

Berlin Cert within the AFNOR Group



Shareholders

Berlin Cert GmbH became a 100% subsidiary of GUTcert on June 1st, 2016.

GUTcert is an internationally recognized certification body for management systems, products, personnel and suppliers and offers knowledge transfer in this field.

Since 2008 GUTcert has been a member of the AFNOR Groupe (Association Francaise de Normalisation) – the French standardization organization similar to the German DIN (German Institute for Standardization).



Services within the network

Through the merger with GUTcert, we offer our customers a comprehensive variety of services, ranging from testing and certification to trainings.



Certifications

ISO 9001
ISO 14001
BS OHSAS / ISO 45001
AZAV
ISO 22000 (-FSSC)
ISO 27001 / ITSX
ISO 50001
Testation acc. to SpaEFV:
Alternative Systems
Energy Audit according to DIN EN 16247

In conjunction with AFNOR et al
ISO TS 22163 (IRIS Rev. 03)
IATF 16949
AS 9100

and EMAS according to



Verifications

Emission reports (ETS)
Carbon Footprint acc. to ISO 14064
Airport Carbon Accreditation

Evaluations

ISCC / REDcert / RSPO
EEG 2009 / 2012 / 2014 / 2017
Biomethane Injection
Guarantees of origin (HKN)

Certified waste management
Privacy Policy
Asset Management ISO 55001

Aluminium Stewardship Initiative
State of sustainable development (DNK and GRI)



Berlin Cert is a **Notified body** for guideline 93/42/EWG Systems (annexes II, V, VI) Products (annex IV)

DAKKS **Certification body** for ISO 13485

Testing laboratory for medical products



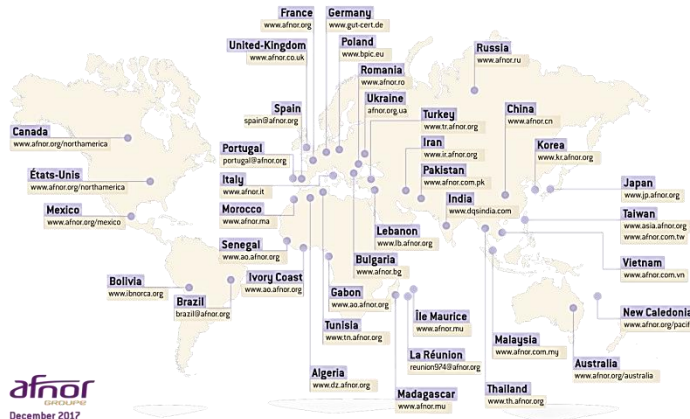
GUTcert Akademie

UM / QM / EnMS / ISMS u.a.
Auditor's and manager's trainings

Inhouse courses

Customized e-Learnings

The AFNOR Group worldwide | Commercial relations with over 100 countries
40 locations

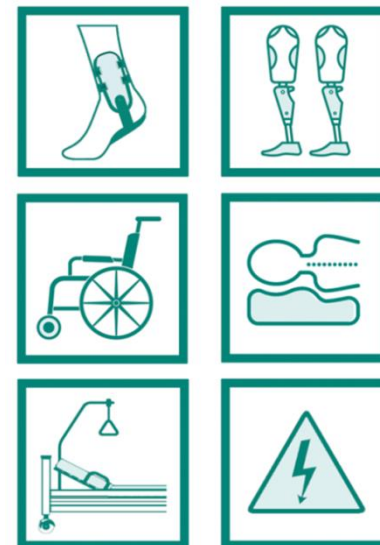


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Berlin Cert

Testing and certification body for medical devices



About us



Notified body and accredited certification body for medical devices

With the help of our team of highly qualified auditors, we certify quality management systems according to DIN EN ISO 13485:2016 as well as quality assurance systems according to Directive 93/42/EEC, Annex II, V or VI.

The safety and reliability of the products represents an essential aspect in the requirements to be complied with. For manufacturers of Class I medical devices or service providers (e.g. medical supply stores, orthopedic technicians), certification of the quality management system is not required by law, but is increasingly asked for within the framework of contracts with trading partners or cost units.



Berlin Cert – accredited testing body for medical devices

The Berlin Cert testing laboratory is accredited by the DAkkS (German Accreditation Body) according to DIN EN ISO / IEC 17025:2005 and recognized by the ZLG (German Central Authority for the safety of medicinal products and medical devices).

Our test engineers offer their support within a wide range of testing services



Testing of active medical devices

- Testing of basic safety and essential performance characteristics according to EN 60601-1
- Evaluation of usability according to EN 60601-1-6
- Testing of propulsion and control systems for electric wheelchairs according to ISO 7176-14
- Comprehensive testing of electric wheelchairs and mobility scooters according to EN 12184
- Comprehensive testing of beds used for medical purposes according to EN 60601-2-52
- Further testing according to the EN 60601 series of standards



Testing of rehabilitation equipment and medical aids



Our range of testing includes diverse product groups within the health and regeneration sectors. For example, we test requirements for geometry, stability, braking performance, energy consumption, speed and strength for



- Wheelchairs, stairclimbers, walking aids, standing aids,
- Beds, patient lifts, changing tables,
- Shower and toilet chairs, bathtub seats, toilet seat boosters,
- Handles & access aids and more

We test, i.e., according to the internationally recognized standards DIN EN 12182; DIN EN 12183; DIN EN 12184; ISO 7176 series; ISO 17966.



External prostheses (artificial limbs)

For our customers we carry out static and fatigue strength tests on complete leg prostheses, prosthetic feet and orthoses. The testing laboratory is accredited by the DAkkS for static and dynamic tests on prosthetic units, adapters and connecting elements according to DIN EN ISO 10328.



Anti-decubitus aids

We test mattresses, supports, alternating pressure systems and seat cushions for pressure relief, shear force, microclimate, operating volume and functional properties.



Orthoses and bandages

The testing of microclimatic properties for products of PG 5 and 23 is a basic requirement for the aids directory registration.

Special tests

Complete normative testing are usually carried out at the end of a *successful product development*. For target-oriented product development, it is advisable to carry out additional *preliminary or partial tests* in the early development stages.



Berlin Cert provides competent support with extensive testing options. In addition to simplified testing, our test experts also carry out testing under more stringent conditions – depending on the individual wishes of our customers – objectively and professionally:

- Preliminary checks
- Objective examination of prototypes and individual samples during development
- Support for large and small businesses and organizations – from start-ups to universities
- Prototype testing
- Objective tests according to the customer's procedures
- Testing methods validated in the Berlin Cert laboratory
- Testing in direct comparison with a secondary product



Ask our experts! You will receive prompt information on the testing options for your product or an individual implementation of your testing method in our laboratory.