FOR IMMEDIATE RELEASE

Hohenstein Earns GLP Certification for Medical Device Testing

Good Laboratory Practice Standard Ensures Traceability and Regulatory Acceptance of Safety Studies

BOENNIGHEIM, Germany, July 23, 2025–Hohenstein, an independent testing and research laboratory, is now certified to conduct medical device testing in accordance with the internationally recognized Good Laboratory Practice (GLP) standard. Their accreditation covers chemical, physical and biological safety testing—reflecting an extensive scope not commonly achieved.

GLP was developed to ensure the integrity and traceability of non-clinical laboratory data submitted to regulatory agencies. The standard outlines strict requirements for how health and environmental safety studies are organized, conducted and documented. It ensures quality assurance, traceability and regulatory compliance across personnel, facilities, materials, reporting and data archiving.

While ISO/IEC 17025 focuses on technical competence in testing, GLP adds a layer of structured documentation and quality assurance required for regulatory use.

“We are pleased that, in addition to our existing ISO 17025 accreditation, we now meet all criteria for GLP certification. This international standard enables global comparability and acceptance of our test results,” said Dr. Timo Hammer, CEO of Hohenstein.

Under GLP, Hohenstein Medical conducts biocompatibility testing for medical devices, including chemical screenings, biological in-vitro tests and microbiological evaluations such as bioburden and barrier effectiveness. GLP-compliant studies are recognized by regulatory authorities worldwide, including the U.S. Food and Drug Administration (FDA), and are often required for product approvals in major markets.

GLP-relevant data at Hohenstein is primarily stored digitally. A climate-controlled paper archive has also been built at the company’s headquarters in Boennigheim.

“Along with meeting regulatory requirements, our approach to GLP also reflects our commitment to building trust with our customers,” Hammer added. “They need accurate results, timely delivery and expert guidance—so that’s where we focus our efforts.”

With GLP certification, Hohenstein expands its ability to support medical device manufacturers in meeting the complex demands of international regulatory frameworks.

Visit Hohenstein.US/Medical for more.

Hohenstein Institute America

304 Sroufe Street
Ligonier, IN 46767
Phone: 800.731.9468
E-mail: USA@Hohenstein.com
www.Hohenstein.US

Contact:

Casey Strauch
Phone: 612.239.8830
E-mail: C.Strauch@Hohenstein.com

A Hohenstein technician examines a sample during GLP-compliant safety testing of medical devices. The company is certified under Good Laboratory Practice (GLP), the internationally recognized standard for non-clinical safety studies.
Photo: Hohenstein

GLP-certified biocompatibility testing at Hohenstein includes chemical screenings, in-vitro analysis and microbial evaluations to support regulatory submissions for medical devices.
Photo: Hohenstein

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About Hohenstein
Hohenstein is a leading provider of independent testing, research and certification services with expertise in medical devices, textiles and consumer goods. With more than 75 years of scientific experience and involvement in international standard development, Hohenstein supports manufacturers, suppliers and regulators with data-driven insights for product safety, quality and performance. The company is GLP certified for non-clinical safety testing of medical devices and conducts biocompatibility evaluations including chemical, biological and microbiological analysis. Hohenstein is also a CPSC-accepted third-party laboratory for CPSIA compliance and a founding member and leading provider of OEKO-TEX® services.

Media Contact
Casey Strauch
Marketing Director, Hohenstein
+1 612 239 8830
C.Strauch@Hohenstein.com