DOMINO

Are you ready for UDI?

Improved outcomes through product identification

Unique Device Identification (UDI) has been recognized 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.

Domino can help

Domino. Do more.

Why a UDI regulation?

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.

Accredited UDI Issuing Agencies

GS1 HIBCC UDI ICCBBA

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:

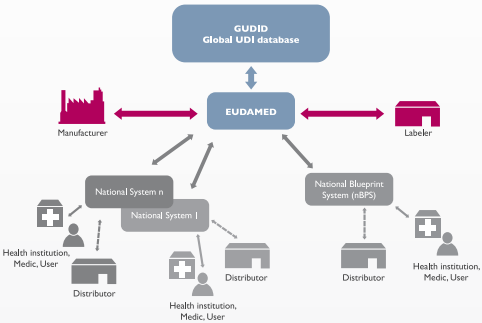
General rule:
Class III devices present a higher potential risk to the patient than Class II and so on...

- **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

EUDAMED



N.B. EUDAMED is a theoretical model and name of a potential and future European EU-wide database for medical devices to which all information should be provided

UDI coding solutions

Domino excels in producing technologies suitable for on line high speed serialisation at item level with machine readable codes.

D-Series CO2 laser

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 protection scan head and IP55 coding cabinet

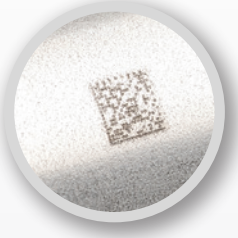
F-Series Fiber laser

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.



Want to make sure you are UDI ready? Contact us via Solutions@domino-na.com
Or tel 800.444.4512

Domino. Do more.

UDI coding solutions

G-Series Thermal ink jet printer

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 overprinting

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

M-Series print and apply labelling

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

DOMINO

Preferred partner

We are the preferred supplier to many multi-national life sciences and medical companies and major OEMs. Our equipment is completely compatible with high speed serialisation systems, and we fully understand your requirements. Our dedicated account teams are backed up by global coverage and technical support.

Service and Aftermarket

GLOBAL SALES AND SUPPORT

- Extensive network globally - ensuring effective integration and operator training combined with fastest ongoing support in over 120 countries
- All engineers trained to the industry acclaimed Domino Global Service Standard
- Dedicated team of experts to support complex installations, OEMs and key accounts

SERVICE AND WARRANTY AGREEMENTS

- Ensuring predictability of lifetime costs via widest range of service, support and warranty agreements tailored to your needs

CERTIFICATION

- Over 30 years experience of commitment to industry directives and end customer certification to meet the exacting needs of the life sciences sector

CONSUMABLES

- Fully comprehensive range of consumables to ensure optimum performance at customer site
- 24 hour online ordering of consumables via www.buydomino.com

TRAINING

- Commitment to start-up and ongoing training available locally, online or Head Office based at Domino's Training Academy

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