

Biocompatibility testing of respiratory gas pathways according to ISO 18562

ISO 18562 versus ISO 10993

In the ISO 10993 series of standards, the biological evaluation of medical devices is regulated. Nevertheless, the respiratory gas pathways of medical devices are not sufficiently covered there. To enable an appropriate biological assessment of respiratory gas pathways in medical devices, the tests defined in the **ISO 18562** series of standards take additional specific requirements into account.

The tests are suitable for

Medical devices, parts or accessories that contain gas pathways or that have gas-mediated contact with the respiratory pathways:

- THERAPEUTIC MEDICAL PRODUCTS, e.g. ventilators, monitoring devices for respiratory gases, anaesthesia workstations, incubators
- PRODUCTS FOR CONDITIONING OF GASES, e.g. nebulisers, humidifiers, filters for ventilators, oxygen concentrators
- Products for the TRANSMISSION OF GASES, e.g. ventilation tubes, masks, Y-connectors

Requirements for test samples

The number of test samples depends on the area of application and the operating lifetime of the product. Our experts can assist you and draft a customised test plan for your product.



Tests according to ISO 18562

Tests are planned on a product- and application-specific basis in accordance with ISO 18562-1..

ISO 18562-2: Testing for particulate emissions

During this test, particles with a diameter of 0.25 µm to 10 µm that could be released from the medical device into the breathable gas stream are quantified. Specified limits are used to protect patients from excessive quantities of particles from gas pathways.



ISO 18562-3: Testing for emissions of volatile organic substances

The semi-quantitative test allows the measurement of emissions of volatile organic substances (VOS) that can be added to the respiratory gas flow through the gas pathways of medical devices.

In addition to volatile organic compounds (VOC), VOS also include very volatile organic compounds (VVOC) and semi-volatile organic compounds (SVOC). The acceptance criteria of the standard ensure that patients are protected from ingesting harmful quantities of VOS.

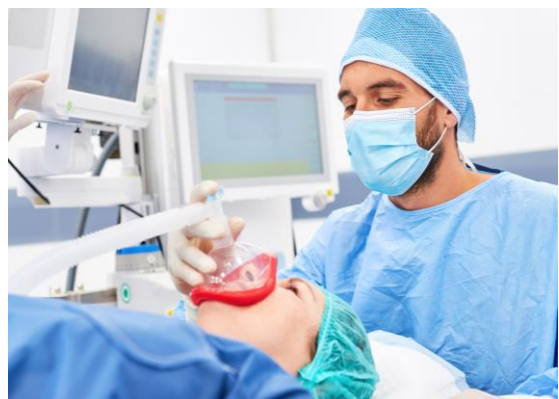
ISO 18562-4: Testing for leachables in condensates

Depending on the application, medical devices with respiratory gas pathways may come into contact with the patient's breath and/or humidified gases. This can lead to condensation in the gas pathways of the medical device. The condensate can also release substances from the materials that may come into contact with the patient.

The test analyses leachable substances in the condensate to protect the patient from high levels of harmful substances.

The following biological and chemical tests can be carried out on the aqueous extract:

- Cytotoxicity according to DIN EN ISO 10993-5,
- Sensitisation according to DIN EN ISO 10993-10, Annex C,
- Skin irritation according to DIN EN ISO 10993-23,
- Organic extractable substances and Elementary extractable substances



Optional:

The following analyses are optionally available:

- **Ozone:** recommended for gas pathways in contact with active electromechanical or electrostatic parts in normal condition
- **CO, CO₂ and NO_x:** recommended for gas pathways in which inorganic gases are generated or concentrated