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# Hohenstein Medical to debut enhanced medical device testing capabilities at MD&M West

*The contract research organization will launch an expanded ISO 18562 gas pathway testing program and ISO 10993-18 particulate characterization package*

**BOENNIGHEIM, Germany & LIGONIER, Indiana (January 6, 2026) —** At this year's MD&M West show, Hohenstein Medical, a division of Hohenstein Laboratories and a GLP-certified provider of testing, research and certification services for medical devices, will debut its expanded ISO 18562 gas pathway testing capabilities for respiratory devices. The program supports testing of devices operating across temperature ranges from -20°C to 50°C.

"Respiratory devices often operate across a wide range of environmental conditions, which introduces additional considerations under ISO 18562," said Dr. Timo Hammer, CEO of Hohenstein Medical. "Enhancing our testing capabilities allows us to support designs that more accurately reflect intended use and evolving regulatory expectations. MD&M West provides an opportunity to discuss these considerations directly with manufacturers facing complex device requirements."

Gas pathway testing supports biological assessment of a device or accessory intended for ventilation or the supply of substances via the respiratory tract. The laboratory's ISO 18562 gas pathway testing is supported by a climate-controlled chamber (~10 ft × 10 ft × 8 ft; ~800 cubic feet) designed to accommodate complete respiratory systems, supporting evaluations that reflect full-device configuration and intended use conditions. This expanded gas pathway testing offering is just one example of the continuous investment in and optimization of Hohenstein Medical's high-capacity testing facilities.

In addition, Hohenstein Medical offers ISO 10993-18 analytical chemistry testing for medical devices, and will offer a particulate characterization package exclusive to MD&M West attendees at no additional cost as part of its chemical characterization services. The package is designed to provide additional context around particulate size and distribution when visual particulate observations are identified. Particulates are a common challenge in biocompatibility assessments and can raise questions during regulatory review.

"We are always monitoring the changing regulatory landscape and collaborating closely with our customers to define efficient, scientifically sound testing strategies that support regulatory review while prioritizing patient safety," said Katie Brinkman, biocompatibility program manager at Hohenstein Medical. "We care deeply about the success of our customers, because at the end of the day, we all want the same thing: to deliver life-saving medical devices to patients as quickly as possible, without sacrificing quality."

Drawing on in-house biological and chemical expertise, Hohenstein Medical works with manufacturers to define fit-for-purpose biocompatibility strategies, anticipate regulatory questions and support patient-focused risk assessment.

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Hohenstein Medical is among the few ISO/IEC 17025 and GLP-certified medical device testing labs accredited in chemical, physical and biological testing—providing a coordinated, integrated approach to medical product evaluation. This full-scope capability supports consistent, efficient studies, producing data of the highest integrity, aligned with FDA, MDR, ISO 10993 and other global regulatory requirements to reduce handoffs and support consistent, regulator-ready data across studies.

Additional details will be available at the Hohenstein Medical booth (#447) during MD&M West and at Hohenstein.US/Medical.

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**About Hohenstein Medical**
Hohenstein Medical is a global, best-in-class GLP-certified and ISO/IEC 17025-accredited laboratory, conducting biocompatibility testing for medical devices, including chemical screenings, biological in-vitro tests and microbiological evaluations such as bioburden and barrier effectiveness. Hohenstein is one of the few laboratories accredited in chemical, physical and biological testing — offering an integrated approach to medical product evaluation. This full-scope capability provides manufacturers peace of mind with consistent, efficient studies aligned with the U.S. Food and Drug Administration (FDA), European Medical Device Regulation (MDR), ISO 10993 and other global regulatory requirements.

Hohenstein Medical offers comprehensive consulting and testing services, including single-use and reusable products, finished devices and components, patient-contact materials and protective equipment — all tailored to the intended use, contact classification and regulatory pathway. The company's team works in close collaboration with clients and customizes study designs when standard methods are not sufficient.

Hohenstein Medical is a division of Hohenstein Laboratories, a leading provider of independent testing, research and certification services with more than 75 years of scientific experience and involvement in international standard development.

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