Label Printing to Meet 2013 FDA UDI Medical Device Regulations § 801.20

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.

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) or simply serialization 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.

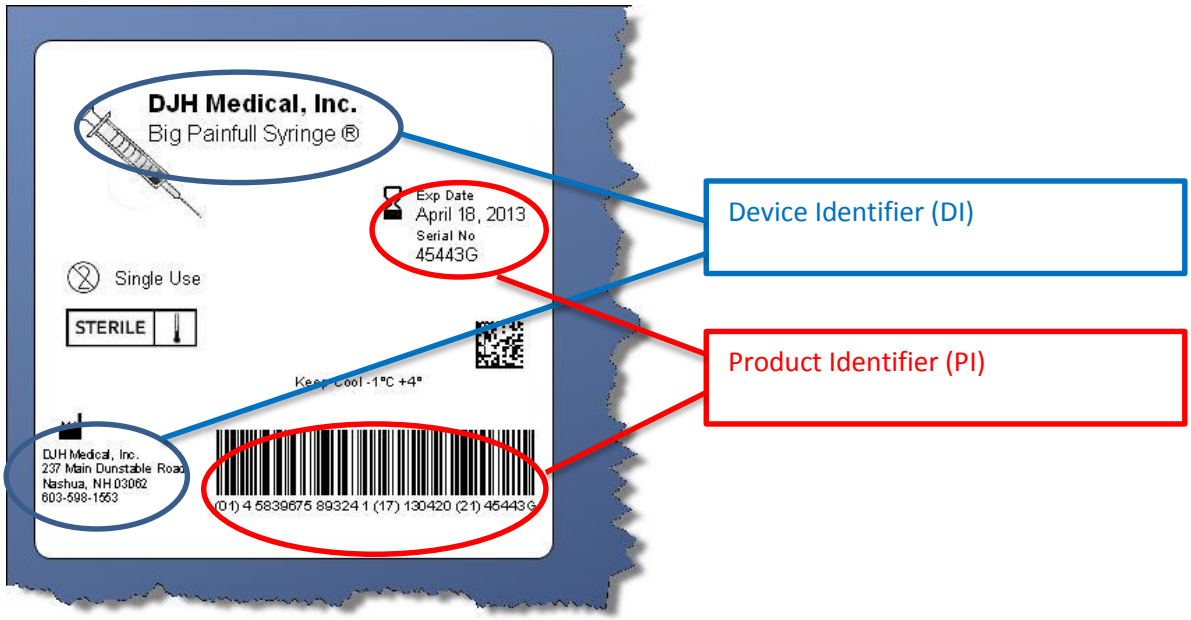

Fig 1: Illustration of an example of UDI compliant labelling incorporating VDP to facilitate individualization.

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.

Available VDP Services:

DoraniX, a US based global company which specializes in VDP services has the capacity to print directly to product (such as pouches, bags etc.) or alternatively onto card, cartons and cut sheets, all of which are commonly used for medical device packaging and protection.

The premium service offered by DoraniX has been facilitated by the development of the ThermaPrint 64 Series of Direct-to-Package Printing Systems. This newly available printing solution is capable of

producing high volume VDP outputs for product identification and bar-coding services particularly applicable to the regulatory requirements of the FDA UDI medical device directive.

Furthermore the individualized offering facilitated by the ThermaPrint 64 Printing System is flexible to fit with manufacturers' requirements, whereby pre-printed packaging requiring VDP labelling can be direct to the pre-prepared product, or alternatively, should a manufacturer prefer, 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. The ThermaPrint 64 Direct-to-Product system is a strong example of such a printing service.

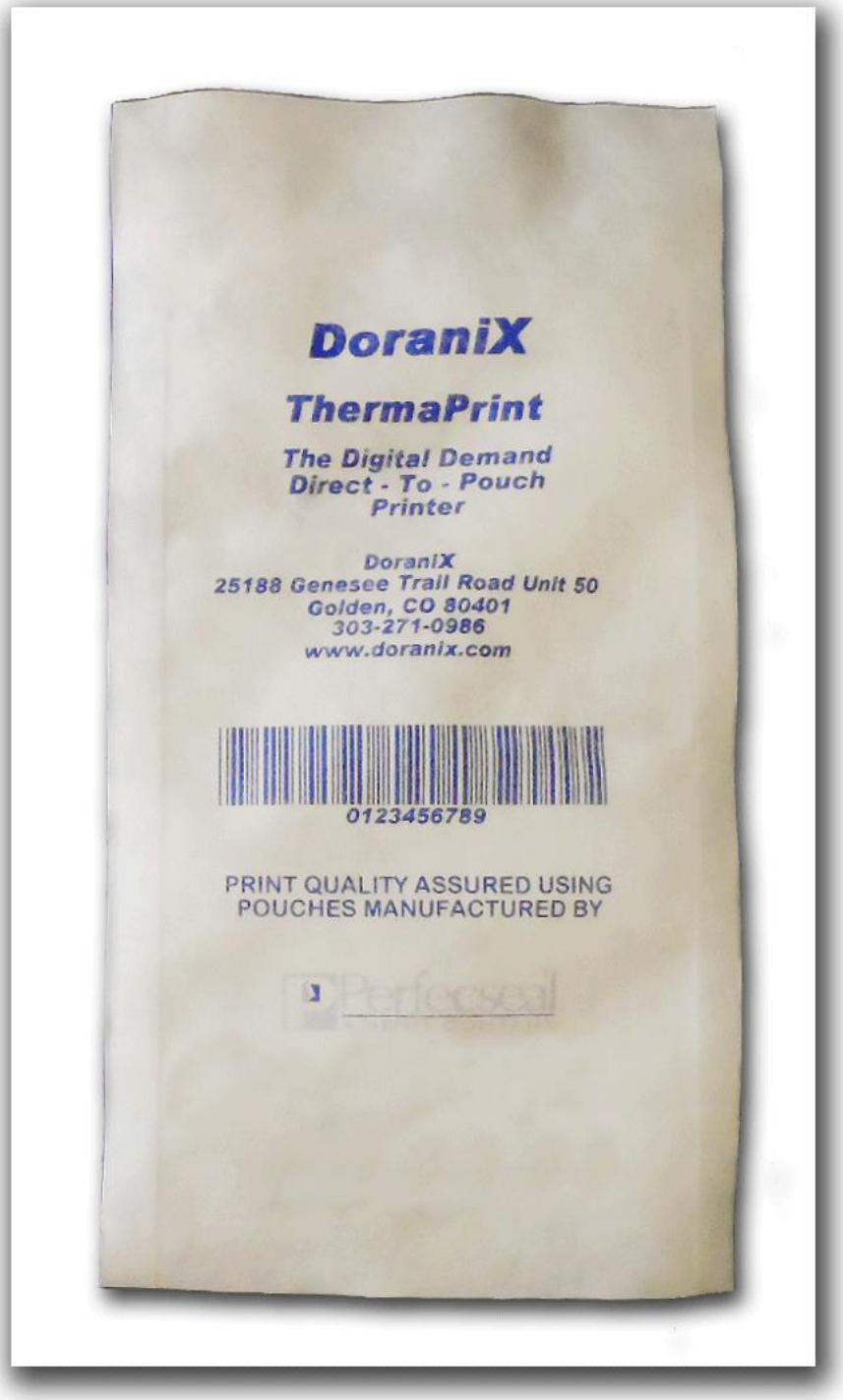

Fig 3: DoraniX VDP print example onto Tyvek® pouch

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

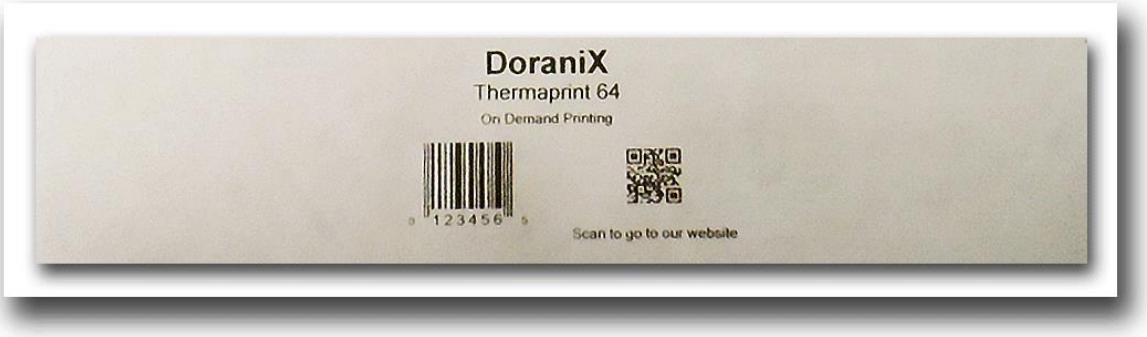

Fig 5: DoraniX VPD print example illustrating differential labelling to accommodate packaging shape