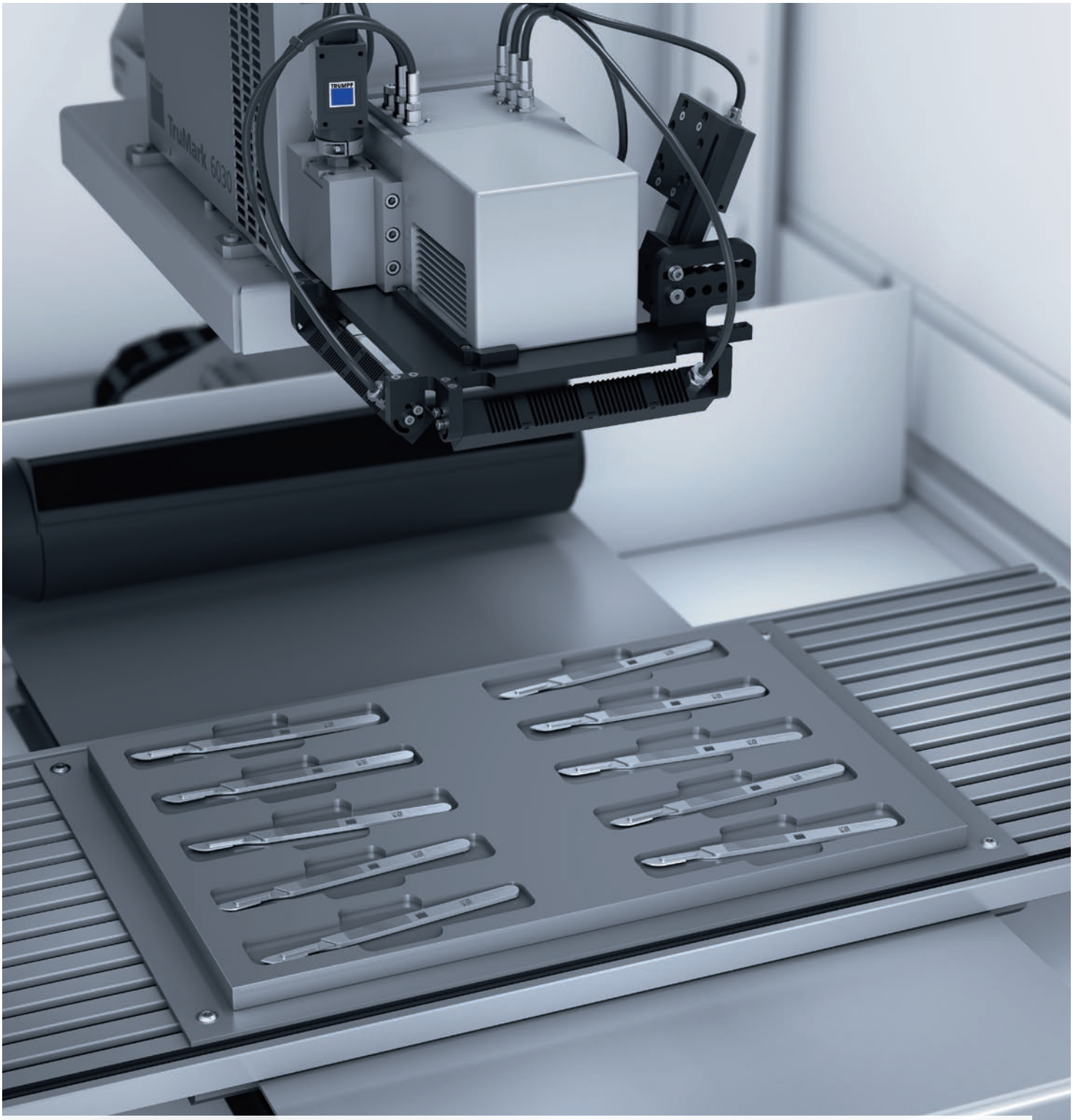

TRUMPF

White paper

Digital image processing for TRUMPF laser marking systems in medical device manufacturing

Contents

Get in touch to find out more

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Background

Medical device manufacturers use lasers to apply permanent marks to medical devices such as implants and surgical instruments as well as to medical utensils such as instrument cases. These marks are subject to strict regulatory requirements, including unique device identification (UDI) standards defined by the EU Medical Device Regulation (MDR) and the US Food and Drug Administration (FDA). To comply with these standards, UDI marks on surgical instruments must remain readable and corrosion-resistant even after multiple cleaning and sterilization cycles. Equally, implants must maintain their biocompatibility, mechanical properties and other characteristics after a laser mark is applied. To meet the new regulations, manufacturers must ensure every device and its packaging bear a unique device identification (UDI) code to ensure traceability. In Europe, this information will, in future, be stored in EUDAMED, the European database for medical devices. As well as data on device manufacturing and quality, EUDAMED will also serve as a repository for documentation of clinical trials and adverse events.

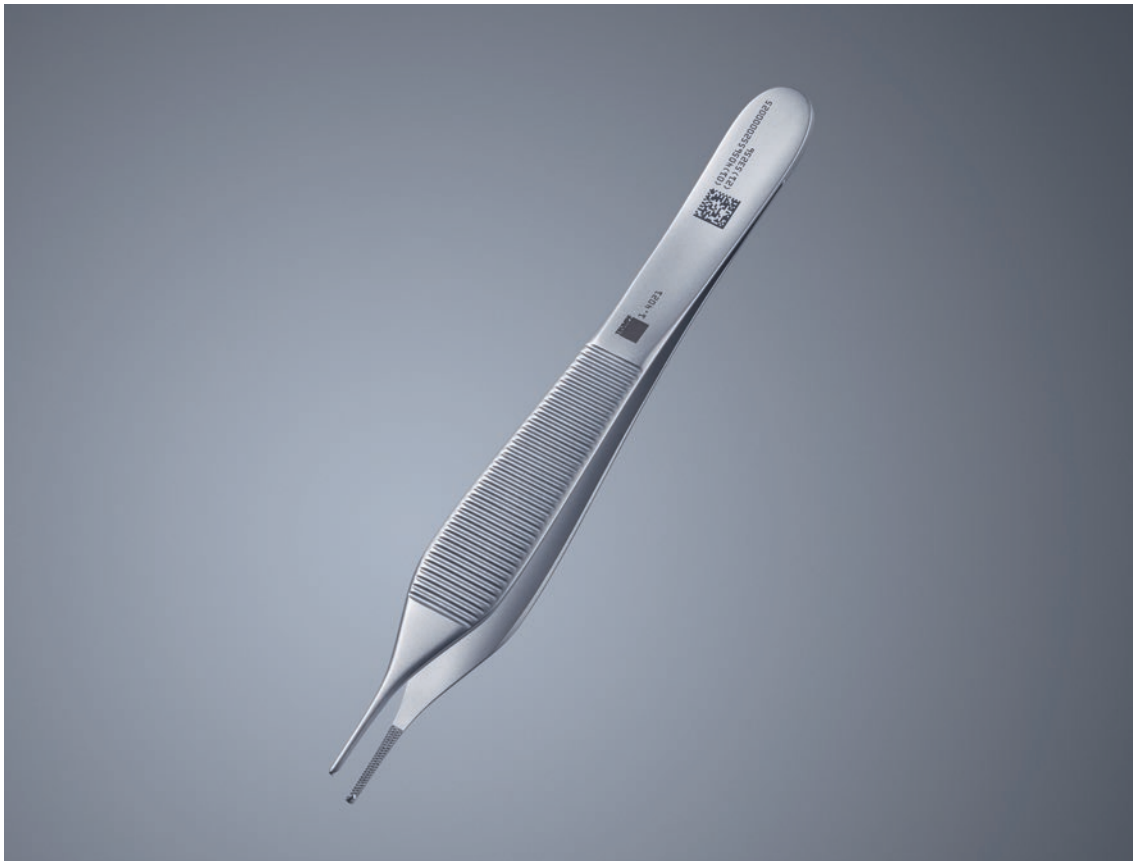


Figure 1:
Tweezers black-marked with a GS1-compliant UDI in a human- and machine-readable form.

Faced with these new regulations, companies are increasingly opting to incorporate intelligent image processing into the laser marking process. Image processing is an efficient tool for medical device quality control that can be integrated directly into the marking process. It can be used both before and, in particular, after the laser mark is applied. Batch numbers, bar codes, 2D codes, CE markings and company logos are just some examples of the information that can be marked on a medical device. Image processing software must therefore be able to read diverse types of information and reliably detect any nonconformances. Storing this information in a central database ensures robust documentation of medical device quality. Image processing plays a key role in this process chain. In future, it will add valuable features to every marking laser in the medical device manufacturing industry.

As well as helping to drive quality assurance, image processing is often used to maximize support for users when it comes to positioning workpieces for marking. Image processing can help to quickly get the workpiece in the right position. Alternatively, users can opt to hand over the entire task to intelligent image processing software, which can recognize the position and shape of a sample workpiece and align the mark accordingly. The benefits therefore extend well beyond quality assurance, with image processing also serving to boost the efficiency and productivity of laser marking while maintaining outstanding levels of processing quality.

The latest generation of TRUMPF marking systems addresses all these customer needs by incorporating an image processing system that paves the way for maximum productivity and top-notch quality standards. With its TruMicro Mark Series 2000 ultrashort pulse lasers for black marking and its new generation of TruMark 6030 lasers for annealing, TRUMPF has introduced a technological advancement that takes reproducibility to the next level. By combining laser technology and intelligent image processing, TRUMPF has created an all-in-one package for medical device manufacturers that fulfills the highest standards of automation and quality.

The TRUMPF approach to image processing

TRUMPF's camera and lighting strategies for its laser marking systems are designed to meet the needs of medical device manufacturers. Thanks to a clever combination of an in-line camera, an external camera and innovative lighting solutions, TRUMPF systems can mark and read even the most challenging surfaces, including those of electropolished medical devices.

The two cameras perform different functions. The in-line camera precisely tracks the laser beam to produce a distortion-free image. Thanks to its high resolution, this set-up helps users position workpieces with impeccable precision while also reading and evaluating 2D codes and texts using OCR/OCV. Such high resolution means that the camera's field of view is limited to a fraction of the marking field, but the marking surface can be rapidly scanned to deliver a larger image of the marking field.

The off-axis camera captures an overview of the workpiece in a single shot. With no scanning required, this provides an extremely fast way to visualize the entire marking surface. Although the resolution is slightly lower, it is still high enough to get most workpieces in exactly the right position. Users can process the image directly in the CAD software to define exactly where the mark should be placed on the device. By locating the camera outside the path of the laser beam, TRUMPF allows the camera's field of view to cover the entire marking field. The off-axis camera is of more limited use when it comes to smaller objects or high-precision positioning requirements, but these needs are comfortably met by the in-line camera.

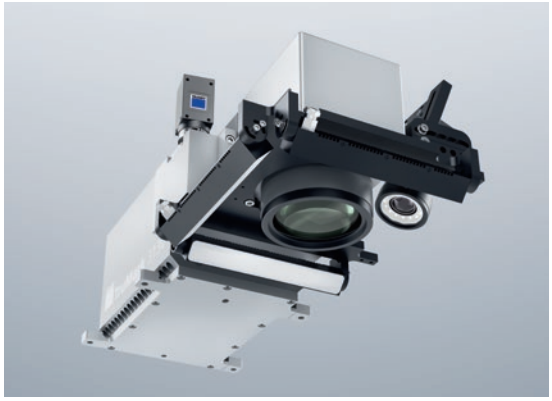


Figure 2:
Laser head with built-in image processing capabilities: in-line camera and external camera with standard illumination.

Innovative lighting strategies for best-in-class image processing in TRUMPF laser marking systems

The key to making image processing a successful part of a stable process is having the right lighting strategy. For example, the wavelength of the light used for image processing must be different to that of the laser. Otherwise the laser light could cause signal interference, such as oversaturation of the camera signal. To ensure the workpiece is illuminated as homogeneously as possible, TRUMPF marking lasers come with diffuse light bars as standard. Depending on requirements, the workpiece can be illuminated from above (bright field illumination), from the side, or from below (dark field illumination).

Medical device manufacturing poses major challenges for image processing. That's because many of the materials used in medical devices have polished surfaces that are highly reflective. In the case of electropolished workpieces such as drill bit shanks and implants, illumination with light bars may produce strong spot-like or linear reflections that could cause localized oversaturation of the camera (see fig. 3, left). This makes it impossible to reliably identify the position of the workpiece or perform visual quality assurance at these specific points. The lost data cannot be reconstructed – even by intelligent software.

TRUMPF is the first marking laser manufacturer to launch an innovative, industry-ready solution that can read codes and characters on these kinds of challenging surfaces. The new method offers a fail-safe way to illuminate highly reflective components without unwanted reflections. It does this by illuminating the workpiece with a flat-dome light, a specially designed guide plate for diffuse light that illuminates the workpiece without casting any shadows. This makes it easy to recognize and read information on even the most highly reflective surfaces. Another advantage of the flat-dome light is its flattened, compact design, which enables it to fit comfortably between the sample part and the marking laser head. The result is outstanding, high-contrast imaging for even the most challenging workpieces (see fig. 3, right).

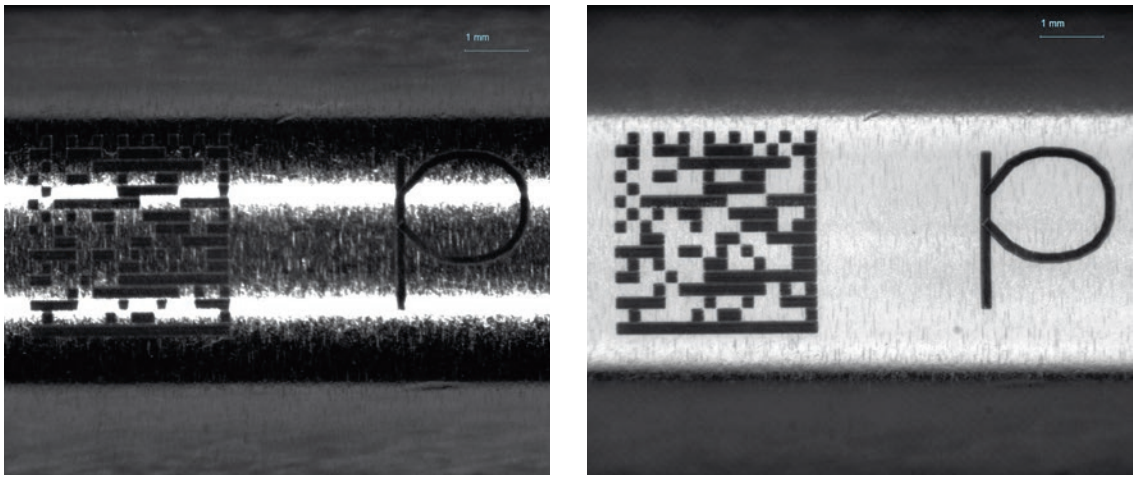
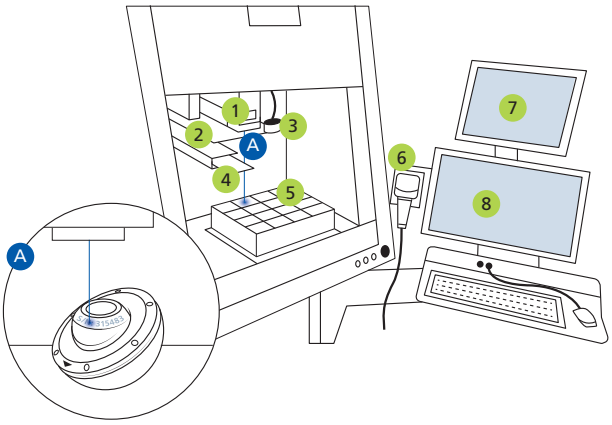


Figure 3:
Left: Without flat-dome illumination, the data matrix code and alphanumeric characters on this drill bit shank are obscured by numerous shadows and reflections, making it impossible to use OCR/OCV. Right: Illuminating the same drill bit shank with flat-dome lighting makes it easy to recognize and read the characters with OCR/OCV software.

Workpieces with less reflective surfaces and less complex geometries can be processed with ease using standard illumination. TRUMPF therefore includes bar lighting in all its image processing systems as a standard feature in addition to the flat-dome light. Quasi-monochromatic LEDs are used to illuminate the workpiece in the marking area. The system illuminates the workpiece from various sides in order to obtain the most homogeneous image. Users can adjust the beam angle, diffuser strength and degree of polarization in order to achieve optimal illumination. Diffuse or soft light is used to illuminate the workpiece as evenly as possible while keeping shadows to a minimum.



1 Marking laser
2 Autofocus sensor
3 VisionLine illumination
4 Flat-dome illumination
5 Custom tray
6 Handheld scanner
7 Image processing for OCR
8 Module Interface (TTM-MI)

Figure 4:
This turnkey marking system with light bars and flat-dome lighting is well equipped to meet the strict regulatory requirements of medical device manufacturing. The package features an automatic sequential control system which is initiated by a handheld scanner. It also includes image processing for positioning, OCR and quality assurance.

Image processing offers numerous different options to enhance laser marking processes. TRUMPF experts help ensure maximum productivity by tailoring these options to each customer's individual requirements. As well as applying tried-and-tested methods to optimize the laser marking process itself, TRUMPF also offers numerous downstream and upstream processes, such as optical recognition and inspection of sample parts and information storage in databases. Before applying a mark, it is standard practice to carry out optical verification to check whether the right medical device has been placed in the system and whether it has already been marked. The image processing system automatically detects the position and alignment of the workpiece and adjusts the orientation of the marking accordingly. Once the mark has been applied in exactly the right position, the system moves to the post-evaluation stage, which involves reading the content of the mark and comparing it to the data on file to ensure it meets the stipulated requirements.

TRUMPF's user-friendly GUI keeps users constantly updated on everything they need to know about the status of the process, including information on which sample parts were successfully marked, any instances of the wrong part being detected, and confirmation of whether codes and text content have been read correctly. Exactly how the process runs is up to the customer: for example, they can decide whether the system should stop the process when it detects an incorrect part or whether it should continue and only report the error once the process is complete.

Image processing is also a useful tool for automatically scanning sample parts that are loosely positioned in trays or dies. It allows parts to be marked and quality-checked fully automatically without any operator intervention.

Together, all these features represent a huge boost to the productivity, precision and quality of the latest generation and previous generations of TRUMPF marking lasers. The key is to find the best image processing solution for each specific case – and that's exactly what TRUMPF application laboratories are qualified to do.

Turnkey laser marking solution for medical device manufacturers

TRUMPF's all-in-one solution for the medical laser marking market offers comprehensive best-in-class performance across the entire UDI marking process. As well as image processing and database connections, this also includes the use of external devices such as handheld scanners to capture data. To make life even easier, the corresponding software comes in various modules that can be tailored to each customer's specific requirements. The illustration in fig. 5 shows a typical workflow.

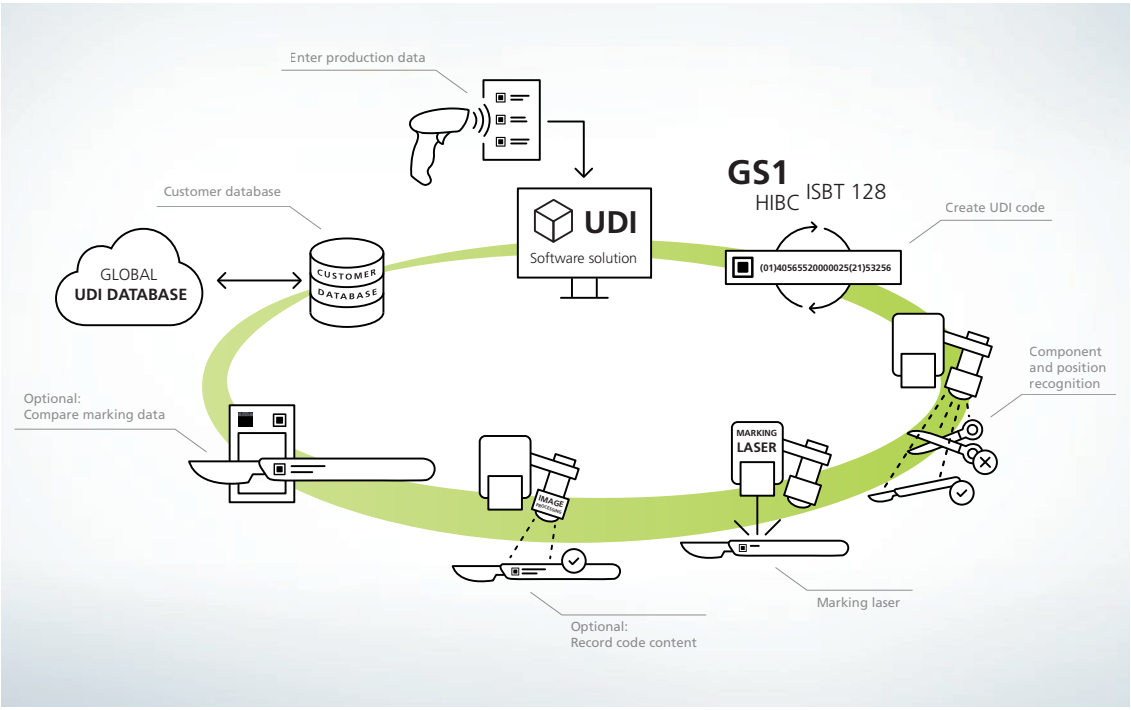


Figure 5: Typical process sequence for laser marking medical devices using a TRUMPF marking system.

Step 1: Customer-specific information can be entered in the system using a handheld scanner or imported directly from a database. TRUMPF offers the option to link up an end-to-end UDI software solution using both standard interfaces and specially programmed custom interfaces.

Step 2: The TruTops Mark Module Interface (TTM-MI) connects the marking laser to all the necessary databases and control systems.

Step 3: The UDI module generates customer-specific codes in accordance with UDI regulations.

Step 4: The TRUMPF VisionLine intelligent image processing system uses state-of-the-art illumination technologies to detect the workpiece and position the marking in exactly the right spot. If a part is wrongly positioned or already has a mark, the software will forward this information to the control system to ensure the part is skipped. A rapid, high-precision autofocus option is also available. This has been tested successfully on all the standard surfaces used in the medical device industry, allowing automation to be used even for the most challenging components.

Step 5: By choosing the best marking laser and process parameters for the job, users can be confident of achieving a high-contrast, permanent mark that meets the required standards for medical device manufacturing. To make this task easier, TRUMPF offers a number of latest-generation laser systems specially designed for the medtech market (TruMark 6030, TruMicro Mark 2000). Equipped with an external power control unit, they deliver constant output power over the entire lifetime of the laser, ensuring high reproducibility and a practical basis for replacing the laser when the time comes. This represents an important new development in medical device manufacturing. It eliminates the costly, time-consuming process of reevaluating the production process each time a new laser is purchased or an existing laser replaced. Quality control based on IQ/OQ validation plays a key role in this context.

Step 6: The VisionLine image processing solution brings automated quality control to the fore. As well as checking batch numbers using the OCR function, it can also recognize, read and evaluate the quality of UDI codes.

Step 7: Having identified the content of the device mark, the system checks it against the database to confirm it is correct. Images can also be stored in the database. This information can subsequently be compiled into a company-specific report. The report typically contains all UDI-relevant and machine-type information and can be stored in the database to ensure robust documentation.

Additional steps

- TRUMPF handles IQ/OQ validation for its laser marking systems.
- A 24/7 service package, available worldwide, meets even the most demanding requirements of three-shift and multi-shift operation.

Conclusion

The latest generation of TRUMPF's intelligent image processing system offers an efficient way to meet the many demands of medical device manufacturing. As well as providing support with positioning and alignment, the software also takes on the quality control tasks that form an integral part of the marking process. With its ability to automatically read batch numbers, bar codes, 2D codes and human-readable text using OCR/OCV, it offers rapid and reliable assistance in detecting nonconformances and automatically identifying noncompliant parts during the marking process. Thanks to its innovative lighting concept, this image processing solution works with virtually all standard surfaces in the medical device sector and is a particularly good choice for highly reflective, curved parts. TRUMPF's intelligent image processing solution is a smart way to enhance quality assurance and increase productivity while maintaining the same processing quality that users have come to expect.

Find out more about smart solutions from TRUMPF:
www.trumpf.com/s/image-processing

TRUMPF

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