



Application Note



Medical Devices Coding on medical masks

Medical masks are considered as personal protective equipment (PPE) and are therefore classified as medical devices. They are subject to local regulations such as the US UDI system, or the European Medical Device Regulation (MDR), and must be labelled accordingly. Videojet can help medical mask manufacturers comply with these legal requirements by offering innovative coding solutions for masks, packaging, and shipping boxes.

Coding requirements

Medical masks that comply with FFP2, FFP3, N95 or KN95 standards are generally required to be labeled directly. Typical coding requirements are:

- Manufacturer's business name, a registered trademark, or an easily understood abbreviation of manufacturer's business name, e.g. company logo
- Testing and Certification approval number, e.g. EN 149:2001
- Filter series and filter efficiency level, e.g., N95, FFP2 or KN95
- The model number or part number, represented by a series of numbers or alphanumeric markings, e.g., 9455 or 9455A
- Lot number
- Date of production

In addition, the packaging cartons of medical masks as well as their shipping cartons have to be labelled. Typical information included:

- Global Trade Item Number (GTIN)
- Lot or batch number
- Date of production
- Quantity per packaging unit

Generally, this information has to be provided in both a human-readable (plain-text) form and a machine-readable form, e.g. a DataMatrix Code.

Coding solutions for medical masks



Medical masks (FFP2, FFP3, N95, KN95)



Packaging



Shipping boxes



Binary Array Inkjet



Binary Array Inkjet printers from Videojet are ideal for high-resolution printing of non-woven fabrics at high speeds.

The Videojet BX6500 provides one printhead with a 2-inch (51mm) print band running at speeds up to 1970 feet/minute (600mpm). For even greater throughput, the BX6600 offers a dual-head configuration operating off a single print engine. That's four continuous inches (102mm) to print graphics and text in a single pass. The heads can also be separated for printing on different areas of the target piece.

For printing onto non-woven fabrics, Videojet recommends using 16-42SR ink.



Thermal Inkjet (TIJ)



Thermal Inkjet printers from Videojet enable non-contact, high-resolution printing of up to 600 dpi on flat or slightly uneven surfaces at speeds up to 984 feet/minute (300mpm). A Thermal Inkjet controller can drive up to 4 print cartridges (0.5" / 12.7mm) independently or together.

For printing onto non-woven fabrics, Videojet recommends using our Cool Black Ink. For printing on unvarnished cartons, Videojet recommends our Water Resistant Black Ink. For printing on varnished cartons, Videojet recommends using our Solvent Black Ink.



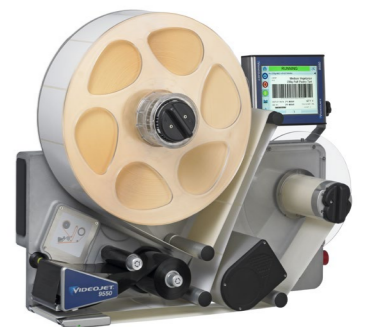
Label Printer Applicator (LPA)



The Videojet Label Print Applicator can aid with high-contrast bar codes and other production information on various substrates like shrink and stretch wrap, cardboard boxes, and shipping boxes.

Direct Apply labeling for common top or side applications requires no applicator and no plant air, thus reducing the number of labels being incorrectly applied and mangled during application. A simple web path achieves label and ribbon changes in less than 60 seconds, and a small footprint with simple mounting helps keep production areas free from clutter. The Label Printer Applicator is available with a 2", 4", and 6" print head.

Additional applicator models (Telescopic-Tamp, Front of Pack and Corner Wrap) are available to fit a range of applications.

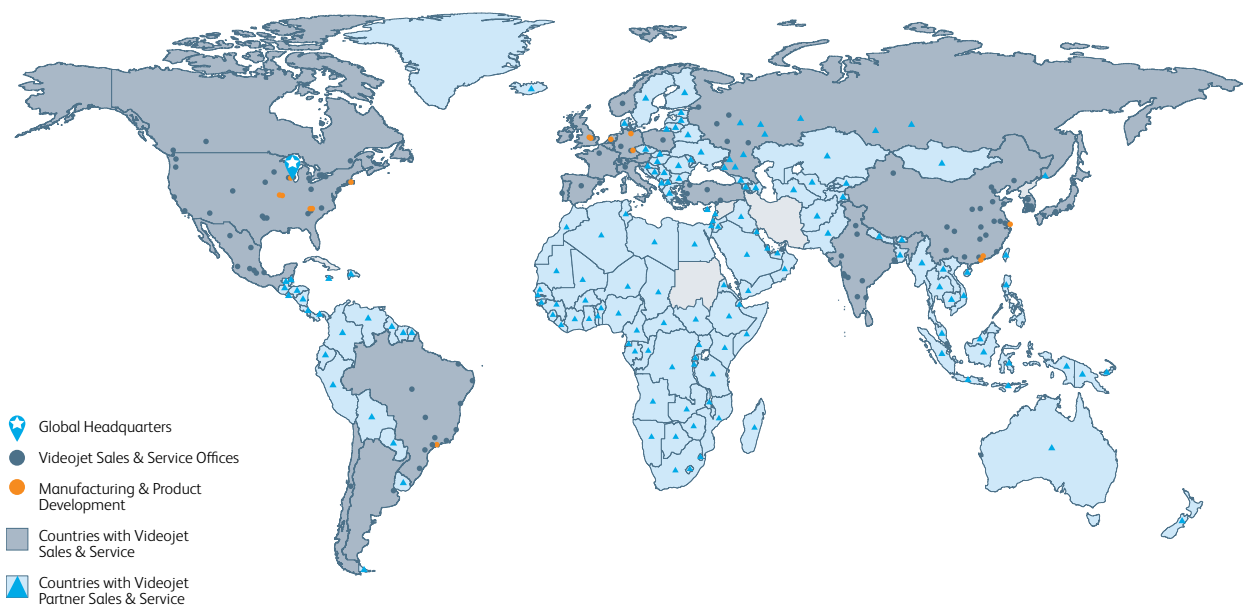


Peace of mind comes as standard

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

A product portfolio including thermal inkjet, laser marking, continuous inkjet and labeling provides consistent, high-quality serialization 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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