

Testing of isolators and safety cabinets in accordance with the Product Safety Act

Safety cabinets and isolators are indispensable devices in laboratories and the pharmaceutical industry, which must reliably fulfil either microbiological or chemical safety requirements, or both, depending on requirements.

TÜV NORD CERT ensures transparency by testing and awarding the GS mark („Tested Safety“). The certification is aimed at manufacturers who want to document and communicate their voluntary commitment to enhanced safety.

tuev-nord.de



Certification and standards

TÜV NORD CERT offers certifications for safety cabinets and isolators: Safety cabinets are certified in accordance with the EN 12469 and DIN 12980 standards, while isolators are tested specifically in accordance with DIN 12980. These standards define the specific performance requirements for different areas of application:

- **EN 12469** defines the performance criteria for biological safety cabinets. It ensures that the safety cabinets protect the operator, the product and the environment from potentially hazardous microorganisms. EN 12469 includes requirements for airflow, filtration performance and the design of the safety cabinets to ensure a safe working environment.
- **DIN 12980** is specifically designed for the requirements of safety cabinets and isolators for the handling of cytotoxic substances and other CMR drugs. It specifies strict requirements for the design and operation of safety cabinets in order to maximise protection against hazardous particulate chemical substances.

Advantages of certification

Safety and trust: The GS mark is known and recognised in Europe and many other countries as a sign of quality and safety. The mark indicates that this product has been tested by an independent institution. In competition with non-certified products, this results in a marketing advantage: certification strengthens the credibility of product information and advertising claims and helps to limit product liability risks.

Certification process

The certification process for safety cabinets and isolators guarantees the highest quality and safety standards. It has several crucial steps:

1. Type examination:

A detailed type examination is carried out in the TÜV NORD laboratories. This test ensures that the product fulfils the specified performance criteria and takes all safety-relevant aspects into account. The manufacturer must provide a test sample and the complete documentation.

2. Documentation review:

The technical documentation and instructions for use are thoroughly checked to ensure that all information is clear and precise and meets the requirements of the standards.

3. Inspection of the production facilities:

An inspection of the production facilities is carried out regularly to ensure compliance with quality standards and the correct implementation of production processes in the long term..

Why TÜV NORD CERT?

Our experts have in-depth specialist knowledge, many years of industry experience and are actively involved in the further development of product standards. We ensure continuous expertise in customer support through regular qualifications. To create a reliable basis for the testing and confirmation of requirements, there is the globally recognised accreditation by the German Accreditation Body. You should not do without this accreditation when choosing your testing laboratory. TÜV NORD CERT has therefore been accredited by the German Accreditation Body in accordance with DIN EN ISO/IEC 17025:2018 and for the certification body in accordance with DIN EN ISO/IEC 17065:2013.

For more information about our certification process for safety cabinets and isolators, please contact us at info.tncert@tuev-nord.de.



Your benefits from working with TÜV NORD

- competent contacts in your area
- current engineering expertise
- many years of experience
- successful reference projects worldwide
- Expertise in cross-disciplinary areas within the TÜV NORD GROUP

For more information contact us at:



TÜV NORD CERT GmbH

Große Bahnstraße 31 · 22525 Hamburg

Am TÜV 1 · 30519 Hannover

Am TÜV 1 · 45307 Essen

Phone +49 800 245-7457

info.tncert@tuev-nord.de · www.tuev-nord.de