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Are you Ready for UDI?

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Unique Device Identification (UDI) has been recognised as a key tool in improving patient outcomes. More efficient recall procedures, reduced medical errors, increased inventory visibility and supply chain security are all enabled through UDI. Under the FDA rule, if manufacturers have not implemented UDI on a number of product categories by September 2014 they may no longer be able to supply product into the USA, with other markets expected to follow shortly with similar legislation. Fee payers and healthcare providers, such as the NHS, will not accept devices without UDI style identification.

On September 23rd 2013, The Food and Drug Administration (FDA) released a final rule requiring that most medical devices distributed in the United States carry a unique device identifier, or UDI. Potential benefits include: • Improved recall procedure and adverse event reporting
• Documentation of product/patient relationship in electronic records and registries
• Visibility of inventory – availability of devices
• Reduction of medical errors – patient's safety
• Supply chain efficiency/security
• Anti-counterfeiting

What is UDI?

A UDI is a unique numeric or alphanumeric code that consists of two parts:

1. Device identifier (DI)

Mandatory, fixed Identifies the specific version or model of a device

2. Production Identifier (PI)

Conditional, varible Identifies one more of the following:
• the lot or batch number from where a device was manufactured
• the serial number of a specific device
• the expiration date of a specific device
• the date of a specific device was manufactured
• the distinct identification code required by § 127.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

Manufacturers are responsible for creating and maintaining the uniqueness of its medical device UDI and shall not be altered.

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FDA Requirements
1. Unique Device Identification (UDI) numbers
2. UDI in human readable and bar code/RFID on the device label or on the device directly
3. Data to be submitted to the UDI Database

Classification Medical Devices
The classification is typically risk based and can vary slightly from territory to territory:
General rule:
Class III devices present a higher potential risk to the patient than Class II and so on...

- **Examples of Class III devices** that currently require a premarket notification include implantable pacemaker, pulse generators, HIV diagnostic tests, automated external defribillators, and endosseous implants, contact lenses for extended wear
- **Examples of Class II** devices include acupuncture needles, daily wear contact lenses, powered wheelchairs, infusion pumps, surgical drapes and an implantable radiofrequency transponder system for patient identification and health information
- **Examples of Class I** devices include elastic bandages, examination gloves, and hand-held surgical instruments

UDI Coding Solutions
Our CO2 D-Series lasers are ideal for carton and blister foil marking, via ablation of the paint. The range of lasers includes a power range of 10W, 30W and 60W lasers to fit all coding needs.
• Flexible, compact and easy to install
• i-Tech scan head - fastest in the market for high speed and complex coding
• 600mm lens i-Tech 15 - 40% larger mark field, ideal for wide web applications
• Robust - IP65 pro

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Our F-Series fibre lasers are ideal for metal parts marking, such as engraving, colour-change coding, stainless steel annealing.
The compact fibre version of our i-Tech range of lasers gives you utmost performance when it comes to high precision marking of your products..
• High contrast marking on various plastics
• Ideal for metal marking
No planned maintenance required - expected life of approx. 100,000 hours for high uptime.

Our G-Series thermal ink jet printers are easy to use, fast and are ideal for:
• Carton marking applications
• 21 CFR part 11 compliance
• Specially developed sector inks ensure excellent dry time, contrast and colour-fastness from manufacture to point of dispensation
• i-Tech components combine to create a flexible, reliable system, including reduced ink wastage through unnecessary cartridge changeover
• Capable of high speed serialisation at item level

V-Series thermal transfer overprinters provide
solutions for coding pouches and packaging in web
applications
• Ribbon drive reduces ribbon use by up to 60%
• Fits into most existing bracketry – easily replace
existing equipment
• New upgraded industrial design

Where larger label information needs to be printed
and applied to products or secondary packaging, the
M-Series print and apply labelling range offer flexible
solutions for full GS1 codes and multiple applicator
options, including corner wrapping of cases.
• Robust stainless steel pallet labeller
• Cost effective print head replacements

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The legal landscape

The EU Regulation 1169/2011 on food information for consumers (FIR) includes the labelling of allergens and intolerant food substances.
Labelling rules in European Directives 2003/89/EC and 2006/142/EC ensure that all consumers are given comprehensive ingredient listing information and make it easier for people with food allergies to identify foods they need to avoid.
However, following implementation of the Food Information for Consumers Regulation (EU) No. 1169/2011, allergen labelling rules will change significantly.
The new regulation, which was published in October 2011, will build on current allergen labelling provisions for prepacked foods and will introduce a new requirement for allergen information to be provided for foods sold non-packed or prepacked for direct sale. The three year transition period was given so that businesses could make the necessary changes to their processes and labelling designs in order to meet the provisions laid out in the legislation.
To address the complexity and potential confusion surrounding the numerous food labelling standards and directives introduced over the years, the European Commission's DirectorateGeneral for Consumer and Health undertook a widespread review and evaluation of all existing regulations. This led to the introduction of a new European Union directive that affects both manufacturers and retailers - The EU Regulation No. 1169/2011 on the provision of food information to consumers. Its aim is to standardise food labelling by simplifying the law, and provide greater clarity to consumers.
The regulation presents clear guidelines covering:

- How foodstuffs and beverages should be labelled, including what information is mandatory
- The presentation, style and positioning of this data
- Advertising and distance selling regulations
- The legal responsibilities of the individual stakeholders

What will change?

The key requirements of the EU Regulation 1169/2011 includes mandatory nutrition labelling, a minimum font size for this, as well as a clearer indication of allergens within the ingredients listing. This covers the provision of allergen information on all 'saleable units' for retail and online sales as well as for nonprepacked foodstuffs. These requirements will directly impact the product's primary packaging, as well as any secondary packaging where larger volumes of items are sold in multiples or in bulk to retailers as well as businesses in the catering and hospitality trade.
By the end of 2014, the transition period between the initial introduction of the EU Regulation and the Directive coming into force, will end. Food and beverage manufacturers will have a legal requirement to display compliant, mandatory information on all product packaging, including ingredient and nutritional value listings which clearly highlight the presence of certain substances or products causing allergies or intolerances within the lists.

The requirement of the Directive to highlight all food allergens on product packaging comes at a time when there is a growing public health concern surrounding the increasing incidences of food-related allergies. According to Allergy UK recent studies confirm a significant increase in the incidence of food allergies, particularly amongst children, with up to 50% diagnosed with an allergic condition. This particular labelling requirement to clearly promote the presence of allergens and intolerant food substances is therefore becoming vitally important to the consumer, as they become more aware themselves, and demand greater information when making their purchasing decisions.
Established brand manufacturers responsible for several thousand product lines will have already recognised the enormity of the task and started to address any changes to ensure compliance. This is likely to involve a redesign of their branded packaging and labelling for each of their products. Considering that DEFRA estimates in the UK the average cost of a single label change to be over £3,000, multiple changes could potentially represent a significant financial burden.
In contrast, food business operators and manufacturers of products using generic packaging in the form of plastic bags and pouches, labels, cardboard boxes and containers are unlikely to have the same resources as the well-established brand owners. But, they will still need to be compliant.

The financial implications

Penalties for non-compliance to the legal requirements set out in EU Regulation 1169/2011 are yet to be clarified, but the industry is discussing possible fines of up to £5,000 per unit. While this figure may appear relatively low as a single unit fine, when imposed across many product units, the costs could easily escalate to something that could have a detrimental impact on the financial successes of a business. The biggest threat is the potential threat to human health. There's also a high price to pay for any loss of reputation to the brand, and to the company as a trusted business operator, as well as the loss of confidence amongst consumers, all of which can have long lasting consequences.

The business process implications

The very nature of generic products is to offer the consumer value for money. Therefore, the cost of any potential changes to their overall packaging to address these mandatory labelling requirements, could result in an increase to the unit sale cost of the product. As a result, food business operators using generic packaging have a need to meet their legal obligations while keeping costs to a minimum in order to protect precious profit margins and to meet consumer expectations. This is where having the right coding and labelling technology in place, which is capable of handling the mandatory labelling requirements, can play a significant role in meeting both these needs.

Technologies to meet the new requirements
There are various coding and labelling technologies that offer producers effective and flexible ways to comply including Thermal Transfer Overprinting (TTO), Thermal Ink jet (TIJ), DOD Piezo, as well as Print and Apply (P&A) labelling solutions:

- **Thermal Transfer Overprinting (TTO**) has long been an established method for the labelling of generic primary flexible packaging, and has been extremely successful in the prepacked snacks sector, typically characterised by high volumes and low margins. In addition, with the increased demand for pre-packed snacks likely to continue, keeping control of any additional coding and labelling costs to ensure compliance, will be crucial to maintaining profit margins. TTO solutions produce superior quality codes in a range of fonts and sizes, with the capability of printing graphics and QR codes while at the same time, provide a significant reduction in downtime and coding errors to maximise output. Domino's V-Series range of TTO printers, for example, offer a unique range of **i-Tech** intelligent Technology features designed to increase overall equipment effectiveness (OEE), such as an intelligent Ribbon Drive to optimise consumable cost savings and a simple **TouchPanel** user interface with access to Domino's intuitive **QuickDesign** software platform.
- **DOD Piezo** ink jet offers the versatility to print clear, high quality product information and graphics directly onto secondary packaging such as multiple saleable packs or containers of bulk foodstuffs. Domino's Piezo offering comprises the C-Series range of outer case coders, software and ancillaries. This combination is able to deliver increased productivity and profitability while having the flexibility to meet the requirements for compliance, such as true type fonts in varying sizes, as well as clear, high resolution output.
- **Print and Apply** systems offer clear and precise labelling at high speeds on the production line and their modular composition facilitates fuss free installation, to address a range of requirements. This offers an alternative means to packaging operators to introduce generic labelling onto their production lines. The Domino modular M-Series family of Print and Apply labellers address the need for printing compliant allergen information in high contrast onto white labels. These are then automatically applied directly to the product itself, or onto the secondary or tertiary packaging.

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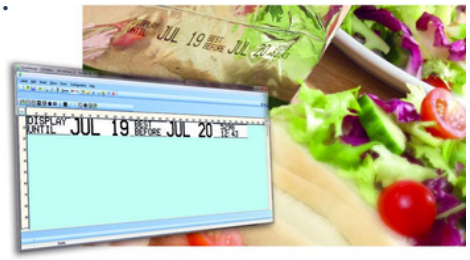
The know-how to make a difference
Within today's legislative-driven environment, the need for consistent and accurate consumer information has never been greater, with the need for timely, automated results across all coding and labelling platforms.
Domino's **QuickDesign** software suite provides a fully scalable solution, from basic message design, to advanced automation tools that use a database of ingredients to automatically search and highlight key words, such as allergens and intolerant substances. **QuickDesign** provides a platform for centralised, automated control of compliant coding throughout the production facility, from Primary packaging, through Outer Case coding to Pallet labelling applications. Furthermore, its full Unicode capability supports applications anywhere in the world, and its database connectivity and template approach minimises the need for data entry and reduces the risk of operator errors.

Compliance – the desired outcome
As the deadline to comply to the mandatory requirements of the EU Regulation 1169/2011 becomes closer, food business operators who have yet to instigate changes to their labelling and coding operations need to take action.

No food producer or food business operator wants to be caught out as the deadline approaches and face the risk of penalties, which are likely to include costly fines, if they fail to meet the new operational standards.
Knowing the exact requirements of the legislation and understanding the impact and consequences should be the first step, followed by a comprehensive audit and evaluation of current operations. Can it handle the new mandatory requirements? Will it offer automated key word recognition for highlighting allergens? Does it have the facility to print the required font and sizes? These are all relevant questions to ask when considering how to ensure generic packaging will be fully compliant.
The management of a significant amount of product information will also be crucial, so ensure the database management system can automatically extract the correct information for each print job, to keep operator intervention and associated errors to a minimum while maximising output. Finally, build in sufficient time to test solutions. It can take time to make all the necessary adjustments to manage the new labelling requirements, so by taking action ahead of the deadline, rest assured that compliance is within reach.



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