Radiation Protection

X-ray and stray radiation equipment is regulated by the German radiation protection legislation. The German X-ray ordinance (RöV) and radiation protection ordinance (StriSchV) determine the requirements for working with ionised radiation in order to protect the public, operating personnel and patients.

We are officially authorised according to § 4a RöV to conduct all necessary technical tests for x-ray and stray radiation equipment in the Federal States of Saxony and Thuringia and issue certificates as prerequisites for the notification procedure.

Contact

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For more information about our services, please visit www.slg.de.com.
Test laboratory for medical devices

Manufacturers of medical devices have to meet high expectations by patients and doctors. Technological innovations characterise the market. At the same time, the legal framework is being tightened.

**Product liability** is vital for medical devices. At SLG, we offer manufacturers of medical devices all testing services and mandatory certifications to enable them to market their products legally. Firstly, we research the valid standards for your product.

**Our services**
- Safety and functionality tests
- Assessing performance
- EMC testing
- Metrological evidence
- Assessment of risk analysis
- Evaluation of medical software
- Classifying laser devices

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**Notified Body - Scopes**

We are notified by the Central Office for Safety Equipment of all German Federal States (ZLG) for products in the following fields:

- **General active medical devices**
  - MD 1102 Respiratory devices, devices for oxygen therapy, inhalation anaesthesia
  - MD 1103 Devices for stimulation or inhibition
  - MD 1104 Surgical devices
  - MD 1105 Ophthalmologic devices
  - MD 1106 Dental devices
  - MD 1108 Rehabilitation devices and active prostheses
  - MD 1109 Devices for patient positioning and transport
  - MD 1111 Software
  - MD 1112 Medical gas supply systems and parts thereof

- **Devices for imaging**
  - MD 1201 Imaging devices utilising ionising radiation
  - MD 1202 Imaging devices utilising non-ionising radiation

- **Monitoring devices**
  - MD 1301 Monitoring devices of non-vital physiological parameters
  - MD 1302 Monitoring devices of vital parameters

- **Devices for radiation therapy and thermotherapy**
  - MD 1401 Devices utilising ionising radiation
  - MD 1402 Devices utilising non-ionising radiation
  - MD 1403 Devices for hyperthermia/hypothermia

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**Certification of medical devices**

As a Notified Body, we are entitled to carry out conformity assessment procedures according to the Medical Device Directive 93/42/EEC for active medical devices as well as issue certifications according to the MDD 93/42/EEC annex procedure as requested by the customer.

The customer may select between the following procedures according to MDD depending on their requirements:
- EC declaration of conformity acc. to annex II (full quality assurance system)
- EC type-examination acc. to annex III
- EC verification acc. to annex IV
- EC declaration of conformity acc. to annex V (production quality assurance)
- EC declaration of conformity acc. to annex VI (product quality assurance)

**CE marking**

A conformity assessment procedure according to MDD 93/42/EEC is required for CE marking and for the use of the Notified Body’s registration number.

**Certification of quality management systems**

We certify your quality management system for medical devices according to **DIN EN ISO 13485**. We also offer certifications according to **DIN EN ISO 9001**.