

1 / Introduction

Traceability and compliance are critical in the medical device industry. With increasing regulatory demands, especially the EU MDR requiring UDI (Unique Device Identification) codes on reusable surgical instruments by 2027, manufacturers and hospitals must adopt reliable marking technologies.

Laser marking has emerged as the preferred solution due to its durability, precision, and ability to meet stringent medical standards. This eBook explores how laser marking can be effectively implemented in both manufacturing and hospital environments, ensuring compliance, safety, and operational efficiency.



Traceability



Patient Safety



Regulatory Compliance



Cost Savings



Workflow Efficiency



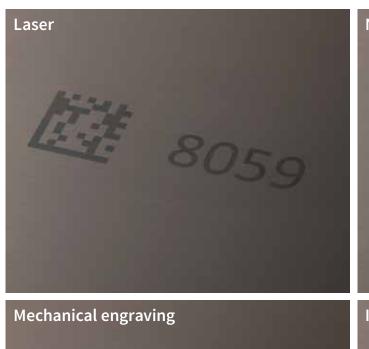
2 / Laser marking in the medical industry

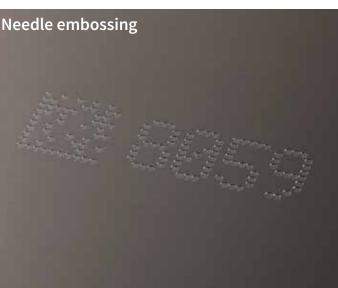
Laser marking offers a non-contact, high-precision method to permanently mark medical instruments and implants. Unlike ink-based or mechanical methods, laser marking does not compromise the integrity of the material and is resistant to sterilization, passivation, and wear.

Materials such as stainless steel, titanium, PEEK, and ceramics can be marked with high contrast and legibility. This is essential for traceability, especially in surgical environments where instruments undergo repeated cleaning and sterilization cycles.

Compared to dot peen, inkjet, and chemical etching, laser marking provides superior quality, lower maintenance, and greater flexibility. It eliminates consumables, reduces setup time, and integrates easily into production or hospital workflows.

Technology comparison









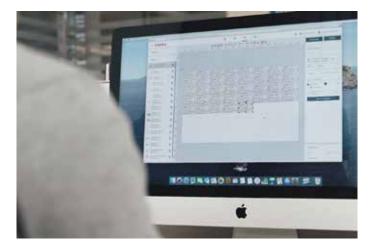
3 / Trotec laser solutions for medical applications

Trotec offers a comprehensive range of laser systems tailored for medical marking. The Speedy series provides flatbed CO₂ and fiber lasers, while the SpeedMarker series delivers high-speed galvo marking for industrial environments.



Trotec's **Ruby®** and **SpeedMark software** platforms support GS1-compliant code generation, automated workflows, and integration with hospital or manufacturing databases. These systems are designed for safety, reliability, and ease of use.

With features like camera-assisted positioning, pre-set parameters for medical materials, and customizable user interfaces, Trotec systems enable precise and compliant marking with minimal training.







4 / In-house laser marking for hospitals

Hospitals face the challenge of marking tens of thousands of instruments before the 2027 deadline. Outsourcing is costly and time-consuming, while in-house marking offers control, scalability, and cost savings.

A typical hospital can implement a laser marking station in the CSSD or maintenance area, using tray-based workflows and vision-assisted positioning. Staff can be trained to operate the system with minimal effort, and marking can be done gradually without disrupting operations.

Trotec provides turnkey solutions including fiber lasers, medical presets, vision systems, and local support. This enables hospitals to meet UDI requirements efficiently and reliably.

5 / UDI Compliance & GS1 Standards

UDI codes must be permanent, legible, and traceable. GS1 standards define the structure and format of these codes, including datamatrix and text elements.

Trotec's software supports GS1-compliant code generation and verification. With SpeedMark Vision, hospitals and manufacturers can ensure accurate placement and readability of codes.

Compliance with GS1 and MDR standards is essential for patient safety and regulatory approval. Laser marking provides a reliable method to achieve this, with full traceability and integration into digital systems.





6 / Advanced Applications

Laser marking is not limited to flat surfaces. With the right fixtures and vision systems, curved instruments, implants, and sterile packaging can be marked accurately.

Passivation-resistant marking ensures that codes remain intact after chemical treatments. Trotec tests materials and provides optimized parameters to ensure compliance.

Automation options include tray marking, barcode scanning, and integration with hospital or ERP systems. This enables high-throughput, error-free marking for large inventories.



7 / Getting Started with Trotec

Trotec offers consultations, demos, and training to help you implement laser marking. Whether you're a manufacturer or a hospital, we provide tailored solutions to meet your needs.

Our systems are designed for ease of use, with plug-and-play setup, pre-configured parameters, and ongoing support. We also offer custom solutions for integration and automation.

Contact us to schedule a demo and see how laser marking can transform your compliance and traceability workflows.



Consultation



Demonstration



Training

8 / About Trotec



Trotec Laser, headquartered in Marchtrenk, Austria, is a global leader in laser technology. As part of the TroGroup, the European innovation leader develops, produces and markets high-end laser systems for precise marking, cutting and engraving of various materials, continuously setting new standards.

Based on more than 25 years of experience, Trotec stands for innovative complete laser solutions: Laser machines, exhaust systems, powerful software and high-quality materials. 14 subsidiaries and a total of around 700 employees look after the more than 40,000 systems installed to date in 90 countries.



