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ISO 18562 Testing of Breathing Gas Pathways

ISO 18562 was released in March 2017 to evaluate the biocompatibility of breathing gas pathways in medical devices. This four-part standard provided the framework to determine acceptability of medical devices that require breathing gas pathways, including guidelines for clinically relevant flow rates.

ISO 18562 addresses three hazards associated with gas pathways of medical devices: emissions of particulate matter (PM2.5 and PM10), Volatile Organic Compounds (VOCs) emitted in a gas stream, and leachables in condensate for devices that deliver humidified gas. This standard also provides three methods to be used for collecting leachable substances: using clinical use conditions to form condensation in the pathway, circulating water in the pathway similar to clinical use, or performing aqueous extraction according to ISO 10993.

Eurofins Medical Device Testing has extensive experience in ISO 18562 testing for breathing gas pathways of medical devices. Involved since the standard's inception, we have developed platform methods for all three parts of the standard.

Choose Eurofins Medical Device Testing to help you:

- Understand the testing requirements of ISO 18562.
- Use particle counters to measure particulate matter emitted from your device.
- Analyze, quantify and identify VOCs using Gas Chromatography Mass Spectrometry (GC/MS).
- Analyze, quantify and identify leachables in condensate using GC/MS, Liquid Chromatography Mass Spectrometry (LC/MS), and Inductively Coupled Plasma (ICP).
- Interpret inhalation toxicity data relevant to breathing gas pathways for your device per ISO 10993-17.
- Perform additional testing, as required, for ISO 10993-5 and ISO 10993-10.
- Ensure a complete regulatory submission while saving valuable resources.

Services Available

- ISO 18562-1: Evaluation and testing within a risk management process
- ISO 18562-2: Tests for emissions of particulate matter
- ISO 18562-3: Tests for emissions of volatile organic compounds (VOCs)
- ISO 18562-4: Tests for leachables in condensate
- Toxicological Assessments
- Complementary ISO 10993 Testing*

*In addition to ISO 18562, all breathing gas pathways must be evaluated by ISO 10993

Instrumentation

- Agilent Time-of-Flight (TOF) or Quadrupole Time-of-Flight (QTOF) with LC
- Agilent MS with GC and PerkinElmer TurboMatrix 350 ATD
- Agilent 7900 ICP/MS
- PerkinElmer Optima 5300 Inductively Coupled Plasma (ICP-OES) Spectrophotometer
- TSI DustTrak™ Aerosol Monitor 8533
- Proprietary Manifold for Assessing the Biocompatibility of Gas Pathways