Integrated laser marking in the UDI era

Stricter requirements by the UDI directive, ever smaller products and extremely high demands on durability and traceability: The labeling of medical devices presents manufacturers with ever-increasing challenges. For years, the laser system manufacturer Trotec has worked with appropriate marking technologies and has developed an innovative solution with specific parameters that guarantees faultless, precise marking throughout the entire product life cycle. Including a built-in camera for practical and instant control of the codes and easy connection to internal customer databases - for higher process reliability and improved production efficiency.

January 1st, 2020 is a special date for the medical device industry: By then, all products - from dressing materials and reusable tools to pacemakers and other implants - must be marked in compliance with the UDI directives (Unique Device Identification) from the American FDA (Food and Drug Association). Thus, the already challenging production becomes even more complex: On one hand, tools are becoming smaller and more delicate. Information such as expiration dates, batch numbers, etc. that needs to find space on the products is, in turn, becoming more comprehensive and must be completely resistant, regardless of the material, and thus readable in the long term - which was not always possible with previous production methods. The aforementioned UDI labeling also requires a very specific, unique coding for later identification and traceability of the tools.

Built-in camera for instant control

For years, Trotec has recognized these high requirements for the production of medical products and developed innovative quality solutions, which realize a highly precise, repeatable and accurate direct laser marking on the workpiece, in accordance with the UDI directive. The required 100% traceability is ensured, but at the same time Trotec is also constantly working on optimizing the work processes involved in laser marking: “The particular advantage of our system solution is its holistic approach: Thanks to an integrated laser focus finder or camera (Smart Adjust), the correct labeling with plain text and the Data Matrix code are precisely positioned on the product using our intuitive marking software SpeedMark. Using automatic readback by a camera, the code can also be verified directly in the marking device. So another workstation is no longer required,” says Trotec Managing Director, Bernhard Kögl, about the product benefits that international customers particularly appreciate.

With the built-in laser camera device, the company makes a significant contribution to more efficient, streamlined production, which is characterized by high process reliability, short processing times and lower product waste. Thus, a significant cost reduction can be realized. Another plus point in terms of lean manufacturing is the easy connection to external customer databases (e.g. SAP) in order to ensure the transmission of codes and complete documentation.

Competitive advantage due to R&D focus

In order to guarantee this high standard of new and further developments in the long term, and thus provide customers with a sustainable competitive advantage, Trotec relies on intensive R&D activities. At the two development sites in Marchtrenk and Markdorf, employees are constantly working on innovative solutions and customized modifications. The experience gained here or through international projects also ensures compliance with complex FDA certification requirements, which are essential for machines used in America.

Customized solutions

In addition to the Medtec overall system, Trotec also offers individual solutions for permanent and tamper-proof marking of all materials used in the medical sector such as ceramic, metal, etc. The focus is always on individual customer requirements, which can be made-to-measure thanks to the large bandwidth available on both hardware and software: From (extended) standard solutions and entire special machines to automation, everything is possible. In addition, Trotec is considerate of the special requirements of increasingly sophisticated medical technology: For example, to enable the labeling of endoscopes in special formats, the company produces labeling systems of up to 1.30 meters in length. Cutting systems for stents and delicate tubing are also in the portfolio.

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