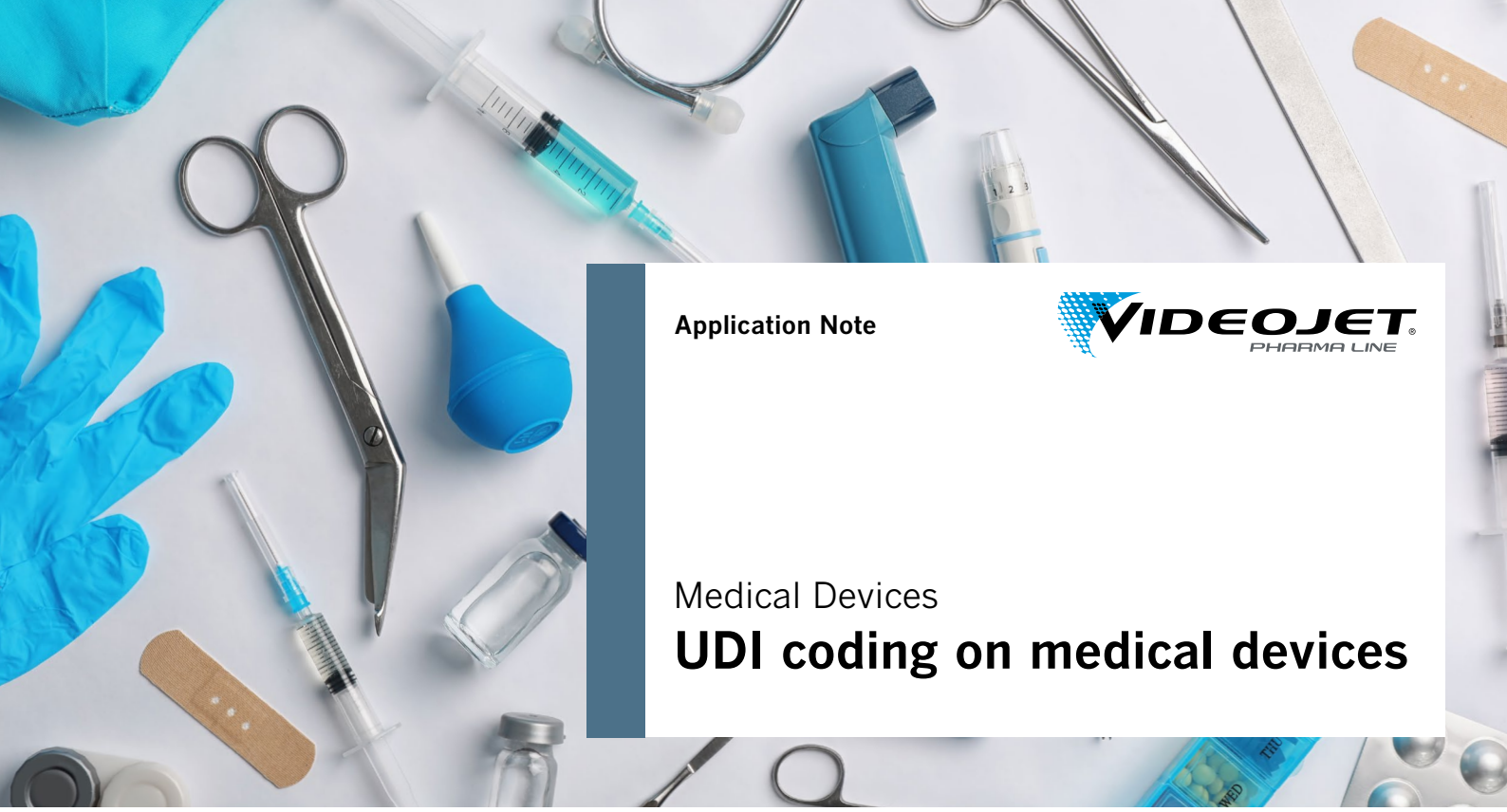


Application Note

VIDEOJET PHARMA LINE

Medical Devices

UDI coding on medical devices

UDI (unique device identification) is a standardized medical device identification system for consistent, unambiguous, and globally harmonized tracking of medical devices during distribution and use, and to facilitate recalls and corrective actions during the lifetime of the devices.

The UDI system started in the U.S. on September 24, 2014. With the Medical Device Regulation (MDR), the UDI system has also been established in Europe and came into force on May 26, 2021 for class III medical devices. Within the next few years, effective dates for other countries and medical device classes will follow, requiring manufacturers to meet deadlines and implement labelling systems to meet UDI standards. With suitable marking and coding technologies, Videojet can help medical device manufacturers to apply high-quality, high-resolution UDI codes on the packaging or the device itself.

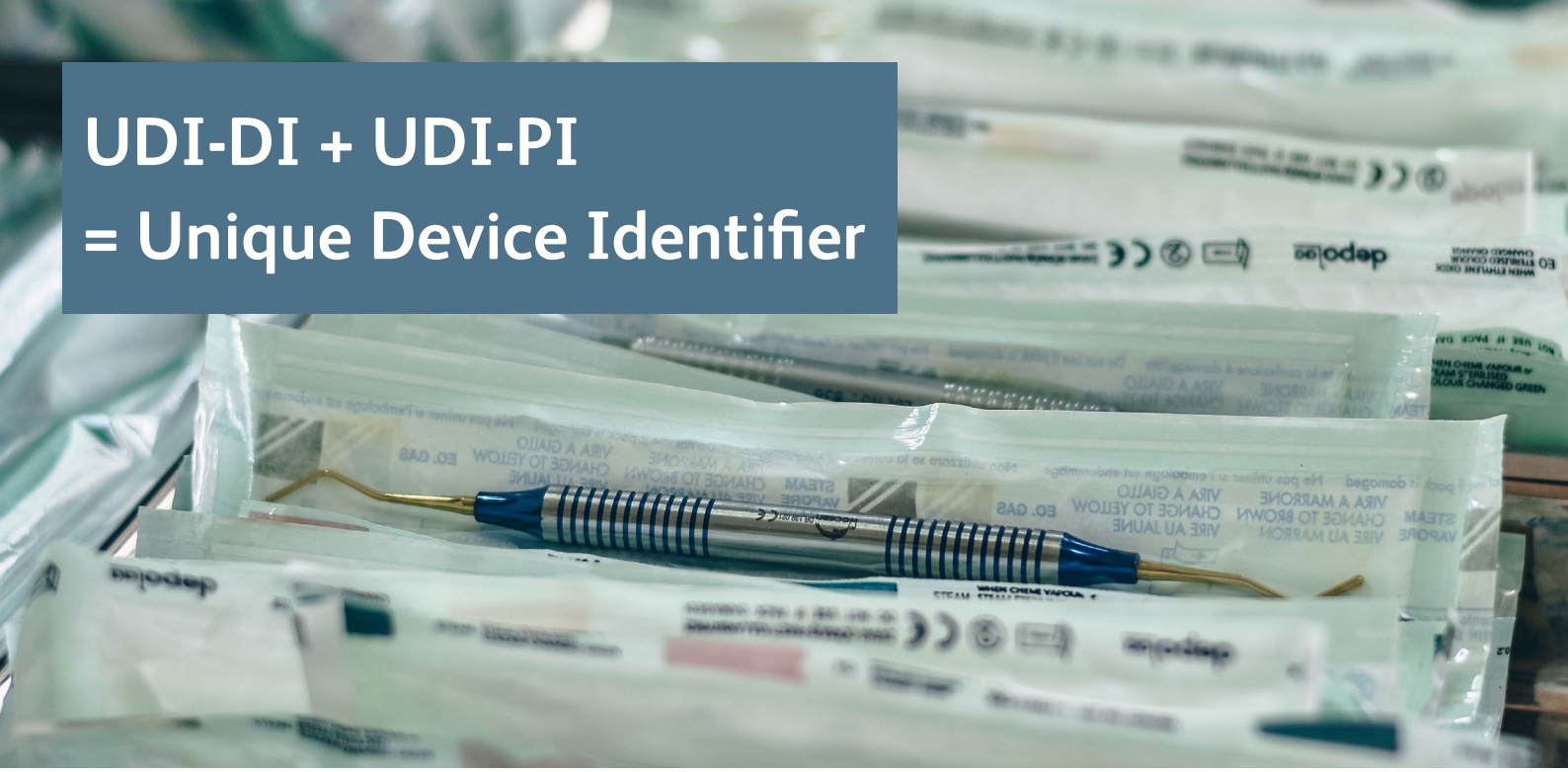
Medical Device Classification

Medical devices play a vital role in the diagnosis and treatment of diseases as well as improving the quality of life for people with disabilities. They are defined as any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for medical purposes, such as diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease, and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means, in or on the human body. Devices range from low-risk disposables typically used in ambulances to high-risk devices used in surgical care.

There are three main classes of medical devices in the U.S. and four in the European Union (EU): I, II (IIa, IIb in the EU) and III. The classification is made on a risk-based approach, depending on the potential risk associated with the device, which means the combination of the probability of occurrence of harm and the severity of that harm.

- **Class I**: e.g. elastic bandages, examination gloves, reusable surgical instruments, oxygen masks and surgical masks, dental floss
- **Class IIa**: e.g. dental materials, hearing aids, contact lenses, diagnostic ultrasonic devices
- **Calls IIb**: e.g. anesthesia/respiratory equipment, external defibrillators, dental implants, nails and plates
- **Class III**: e.g. pacemakers, prosthetic heart valves, heart catheters, artificial joints, surgical suture material, breast implants

The Unique Device Identification (UDI) system aims to facilitate the traceability of medical devices, significantly increase the effectiveness of post-market safety-related activities, and enable better surveillance by authorities, as it allows the unambiguous identification of a specific medical device on the market. Moreover, it is intended to help reduce medical errors and combat counterfeit products. For this purpose, the device itself (in case of reusable products) and all higher levels of packaging must be labelled with a UDI before it is placed on the market (except for custom-made products and performance investigational devices). Depending on the device class, different implementation deadlines apply per country.



UDI-DI + UDI-PI = Unique Device Identifier

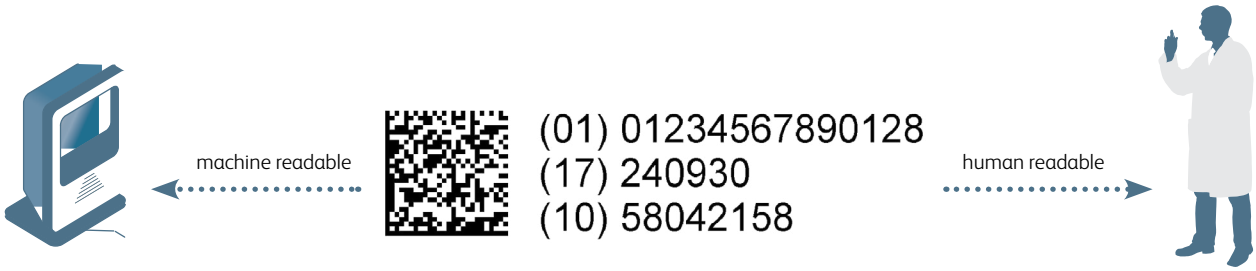
Coding Requirements

In order to establish a system to adequately identify medical devices through distribution and use, all devices must bear a unique device identifier (UDI) in human readable (plain text) and automatic identification and data capture (AIDC) format (bar code) on the label and on all higher levels of packaging. Shipping containers are not considered to be a higher level of device packaging. In case of significant space constraints on the unit of use packaging, the UDI can be placed on the next higher packaging level.

Medical devices that are reusable, such as surgical instruments, must bear a UDI on the device itself (direct marking), unless any type of direct marking would interfere with the safety or performance of the device, or the device cannot be directly marked because it is not technologically feasible.

The uique device identifier for medical devices is composed of two parts: Device Identifier (UDI-DI) and Production Identifier (UDI-PI):

- The **Device Identifier (UDI-DI**) of the UDI is a unique numeric or alphanumeric code specific to a model of medical device. This mandatory, fixed portion of a UDI identifies a manufacturer's specific product and package configuration. Examples of the UDI-DI include GS1 GTIN (Global Trade Item Number), HIBC-UPN (Universal Product Number), or ICCBBA ISBT 128-PPIC (Processor Product Identification Code).
- The **Production Identifier (UDI-PI)** of the UDI is a numeric or alphanumeric code that identifies the unit of device production. The different types of Production Identifier include variable production data, like lot or batch number, expiration date, serial number (mandatory for implants), or date of manufacture.



UDI coding solutions for medical device packaging

Several technologies are available for applying the UDI on the label, the packaging, or the device itself. Regardless which technology is used, the manufacturer needs to ensure that the UDI is readable for the expected service life and that placing the UDI is not creating any negative impact on the benefit-risk ratio of the device. The optimal marking and coding technology for a given application depends on factors including the packaging substrate, equipment integration, production speeds, and code requirements.

DuPont™ Tyvek®

DuPont™ Tyvek® is made of very fine and continuous filaments of virgin high-density polyethylene (HDPE). Its unique structure creates a material that is porous yet provides an effective barrier against microorganisms to keep medical equipment and pharmaceuticals sterile throughout their lifecycle. To apply UDI codes on Tyvek®, **thermal inkjet (TIJ)** printers, **thermal transfer overprinters (TTO)** and **UV laser marking machines** are ideal solutions.

Thermal inkjet performs extremely well on lidding substrates for medical devices, such as medical grade paper and DuPont™ Tyvek®. TIJ printers from Videojet use a non-contact printing technology that enables high-speed, high-resolution printing up to 600 dpi on flat and slightly uneven surfaces. The pixel reduction feature and pixel trimming feature of the Wolke m610 printers help to improve print quality, vision inspection, bar code grading, and reject rate by avoiding ink bleeding on Tyvek®.

Folding Cartons

Folding cartons are one of the most widely used packaging for pharmaceuticals and medical devices. They are versatile in form and function, protect the product inside, and are good marking carriers. For marking folding cartons with UDI codes, **TIJ** printers and **CO_2 laser marking machines** are well-suited.

In order to help ensure optimum marking quality on carton packaging and UDI readability during the expected life of the product, Videojet offers a testing service together with the Paper Technology Foundation (PTS) to help manufacturers find the optimum combination of carton type, coding technology and consumables. Our **Code2Carton service** is available for Videojet CO_2 laser marking systems, TIJ, and TTO printers.

Pouches

Pouches can be made of materials such as Tyvek®, medical paper, metal foil, or film. Foil pouches protect medical devices from moisture, light, oxygen, or other gases and are puncture resistant to withstand the stresses of sterilization, distribution, and storage. To apply UDI codes onto pouches, **TTO, TIJ,** and **continuous inkjet (CIJ)** printers are most suitable.

Thermal transfer technology uses a heated ribbon to precisely melt ink onto flexible packaging such as films, pouches, and labels to provide crisp, high-resolution, variable-content codes, texts, or graphics. The ability of TTOs to print high-quality bar codes with excellent edge definition helps ensure maximum readability and scannability. With integrated iAssure™ code quality verification technology, minimal wear parts, airless all-electronic operation, and fast-change ribbon cassette, Videojet TTO printers offer maximised uptime advantage.

UDI direct marking solutions for medical devices

Direct Part Marking

If a medical device is intended to be used more than once, not only its packaging needs to be labelled, but also the device itself must bear a permanent mark providing the Unique Device Identification (direct part marking). **Laser marking systems** are commonly used to directly mark medical devices due to their ability to produce permanent, crisp codes on many hard plastics, glass, or metal that withstand intensive wear and repeated sterilization.

The **UV laser** is particularly well suited for marking polyethylene fibers such as DuPont™ Tyvek® and rigid plastic materials such as white HDPE and LDPE, as well as glass and silicone. The Videojet 7810 UV laser marking system delivers high-contrast, permanent codes that are resistant to abrasives, chemicals and sterilization processes to provide lifetime traceability. The UV wavelength of the laser creates a colour change through a photochemical reaction on the device or packaging material without damaging it.

Fiber laser marking machines operate by delivering a wavelength of 1.064 micrometers and are ideal to apply high-contrast, permanent marks on high-density materials such as metal, aluminium, stainless steel, and plastics. The Videojet 7340 (20-watt) and 7440 (30-watt) are versatile fiber laser marking systems that feature the Lightfoot™ marking head, the smallest fiber laser marking head on the market, designed for simple integration, reduced installation costs, and increased range of installation opportunities. It is an ideal solution for manufacturers who have space limitations, are looking for simple integrations, or do frequent rapid changeovers. Due to a water and dust tight IP69 laser marking head, it is optimised for washdown and harsh environments and will not require any additional housing or protective equipment.

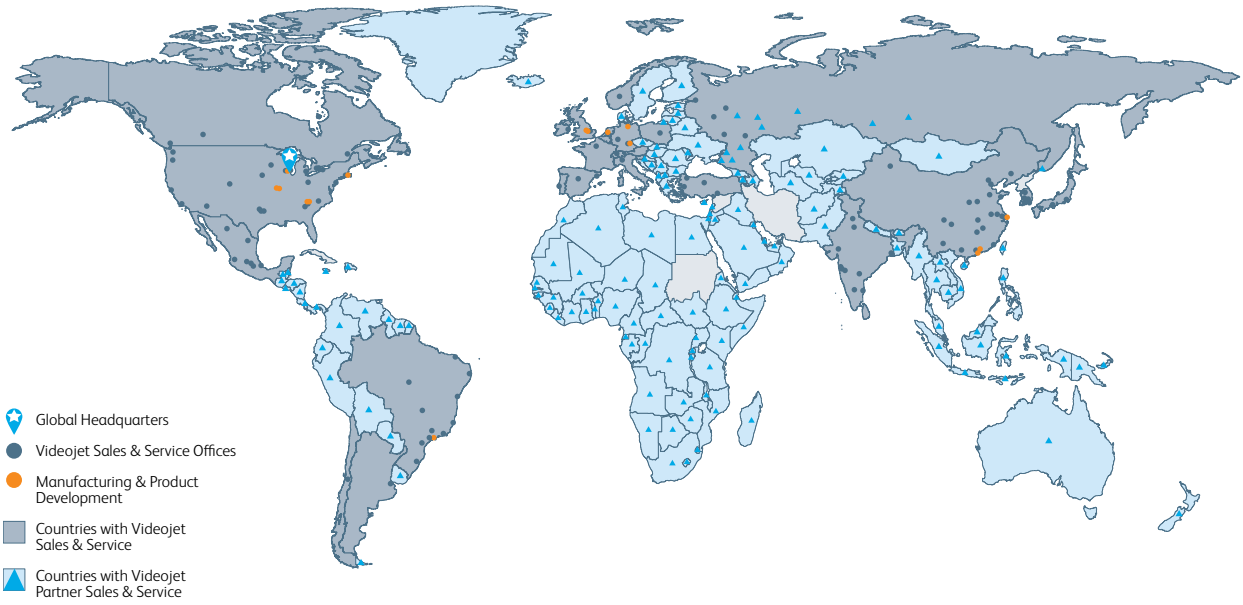
In addition to laser marking, **continuous inkjet (CIJ)** or **thermal inkjet (TIJ)** printers could be also taken into consideration to directly mark medical devices. The Videojet ink selection includes fast-dry, abrasion and transfer-resistant inks with excellent adhesion to a wide variety of plastic materials, metal, glass, or paper.

Peace of mind comes as standard

Videojet Technologies is a world leader in industrial coding and marking solutions with a dedicated global healthcare team supporting organisations and supply chain partners with solutions, certifications and fast, reliable service.

A product portfolio including thermal inkjet, laser marking, continuous inkjet and labelling provides consistent, high-quality serialisation and traceability codes, helping the pharmaceutical and medical device industries safeguard their products against counterfeiting and protect consumer safety. With a wide range of technologies addressing virtually any application, Videojet is the expert in realizing the specific requirements of a wide range of healthcare applications.

With decades of knowledge, Videojet Technologies' expertise in industry standards and global regulations makes them the right partner for understanding complex coding needs. Videojet solutions code 10 billion products a day worldwide, playing a vital and responsible role in the world. With over 4,000 associates serving 135 countries, Videojet has the capability to provide local service through global resources.



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