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Herstellung und Verkauf chirurgischer und endoskopischer Instrumente.
Manufacture and Sales of Surgical and Endoscopic Instruments.

Media Information

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nopa instruments successfully completes MDR certification

nopa is one of the first companies in the industry to meet the requirements of the new European Medical Device Regulations (MDR) and thus remains a reliable supplier for its customers even after the transitional periods have expired

The Tuttlingen-based manufacturer of surgical and endoscopic instruments as well as sterilisation containers, which celebrated its 40th anniversary in April, is one of the first companies in the industry to meet the requirements of the new European Medical Device Regulations (MDR) and thus remains a reliable supplier for its customers even after the transition periods have expired.

Norbert Pauli, founder and managing partner of nopa instruments: "While many of our competitors were counting on the European Union to defuse or even withdraw the new regulations for placing medical devices on the market for reusable class I medical devices before they came into force, we have been pushing full steam ahead with the implementation of the new regulations in order to be able to ensure the sustainable supply to our customers. - Our foreign customers have recently been urging us more and more vigorously to provide the certificates as quickly as possible so that they can continue to participate in tenders."

The EU Regulation on Medical Devices, which was politically initiated as a consequence of the breast implant scandal and came into force on 26.05.2021, is intended to significantly improve patient safety. Hence, all medical devices sold in the European Union must be re-approved by 27.05.2024 at the latest, and the requirements for approval have increased significantly compared to the previous regulation. Manufacturers of reusable surgical instruments are particularly affected by this, as the MDR creates a new category of medical devices in the form of product class Ir, which drastically increases the approval requirements for these products. In view of the large number of different surgical instruments, the instrument manufacturers are therefore particularly affected by the new regulation.

"The revision project MDR gained an incredible momentum within a very short time. Since only a few sub-sectors of our industry were affected by the new regulations as much as we instrument manufacturers, it was clear from the start that it would be difficult to convince the EU to revise their new ruleset just for us. - In Spain or Lithuania, people are not so interested in the effects on Tuttlingen. Therefore, we quickly initiated our undertaking to implement the new regulation for our more than 16,000 articles. The success proves us right: those who started the implementation in time and pursued it with vigour will have completed the re-registration by the end of May 2024," Pauli concludes.