

Reference: Test Equipment Management with PRIMAS validated for the KLS Martin Group

The KLS Martin Group is the umbrella brand for the companies Karl Leibinger Medizintechnik, Gebrüder Martin, KLS Martin and Rudolf Buck as well as for numerous subsidiaries and representative offices around the world. The company manufactures a wealth of different medical products - from surgical laser systems and implants for the mouth, jaw and face to sterilization containers.

KLS Martin Group was looking for a test equipment management solution that would meet the requirements of the medical device manufacturer's GMP and ISO 13485-regulated environment. Testo Industrial Services established the PRIMAS validated IT solution.

The goal

KLS Martin wanted a test equipment management system tailored to its needs and requirements. The holistic solution was to cover the entire process - from calibration, through logistics, and all the way to gauge management in a validated IT system. In addition, KLS Martin wanted to centrally manage the approx. 4500 test devices of its three locations in a GMP-compliant test device management system. This enables the medical device manufacturer to meet the requirements in the GMP and ISO 13485 regulated environment.

Services of Testo Industrial Services

- Introduction of a holistic test equipment management system including project planning: computer-aided management of test equipment, calibration, pick-up and delivery service
- Extensive protective measures to ensure the Data Integrity & Data Security
- Individual authorization concept for access to Calibration & test equipment data
- Initial validation and maintenance of the validated status according to GMP specifications over the entire system life cycle of PRIMAS validated
- Process optimization & central contact for Gauge management and order processing at Testo Industrial Services



Your advantage: Our competence

- Establishment of a GMP-compliant test equipment management system
- Fast implementation with extensive validation
- Holistic solution: all test equipment and all processes related to calibration combined in one solution
- Mapping of the company structure and locations in the system
- Close cooperation and ongoing coordination between the Testo Industrial Services validation team and the KLS Martin Group employees



„We wanted a partner who could support us in all processes related to the calibration of test equipment. From the introduction of PRIMAS validated and also during the validation of the system, regular meetings were held with the experts from Testo Industrial Services. Through some Configuration options, the IT system could be well adapted to our needs and requirements. The entire validation project was straightforward and ended with the handover of the documentation. The team from Testo Industrial Services was able to optimally understand our needs and implemented our requirements perfectly.“

Ingo Preiser
Head of Quality Assurance KLS Martin Group, Mühlheim

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