Taking the Stress out of the FDA's UDI Labelling Regulations

With the application of the FDA's final ruling on medical devices Unique Device Identification (UDI) system in September 2013 there are now new regulations in force which means that medical device manufacturers will be compelled to implement important labelling changes over the forthcoming years. This will involve investment in labelling and product marking accompanied by restructuring manufacturing practices and supporting IT systems. By 2018 all medical devices (Class I-III) will be required to bare identifying information which is compliant with the § 801.20 standard, and by 2020 all devices (even with previous exemptions) will be forced to comply. The higher classification devices (Class III & II) will be required to achieve this standard of new regulations much sooner, some coming into force by the end of 2014. *DoraniX integrated printing solutions has the expertise and experience to supply a full printing and labelling facility in order to take the stress out of adapting to these identification changes.*

Labelling Requirements:

In order to conform to regulatory requirements, it will become mandatory for all medical devices to exhibit a labelling system on both primary and secondary packaging which will include a 'Device Identifier' (DI) and a 'Product Identifier' (PI). The end outcome of the FDA's insistence of a UDI practice is to ensure that a barcoding system will in the near future ensure tracking and traceability of devices throughout their life cycle. This is set to ensure optimization of patient safety and enhance ease of produce recalls and safety warnings in the occurrence of Adverse Events.

The **DI** must present information about the Labeller and specific model of device.

The **PI** must include (*but not be limited to*) the following:

- Lot or batch number within which a device was manufactured
- Serial number of the specific device
- Expiry date of the specific device
- Date of manufacture
- Distinct Identification Code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based products (HCT/P) regulated as a medical device.

Due to the fact that each label for a specific device must be uniquely different this has direct implications on printing for every individual device, covering both primary and secondary packaging. This being the case, the most sensible approach would seemingly be to employ the practice of Variable Data Printing, using emerging technology to individualize labels in an organized and reliable manner.

Variable Data Printing:

Variable Data Printing (VDP) also known as Variable Information Printing (VIP) is the process whereby using digital print mechanisms, all elements of the print, including data, graphics and images may be altered automatically from one piece to the next without interfering with the printing process. It also means that data collated from databases and external filing systems may be merged into the printing process, individualizing each piece without slowing or delaying the run.

VDP has been used in recent years for direct marketing and advertising however it seems that it will now become a core factor in achieving medical device UDI compliance. VDP software which facilitates file merging and data cleansing is now widely available and which automate data preparation for the printing process.

Taking into consideration that medical devices encompass a huge spectrum of products with varying uses, the requirements for VDP on them will clearly differ too. For example, an implantable device (such as an artificial hip component or breast implant) will require application directly to the material. Etching is most commonly used for metallic products, however VDP may be applied to printable material - disposable packaging such as ostomy pouches will command this too. In contrast other devices such as insulin injector pens, inhalers or blood glucose meters will be suitable for labelling prior to secondary (or structural) packaging and in these cases adhesive labelling could be deemed entirely appropriate. For this reason when procuring VDP services the labelling requirements including device classification, materials and packaging process must be taken into consideration.

Fig 1: Illustration of an example of UDI compliant labelling incorporating VDP to facilitate individualization.

VDP printing directly onto secondary packaging such as cut card sheets, pouches, foil, lids and bags is more convenient and time conserving for the manufacturer. This is also a primary consideration when determining the printing partner.

DoraniX Printing Services:

DoraniX is a US based Global designer, manufacturer and supplier of highly specialized printing solutions suitable for a wide range of applications. As a company we have invested substantially in designing and developing our new range of direct-to-product printing range the ThermaPrint64. This innovative range of printers takes our printing facilities to a new level, providing us with the capacity to offer labelling applications to a wide range of materials including primary and secondary medical packaging.

The ThermaPrint64 range of printers are an innovative step forward from the original ThermaPrint series, offering advanced connectivity capabilities (USB and Ethernet), and therefore increased, yet simple, improved connectivity capabilities.

As outlined above this new innovative range of printers was designed with the capability to cope with a large spectrum of packaging materials. These include pouches and bags (direct-to-product) or alternatively card, cartons and cut sheets, all of which are common in the medical packaging environment. Another distinct advantage of the ThermaPrint64 range is the ability to print directly onto Tyvek® pouches and Tyvek® lids; this enhances the convenience of the whole packaging process. It is possible to print directly to blister back packaging, tags and other flat packaging materials. This whole process eliminates the hassle of label printing, however where this is not feasibly possible, the Label-Printing-Applicators are a perfect option for heavy duty table top label preparation.

Further to this, as the ThermaPrint64 Series was created intentionally to undertake high-volume VDP batches, it is perfect for creating labels and identification systems that adhere to all the stipulated requirements recently introduced by the FDA regulation. The bar-coding options and graphical capabilities provide the manufacturer with outstanding flexibility allowing the option of creating packaging prior to labelling and printing directly to pre-prepared packaging, or alternatively producing a full packaging printing preparation including logo and branding, alongside fulfilling UDI regulatory requirements.

Fig 2: DoraniX ThermaPrint 64 Direct-to-Product printing system

Ultimately in the near future medical device manufacturers will be required to ensure that all devices are adequately labelled and identifiable within the constraints of the newly applied FDA UDI guidelines. Any procurement decisions relating to labelling needs must be supported by proven and technologically sound printing solutions, incorporating the specificity of the class of device and current stage of identification in order to achieve regulatory approval. At DoraniX, we believe that we are an excellent choice of partner for all VDP requirements offering an unrivalled level of service combined substantiated by outstanding experience within the medical packaging sector. Our team are able to offer support and technical expertise alongside educated advice and personal contact. We truly believe that we are the leading provider in innovative product identification and bar coding products, and we *do* have the capability to take the stress out of the UDI labelling headache for medical devices.

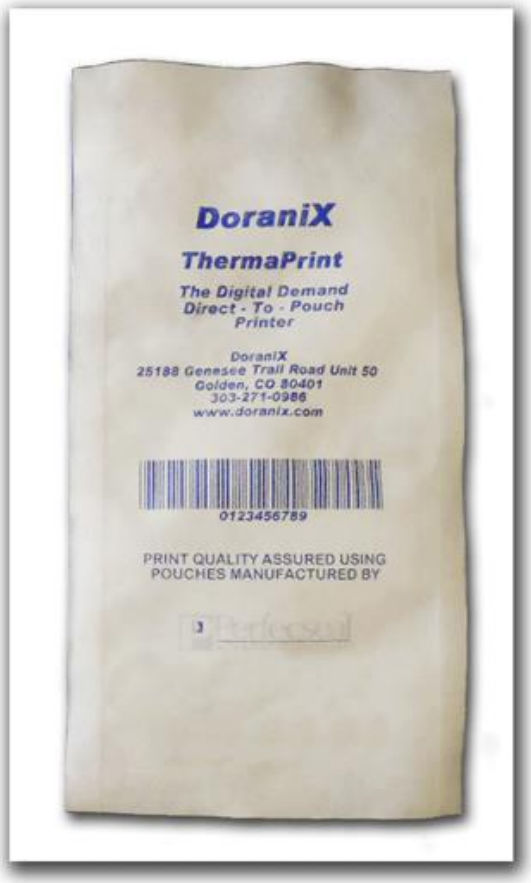

Fig 3: DoraniX VDP print example onto Tyvek® pouch

Fig 4: DoraniX VDP print example incorporating bar coding and QR code

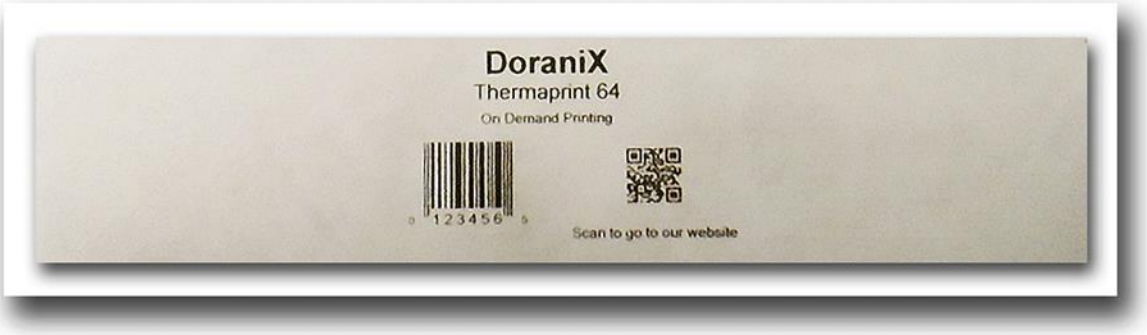

Fig 5: DoraniX VPD print example illustrating differential labelling to accommodate packaging shape

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