UniversalPromo, Inc.
PRINT SOLUTIONS™
SINCE 1972



PRINTING ON MEDICAL DEVICES:

A DESIGN ENGINEER'S GUIDE TO COMPLIANCE, MATERIALS, AND PROCESS



Medical device printing operates within one of manufacturing's most closely regulated fields, where precision and process control directly impact product safety and compliance. Getting labeling, ink selection, and sterilization compatibility right from the start keeps a device program moving smoothly to market.

UniversalPromo, Inc. (UPI) has served OEMs, design engineers, and regulatory affairs teams since 1972, printing on plastic, metal, and glass substrates for medical devices subject to FDA classification requirements. This guide walks through what a design engineer or regulatory affairs manager needs to confirm before choosing a printing partner for a medical device program, covering FDA classification, ink selection, clean environment production, and documentation requirements.



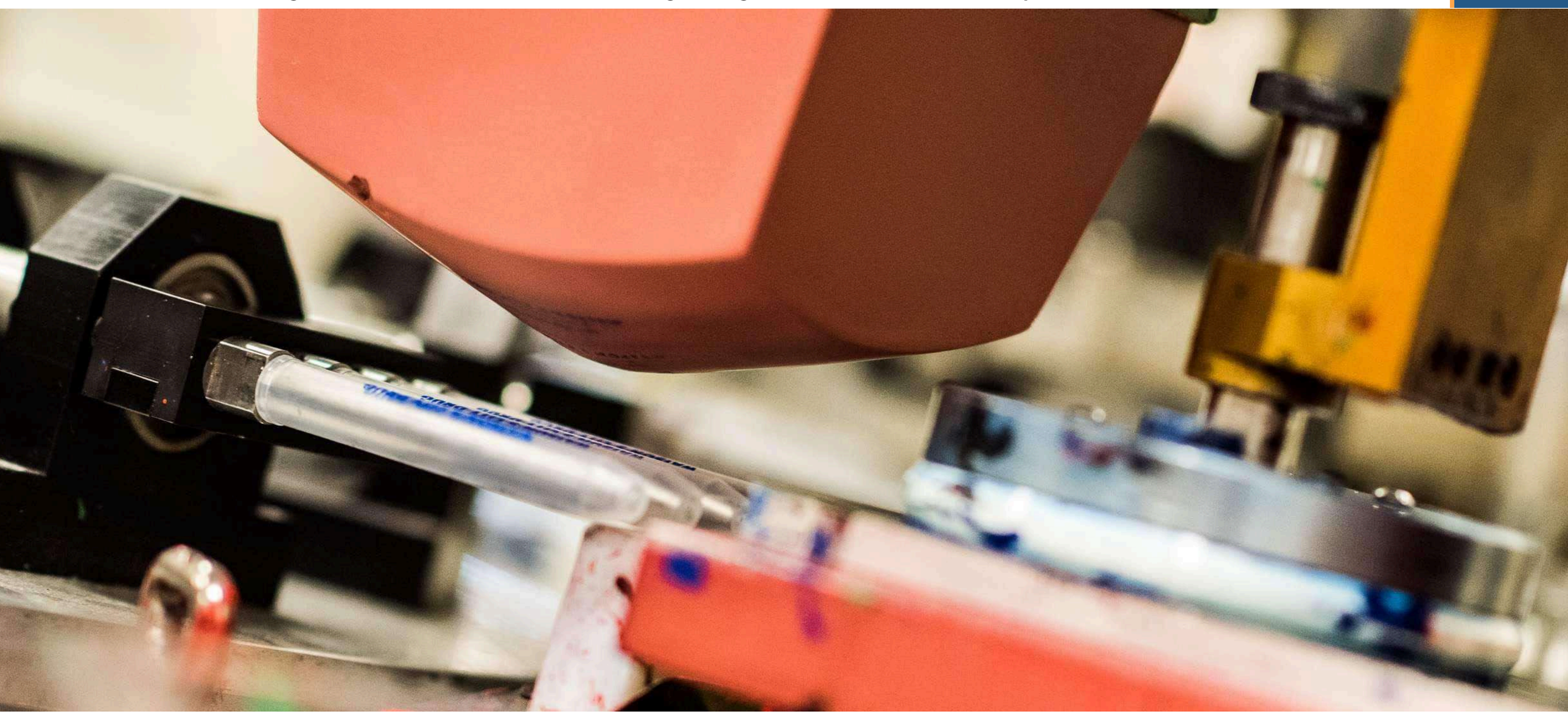
Why Printing Is a Regulated Step in Medical Device Production

Printing on a medical device does more than apply a logo. It places lot numbers, sterilization icons, and regulatory markings. These marks must stay legible throughout the device's use in a clinical or lab setting. The FDA treats them as part of the device's labeling, so print quality and process control face the same scrutiny as the device itself.



Biocompatibility, Sterilization, and Traceability Requirements

A print that peels, smears, or reacts during use signals a compliance failure. Inks that come into contact with skin or bodily fluids need biocompatibility testing, and markings must survive the sterilization method assigned to that device, whether that's chemical, gas, or thermal. Lot and date codes printed onto the device also support traceability if a recall becomes necessary.



FDA Device Classification and Printing Implications

The FDA assigns each device to Class I, II, or III based on the risk it poses to a patient. Since 1976, this three-tier system has guided how much documentation a print partner keeps on file and how closely reviewers examine the printing process during an audit.

Class I, II, and III Requirements Side-by-Side

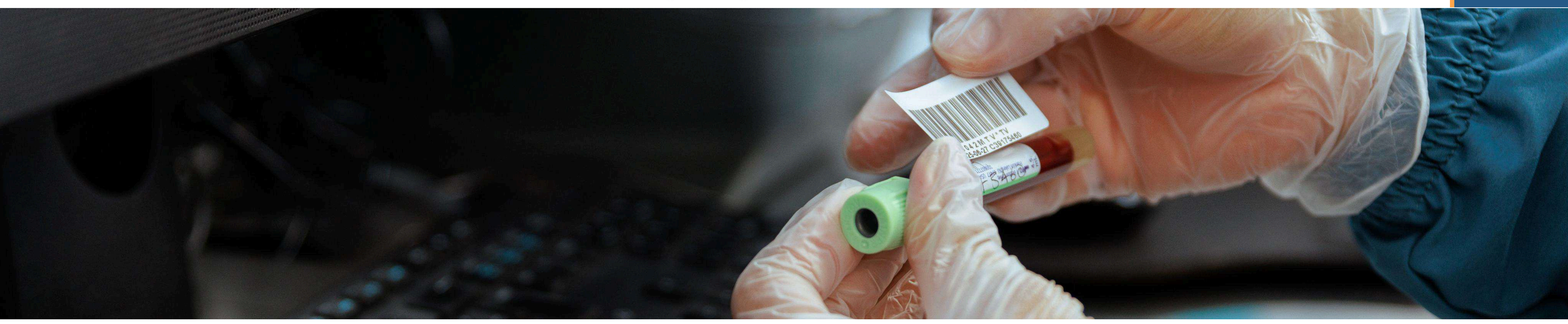
Each class builds on the one below it, adding oversight as risk climbs:

Class I. General controls cover manufacturing, reporting, and record-keeping for low-risk devices.

Class II. General controls apply alongside special controls such as labeling rules, performance standards, and testing requirements.

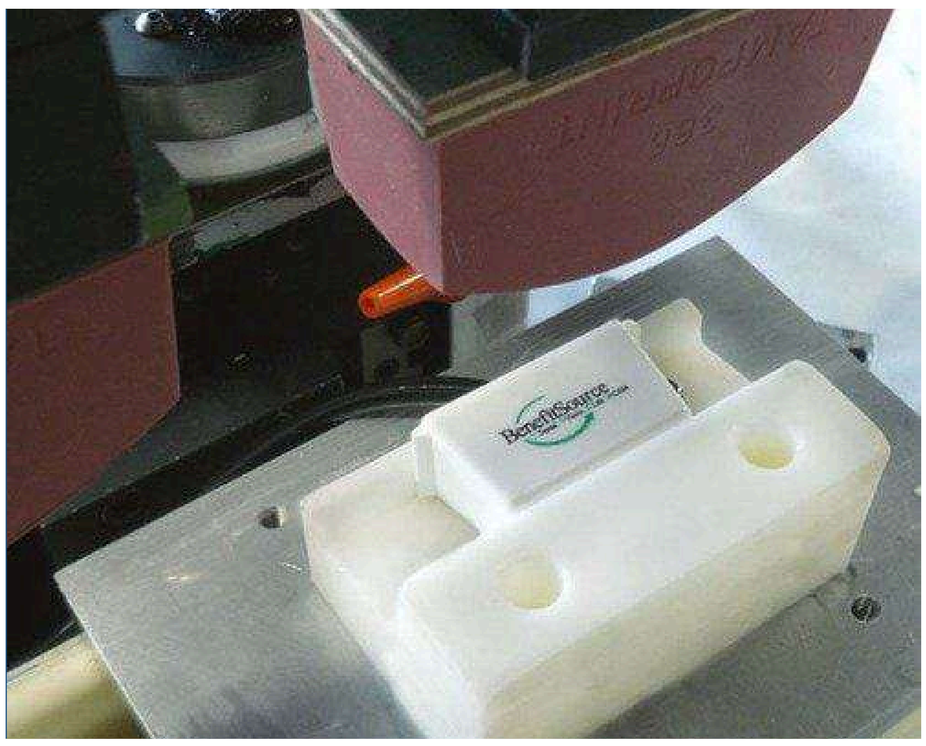
Class III. General controls and premarket approval apply to devices that support or sustain life, get implanted in the body, or carry a higher risk of injury.

Printing on a Class III device calls for the fullest documentation trail of the three. The print run itself becomes part of the device history record.



Selecting the Right Printing Method for Your Device

The right printing method depends on the device's shape, substrate, and how much surface area the mark covers. UPI applies several printing processes, and part geometry is usually the primary deciding factor.



Pad Printing for 3D and Contoured Surfaces

Pad printing transfers a two-dimensional image onto a three-dimensional surface using a silicone pad. This method suits curved, contoured, or irregular device housings well. UPI runs pad printing with Class VI medical-grade inks across substrates including polyurethane, polypropylene, polyethylene, metal, glass, PVC, and Pebax®.



Laser Engraving, Hot Stamping, and Digital Printing

Flat surfaces, permanent UDI codes, or foil finishes may call for a different approach. Laser engraving, hot stamping, and digital printing round out UPI's capabilities. A design engineer can weigh these options against pad printing during early design reviews.



Ink Selection for Medical Applications

Not every pad printing ink can be used on a device that touches skin, blood, or sterile packaging. UPI works with Class VI medical-grade inks designed for direct contact with the human body during use.



Class VI Biocompatibility Testing

Class VI inks used at UPI have passed biocompatibility and drug resistance testing. They match the adhesion and print quality of standard pad printing inks, plus the added qualification for direct use on medical devices.



Sterilization Compatibility: Chemical, Gas, and Thermal

Medical devices undergo sterilization through different methods depending on material and intended use. UPI's medical-grade inks resist chemical, heat, and gas sterilization techniques. Lot codes, warnings, and branding stay legible once the device completes its sterilization cycle.



Clean Environment Standards

Printing itself can introduce contamination in an uncontrolled space. UPI runs medical device print jobs inside a designated clean environment built for this concern.



How Controlled Environments Protect Device Integrity

The clean environment holds temperature and humidity within controlled ranges and filters incoming air through HEPA filtration. Medical-grade inks are applied in these conditions to keep particulates and other contaminants away from the device surface during printing. Together, they protect the device's safety and effectiveness after it reaches a patient.

Documentation and Compliance Records

A print run without paperwork is hard to defend during an FDA audit. UPI documents our printing process for every job, giving design engineers and regulatory teams confidence as their products go to market.

What to Request from a Print Partner

Ask a print partner for these records before a program moves into production.

Process documentation. A written record of how the print job ran and how it was controlled.

Material safety data sheets (SDS). Safety information for every ink used on the device.

Certificates of compliance. Confirmation that materials meet the standards specified for the job.

UPI shares these records on request for every medical device print run.

Certificates, SDS, and Process Audit Trails

These records matter most when a device recall or audit requires tracing a lot back to its print run, ink batch, and process settings. Keeping this paperwork on file with a print partner, rather than chasing it down after a problem surfaces, saves time when regulators or internal quality staff require the information.





Artwork and Design Considerations for Medical Devices

Artwork for a medical device has to be produced onto a small, curved, or metallic surface with full legibility. UPI's graphic design staff work with your design engineers early in development to optimize your device's functional and aesthetic potential.



Legibility Requirements, Color Constraints, and Surface Geometry

Surface geometry, ink opacity, and color matching all deserve review during the design phase. In addition, producing small text on a curved surface has a higher risk of distortion than text produced on a flat label. UPI's designers use the Adobe Suite and CorelDRAW alongside color matching technology to keep branding and print quality consistent across substrates and finishes.

Prototyping vs. Production: How the Process Changes

Printing requirements can shift once a device moves from a handful of prototypes to a full production run.



What to Expect at Each Stage

Timelines vary based on device complexity, production quantity, and validation requirements; for example, programs that require adding decoration across multiple items can take several months. Repeat production orders on an established design return in about two weeks. For devices in New Product Introduction (NPI), lead times for initial prototypes and sample runs range from two to four weeks.

Partner With UPI on Your Medical Device Program

UPI has worked in medical device pad printing since 1972, applying pad printing, laser engraving, hot stamping, and digital printing for OEMs and design companies moving devices from prototype to market. We hold ISO 9001:2015 certification and FDA registration for medical device work, and we document every print job for compliance review.

For project-specific questions about classification, sterilization compatibility, or clean environment production, contact us or request a quote today.

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About Us

With over 40 years of experience, UniversalPromo, Inc. has built a reputation on providing workable solutions to even the most complex print jobs. We have assembled our team of Minneapolis-based dedicated professionals providing experience and drive to perform with excellence. This ensures that every member of our staff is ready and able to assist you.

Our company began as a custom tooling and engineering company and we have carried that same technical savvy and attention to process and detail into our printing as well. UPI is an industry leader in medical device pad printing and uses only biocompatible inks, foils and additives regardless of each product's use. UPI provides value adding services to plastics manufacturers, store display manufacturers, fabricators, injection molders, blow molders, roto molders, 3D printers, and more! This means that when you choose UniversalPromo, Inc. you can rest assured that you are receiving the most experienced printer service possible.

Contact Us **Request a Quote**



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