UDI introduces new coding demands for personal hygiene producers

By Nicola Rapley

Nicola Rapley, Marketing Manager for cosmetics, personal and home care at Videojet Technologies, looks at how coding and marking plays a key role in the personal hygiene segment with particular focus on recent regulatory demands for the use of Unique Device Identification (UDI).

Videojet Technologies is a world-leader in the product identification market, providing in-line printing, coding, and marking products, application-specific fluids and product life cycle services. Our goal is to work in partnership with our customers to improve their productivity, to protect and grow their brands and to stay ahead of industry trends and regulations. For the personal care industry, feminine hygiene and male contraceptive products are considered Class II medical devices due to the way they come into contact with the human body. This has meant many companies who have until now run reasonably simple coding applications such as date, batch and lot information, are now being demanded to apply new, more complex data to meet the Food and Drug Administration's (FDA) regulations for UDI.

Unique Device Identification (UDI) is a method used to mark and identify medical devices entering the healthcare supply chain. Each version or model of a device will have a unique number assigned by the manufacturer. This number must be added in both machine (AutoID) and human readable format on both the device and packaging.


(01)86912345678900
(21)1323424679
(17)081015
(10)X252061322
Enceptracet®
50 g/l; solution for infusion
Human normal immunoglobulin for intravenous administration
5 g in 100 ml

These standards have been developed by the IMDRF (International Medical Device Regulator Forum), the US Food and Drug Administration (FDA) and the European Commission for an improved and consistent approach to patient safety. The standards will also help optimize patient care through the ability to track devices through their distribution and use, and will come into effect in September 2016 as part of a phased roll out across the four device classes: Class I (low risk), Class II (higher risk), Class III (highest risk) and implantable, life-supporting and life-sustaining devices. This means that manufacturers must be ready to act in order to stay compliant.

Legibility and contrast are crucial for regulatory and traceability codes and high read rate bar codes on personal care and medical device packaging. It's important that manufacturers have the correct printing and marking solution to ensure they are compliant with UDI legislation. The correct technology depends on the substrate that's being marked. Thermal Inkjet (TIJ) printers allow for more complex coding options and the ability to print linear bar codes, alternate fonts, logos, and 2-dimensional codes such as GS1 DataMatrix and QR codes onto paperboard at high speeds, without compromising on print quality.

Continuous Inkjet (CIJ) printers are a flexible solution with the ability to print up to 5 lines of text as well as 2D and linear bar codes across a wide range of packaging types, whereas Thermal Transfer Overprinters (TTO) are ideal for printing high resolution images on flexible packaging film and labels.

For devices that need a permanent mark, laser marking equipment is the perfect choice. Laser marking is a non-contact marking method that offers advantages such as mark quality, permanence and fewer consumables. From CO_2 to Fiber and UV to YAG, laser sources have different power outputs to help address a range of substrates and applications.

Videojet has a wealth of knowledge and experience in the coding and marking industry, and utilizes key expertise to identify and recommend the best solution for your application.

Call **+971 50 199 6914**
Email **MEA.Sales@videojet.com**

Videojet Technologies Inc.
DHR MEA General Trading LLC
Warehouse #1, Plot # B416-5483
Nad Al Hamar
P O Box 215670
Dubai, UAE