Medical Device NEWS

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Navigating PFAS: Preparing for medical device regulatory hurdles

The bioaccumulation of PFAS compounds within the body is linked with a wide array of health issues. These compounds are widely used in the medical device industry due to their durability, heat resistance, and lubricity; but with a dizzying 15,000+ compounds, the health and environmental impacts of use are largely unknown. Also known as forever chemicals, these accumulate over time and is of concern as recent studies link PFAS with a wide array of health issues, so their toxicological effects must be studied and characterized to ensure long-term patient safety. *Read more on p. 2*

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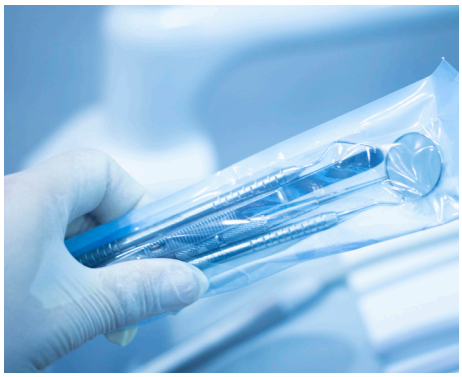
Contact US *to learn more about how we are Testing for Life.*

Turn scientific evidence into regulatory success when you partner with our consultants

The launch of Consulting Insights establishes Eurofins Medical Device Services' consulting division and signals a clear intent to deliver end-to end client solutions. *Read more on p. 3*



Regulatory Must Reads: Stay on top of the latest ISO updates

The regulatory landscape is an ever-evolving moving target where medical device manufactures must stay informed and poised to pivot their products to meet changing needs of patients and regulators.. *Read more on latest updates and how we can help navigate on pages 4-6*

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Navigating PFAS: Preparing for medical device regulatory hurdles

Leonard Harris, Senior Scientific Advisor, Eurofins Medical Device Services

The bioaccumulation of PFAS compounds within the body is linked with a wide array of health issues. These "forever" compounds are widely used in the medical device industry due to their durability, heat resistance, and lubricity; but with a dizzying 15,000+ compounds, the health and environmental impacts of use are largely unknown. Known as forever chemicals, these accumulate over time and are of concern as recent studies link PFAS with a gamut of serious health issues, so their toxicological effects must be studied and characterized to ensure long-term patient safety. As such, government and regulatory agencies are enacting measures to limit or ban the use of these compounds, leaving many manufacturers wondering how to mitigate imminent PFAS regulations and the impact these will have on their medical devices and raw materials suppliers.

Eurofins Medical Device Services launches PFAS testing solutions

Eurofins Medical Device Services North America is pioneering PFAS testing in the medical device industry with GMP PFAS testing and PFAS Risk Assessments in 2025. Using a combustion ion chromatography system at the Lancaster, PA, campus, the process screens for the presence of PFAS in medical devices, both intentional and unintentional, from concept and supply chain to final finished product. This testing quantitates compounds through screening for the fluoride ion within a GMP quality system to ensure data withstands regulatory scrutiny.

Leading medical device manufacturers are preparing for regulations, developing mitigation strategies for the future in terms of fiscal liability regarding the effects of these compounds, the environment, and the population. Implementing PFAS testing early in device development will allow device manufacturers to get ahead of regulations and avoid future shutdowns, recalls, and liability concerns, while supporting sustainability goals.

New Eurofins Consulting Insights turns scientific evidence into clear regulatory success with end-to end client solutions

Craig Hopson, Senior Director of Medical Device Services Consulting, Eurofins Medical Device Services

Eurofins Medical Device Services has launched Consulting Insights, establishing a new consulting division and signaling the company's clear intent to deliver end-to-end client solutions. Consulting Insights, a division of Eurofins Medical Device Services, is designed to translate scientific evidence into actionable regulatory insight. We connect non-clinical data development with practical regulatory guidance, moving your team across the medical device development lifecycle.

Clients are already seeing the difference in core deliverables. Toxicological Risk Assessments arrive with transparent rationales tied to materials, use conditions, and clinical context. Biological Evaluation Plans are sized to actual risk and map directly to extraction and analytical work, making testing purposeful – not generic. Biological Evaluation Reports link study results and literature into conclusions that are easy to navigate and difficult to dispute. Together, these documents read as a single narrative and often reduce the number of clarification rounds, which saves time and preserves budgets.

Eurofins' approach begins at inception. Our consultants create data development plans to align testing requirements with regulatory strategy. Whether guiding FDA engagement via Q-Submission or supporting your premarket submission, our regulatory experts and scientists work in lockstep to produce integrated, reliable, and actionable data.

People and technology make this scalable. This new business unit for Medical Device Services is led by me; I bring 20+ years building high performing consulting organizations. Our dedicated Regulatory Intelligence team, led by Hal Stowe, tracks emerging guidance and reviewer trends and translates them into practical insights for clients and for our service design. Consulting operations strategy, led by Ashley Harger, focuses on standardizing processes and implementing project tracking, resource allocation, and reporting systems, so that leaders see utilization, bookings, delivery health, and completion cycles in real time.

Consulting Insights is here to support our MedTech partners. Whether you're a start-up navigating the regulatory landscape towards your first 510(k) premarket notification, a mid-sized manufacturer refreshing Biological Evaluation Reports and Toxicological Risk Assessments to align with ISO 10993 or a global MedTech group charting a De Novo pathway for your next-generation device, we meet you where you are. We also support combination products that need coordinated drug and device evidence, packaging and sterilization validations ahead of launch, and remediation programs that benefit from disciplined program management leadership. When you want science, strategy, and execution operating as one to streamline the path to FDA authorization, Eurofins is your trusted partner.

Are you ready for the significant changes coming to ISO 10993-1 and 3 in the very near future?

Kimberly Ehman, PhD, DABT, Head of Regulatory Toxicology, Eurofins Medical Device Services

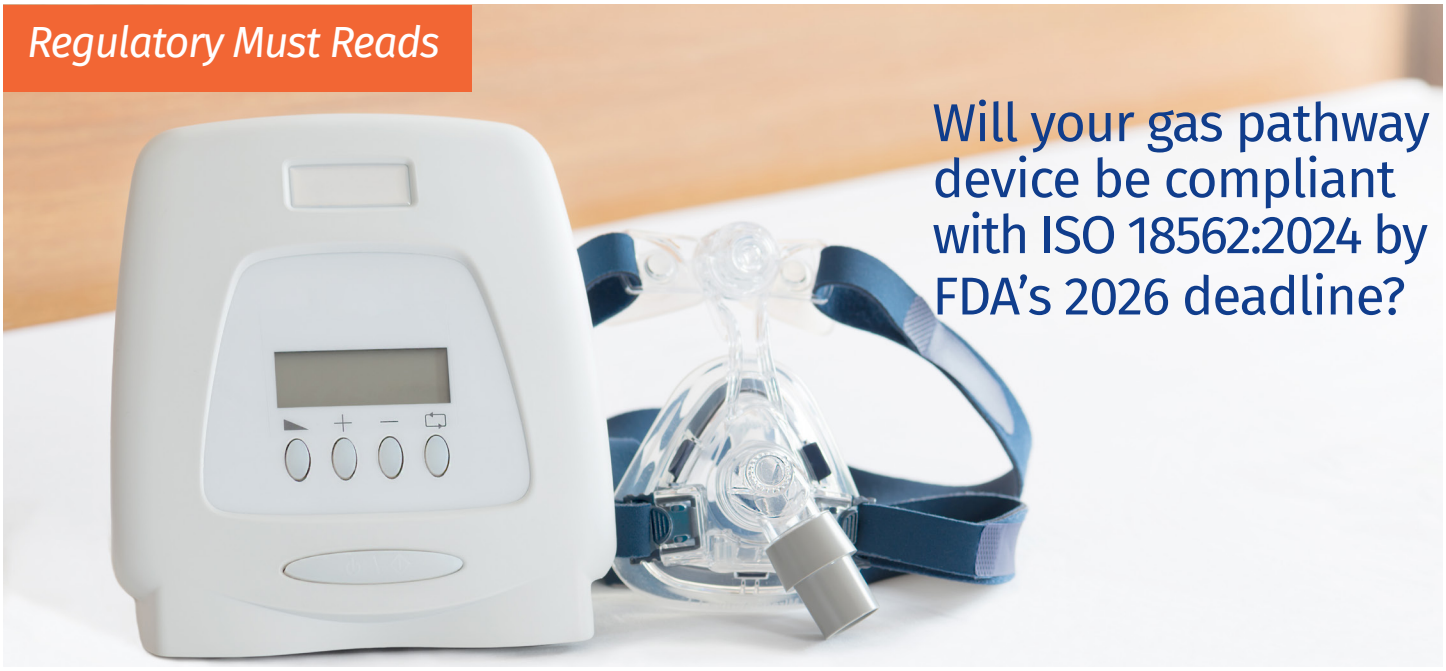
There have been extensive discussions around the changes coming to ISO 10993-1, which is expected to be published this fall. Some of the major changes include emphasis on a risk-based approach, life cycle considerations, changes to calculation of exposure duration, and overall modifications to how medical devices will be categorized. As many devices will now be categorized differently, there may be additional testing requirements (e.g., genotoxicity) that were not previously considered in your previous test package. Also, ISO 10993-3, the standard for genotoxicity, carcinogenicity, and developmental and reproductive toxicity (DART), is also under revision and expected to move to Final Draft International Standard (FDIS) this fall. Here are highlights of some of the major changes coming to ISO 10993-3.

Eurofins toxicologists have been extensively involved in the development of both the ISO 10993-1 and -3 revised standards and are available to provide support if you have questions or concerns around how these changes may impact previous or new submissions.

ISO 10993-3 was last updated in 2014. During the last 11 years, there have been considerable shifts in the way biological endpoints can be addressed, particularly with respect to the use of chemical characterization and toxicological risk assessment. As such, the updates to the revised version of ISO 10993-3, which is currently a Draft International Standard (DIS), reflect these different approaches.

ISO 10993-3 is applicable when the need to evaluate a medical device for potential genotoxicity, carcinogenicity, reproductive toxicity, and developmental toxicity has been established. The current version of the standard (2014) is titled "Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity." In the ISO/DIS 10993-3, the title has changed to "Biological evaluation of medical devices – Part 3: Evaluation of genotoxicity, carcinogenicity, reproductive toxicity, and developmental toxicity." The updated title, which includes the addition of "developmental toxicity," reflects several changes throughout the standard that focus on evaluation of these endpoints through the use of chemical characterization (ISO 10993-18) and toxicological risk assessment (ISO 10993-17). One of the main reasons for the shift in terminology from "test" to "evaluation," particularly with carcinogenicity and DART endpoints, is due to the limitations and challenges that medical devices (or extracts) present in these biological assays. Some other significant changes include the addition of an annex on genotoxicity evaluation of nanomaterials, guidance around genotoxicity evaluations for constituents that are not easily detected using non-targeted chemical characterization approaches (e.g., aldehydes), and approaches for the evaluation of non-genotoxic carcinogenicity.

If you have any questions around the potential impact of ISO 10993-1 or -3 changes in your medical device testing program, Eurofins toxicologists are available to support your device-specific questions and help you design a test program that meets both current and upcoming regulatory requirements.



Will your gas pathway device be compliant with ISO 18562:2024 by FDA's 2026 deadline?

Kevin Wells, Research Fellow, Extractables & Leachables Testing; Andrew Blakinger, Senior Manager, Chemistry, Extractables & Leachables Testing and Toxicology Services; Eurofins Medical Devices Services

As we head into the fall of 2025, it seems odd to discuss compliance with a 2024 standard; however, the grace period for compliance ends soon. We are now less than a year away (July 2026) from the FDA requiring all gas pathway medical devices to have testing completed according to the 2024 version of ISO 18562. ISO 18562-1 through ISO 18562-4 outline testing required to ensure patient safety for any medical device used to supply gas to a patient. Eurofins Medical Devices Services has the capabilities to perform the three analytical portions of the ISO 18562:2024 series as well as the corresponding risk assessment.

The previous version of ISO 18562 series was published in 2017. Let's take a quick look at some of the testing changes from the 2017 version to the 2024 version.

ISO 18562-2:2024 Test for emissions of particulate matter:

Eurofins Medical Devices Services uses a calibrated particle counter to measure the number of particulates emitted from the device. Under the 2024 version, the minimum duration of sampling should be the maximum intended cumulative daily exposure. In most cases, this means a 24-hour sampling period is most appropriate, although a shorter duration may be justified in some cases for non-continuous use devices.

ISO 18562-3:2024 Test for emissions of volatile organic substances:

Part 3 of the standard was updated to require evaluation of a broader range of Volatile Organic Substances (VOS), including very volatile, volatile, and semi volatile organic compounds. Eurofins evaluates these three categories of VOS via a thermal desorption GC/MS method based on ISO 16000-6:2021. The 2024 standard also directs testing for aldehydes and carbonyls. Eurofins developed an LC/MS method to evaluate and target the aldehyde and carbonyl compounds from the gas pathway devices. Another update to the 2024 version is centered around the time course required for testing of prolonged and/or long-term use devices; the outcome is that VOS sample collection may now have to extend beyond 30 days.

ISO 18562-4:2024 Test for leachables in condensate:

Part 4 of the 2024 standard includes possible justification for not performing the leachables in condensate testing if the experimentally determined amount of condensate that reaches a patient under worst-case clinical conditions is no more than 0.1 mL in 24 hours. But in practice, it is often difficult to determine this condensate value experimentally. If testing is needed, the 2024 version of the standard requires GC/MS, LC/MS, and ICP/MS testing during the evaluation of leachables in condensate. In order to ensure this testing is conducted in alignment with FDA's current expectations, Eurofins follows the guidelines outlined in FDA's Draft Guidance "Chemical Analysis for Biocompatibility Assessment of Medical Devices," published in Sept. 2024.

Final Thoughts

If you believe that your gas pathway device has not been evaluated to the 2024 version of ISO 18562 or was not in alignment with current regulatory expectations, we recommend contacting Eurofins Medical Device Services to ensure that your gas pathway device is fully compliant prior to the July 2026 deadline. Our skilled team of experts can conduct the required testing as well as the corresponding toxicological risk assessments to ensure a smooth regulatory approval process for your device.

Ethylene Oxide (EO) Sterilization – Changes to ISO 11135 and ISO 10993-7 you should know

Jessi Dōne, Sr. Director of Microbiology & Sterilization, Medical Device Services

Ethylene oxide (EO) sterilization continues to play an essential role in ensuring sterility for heat- and moisture-sensitive medical devices. However, recent revisions to ISO 11135, governing EO sterilization validation, and ISO 10993-7, addressing EO residuals, are changing the regulatory landscape and how manufacturers bring products to market.

The most impactful updates involve lowering allowable EO residual limits based on device size and intended use. ISO 10993-7 now enforces stricter thresholds for both EO and ethylene chlorohydrin (ECH) residues, particularly in smaller or implantable devices where exposure per patient body weight is proportionally higher. This ensures reduced toxicological risk and greater patient safety.

ISO 11135 complements this by reinforcing cycle development, process validation, and monitoring requirements. Manufacturers must not only demonstrate sterility assurance but also prove through robust testing that residual EO complies with new toxicological limits. These changes increase the burden on device makers—requiring improved aeration strategies, additional testing, and careful material selection, since some polymers retain EO longer.

For end users and patients, the benefit is clear: medical devices with lower risk of irritation, carcinogenicity, or systemic toxicity. For manufacturers, the challenge lies in adapting processes without delaying time-to-market or increasing costs excessively.

For manufacturers, the challenge lies in adapting processes without delaying time-to-market or increasing costs excessively.

How Eurofins Medical Device Services can help

Eurofins Medical Device Services provides comprehensive expertise and laboratory support to help manufacturers meet these evolving requirements. With specialized capabilities in EO residual testing, toxicological risk assessments, and sterilization cycle validation, Eurofins partners with clients to ensure compliance with ISO 11135 and ISO 10993-7. Our global network offers guidance on material compatibility, customized aeration studies, and regulatory strategy, helping device makers reduce risk, accelerate product release, and maintain patient safety as the top priority.

By leveraging Eurofins' technical depth and regulatory knowledge, manufacturers can navigate these stricter EO standards confidently—turning compliance into a competitive advantage.

Engage with our experts

MEDevice Boston 2025
September 30-October 1
Boston Convention & Exhibition Center
Booth #1035
Innovation Spotlight Theatre Presentation
Wednesday, October 1 at 11:00 am-11:45 am
Title: *PFAS in the Medical Device Industry: Implications and Regulatory Considerations*
Presenter: Leonard Harris
In this discussion, we will explore the role of PFAS in medical devices, outline the emerging regulatory landscape, and discuss strategies for identifying and managing PFAS across the supply chain. Attendees will gain insight into possible sources of PFAS that may be unexpected and how to assess a manufacturing train to reduce risk.

MedTech Conference
October 5-8
San Diego Convention Center
Booth # 833 / 831

MD&M Medtech Midwest 2025
October 21 - 22, 2025
Minneapolis Convention Center
Booth # 3313

Medevice Silicon Valley
November 19-20
Santa Clara Convention Center
Booth # 952

Want to speak directly to our team?

Contact US at: ***Medical-Device@BPT. EurofinsUS.com***

Visit: ***Eurofins.com/medical-device***

Need a testing partner to ensure your medical devices are safe and meet regulations?

Schedule time with one of our Scientific Business Development experts like **Shaundrea Rechsteiner.** Regional Sales Manager of Medical Device Services Midwest, Shaundrea has 30+ years of medical device testing experience, with extensive knowledge in sterilization, chemistry, and toxicology. Contact Shaundrea @ ***shaundrea.rechsteiner@bpt.eurofinsus.com.***

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E&L, Biocompatibility, Toxicology

Tailored into a single workflow, our coordinated packages optimize timelines with toxicologist-guided studies. Minimize delays and headaches while ensuring regulatory compliance.

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2. E&L and Chemical Characterization
3. Toxicological Risk Assessment
4. Biocompatibility Testing

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