to simplify operations, know more about their businesses, and empower their mobile workforces. For more information, visit www.zebra.com.