ISO 18562–Part 4
Leachables

The testing associated with part 4 of ISO 18562 quantifies and analyzes hazardous water-soluble substances that could leach in condensate, entering into the gas pathways of the device, and transfer to the patient.

Compounds that are leached from the respiratory device are detected and identified. A safety assessment of the device on the patients is then conducted.

From neonatal incubators to CPAP machines, we recognize that the accuracy of our results directly impacts some of the most compromised patients around the world. That is what we are motivated by everyday."

~Dr. Matthew Heidecker, Vice President

Engineering
Testing
Production

Your Full-Service Biocompatibility Partner.

PSN LABS

5368 Kuhl Road
Erie, PA 16510

814.464.0790
info@PSNLabs.com

www.PSNLabs.com

PSN LABS

www.psnlabs.com
info@psnlabs.com

ISO 18562 Testing

Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications

ISO 9001:2015 Certified
ISO 13485:2016 Certified (Molding)
ISO/IEC 17025:2017 Certified (Testing)

- Ventilators
- Neonatal Incubators
- Anesthesia workstations
- Breathing systems
- Breathing Tubes
- Resuscitators
- Oxygen conserving devices
- Oxygen concentrators
- Masks
- Nebulizers
- CPAP Machines
- Humidifiers
- Etc

ISO Certified Labs

Our state-of-the-art Testing Laboratory is ISO/IEC 17025:2017 accredited and fully equipped to support all your material and product testing needs. Our lab operates as a stand-alone service, as well as being integrated into our full spectrum of engineering services.

PSN's experience and expertise crosses over a wide range of industries, products, and manufacturing processes, allowing our team to be a best-in-class choice to help determine and correct the risks associated with device manufacturing.

ISO 18562

In 2017, ISO 18562 was released and added to ISO 10993-1 as the standard for toxicity studies in respiratory devices and components, required by United States and European Union regulatory bodies. The standard analyzes three areas of potentially hazardous materials:

ISO 18562-2: Particles

ISO 18562-3: VOCs

ISO 18562-4: Leachables

The PSN Test Lab is equipped with industry leading equipment for qualification of devices and the generation of data for FDA submissions. At PSN, we are so much more than just a test lab. Our team of scientists and engineers are trained to isolate confounding variables and provide clear analysis to guide the commercialization of new medical devices.

ISO 18562–Part 2
Emissions of Particulate Matter

The testing associated with the first of three sources of potentially hazardous materials looks specifically for particles from 0,2 µm diameter to 10 µm diameter that are being emitted by the device and/or its components. The emission of any particles could enter the respiratory system via the respirable gas stream, causing dangerous conditions for the patient.

ISO 18562–Part 3
Volatile Chemicals

Volatile Organic Compounds (VOCs) can be emitted from the gas pathways of respiratory medical device, including its plastic parts and accessories, adhesives and greases.

This testing program will detect any potential contamination that could be conducted to the patient, while using these life saving devices, from the polymeric compounds of the device components.

The detection of these chemicals is extremely important to devices, as VOCs can cause irritation to the patients respir-

Purpose:

- Volatile Organic Compounds (VOCs) above the FDA threshold are required to be reported
- Toxicological Data
- Threshold of Toxicological Concern (TTC)

Next Steps:

Should testing conclude that the VOCs are above regulated levels, PSN is equipped to then analyze the manufacturing process and/or materials of construction to provide the necessary corrections, reducing exposure to harmful VOCs to the patient and assisting in FDA 510(k) submissions.

Your Full-Service Biocompatibility Partner.