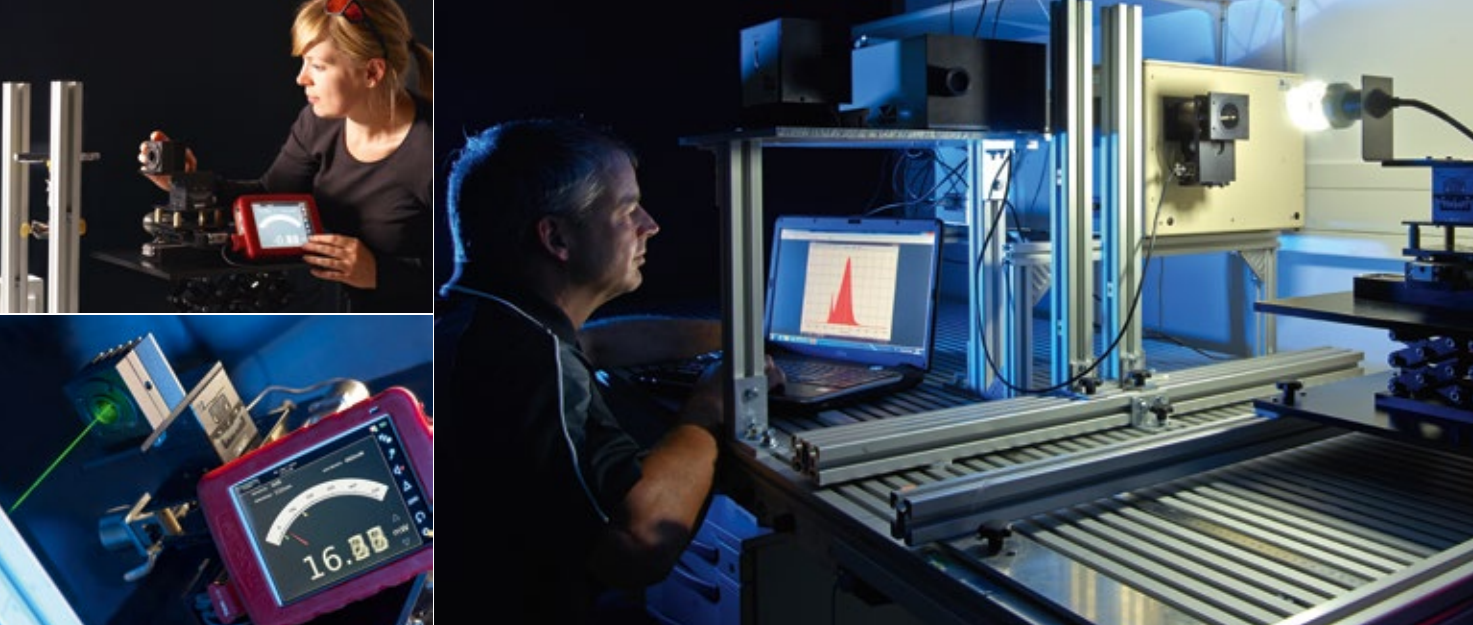




Medical devices and laser safety

For the safety of patients and
operating personnel



Radiation Protection

Laser classification and photobiological safety

In order to protect consumers' health we test lasers and LEDs e. g. according to the following standards:

- Complete assessment of safety of laser equipment as well as laser classification acc. to DIN EN/ IEC EN 60825-1 (all standard editions)
- Complete assessment of photobiological safety of lamps and lamp systems acc. to the parameters defined in DIN EN 62471

Testing of x-ray and stray radiation equipment

SLG is acknowledged in accordance with §6 of the German X-ray Ordinance (RöV) for testing and trial of medical and technical x-ray and stray radiation equipment.

Training on expertise in radiation protection

Our partner institute SLG Akademie GmbH provides acknowledged training courses on radiation protection acc. to RöV. Visit www.slg-akademie.de for more information.

Contact

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Do you have any questions?

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For more information about our services, please visit
www.slg.de.com.



SLG – Notified Body CE 0494 and accredited as well as recognised test laboratory. We carry out standard compliance tests and conformity assessment procedures according to the Medical Device Directive 93/42/EEC for active medical devices.





Testing active 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 testing services and mandatory certifications to enable them to market their products legally.

Our services

- › Standard research
- › Safety and functionality tests
- › Assessing performance
- › EMC testing
- › Metrological evidence
- › Assessment of risk analysis
- › Evaluation of medical software
- › Classifying laser devices
- › Thermography
- › Determining aluminium equivalent
- › Classification of ophthalmologic sources acc. to DIN EN 15004-2
- › Measuring ultrasonic fields with hydrophone

Certification services

As a Notified Body, we carry out conformity assessment procedures acc. to the Medical Device Directive 93/42/EEC for active medical devices within our notified scope and acc. to the annex procedure as requested by the customer.

The customer may select between the following procedures acc. 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

In many cases 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.

Our notified scopes

We are notified by the German Central Authority of the Federal States for Health Protection (ZLG) for assessing products of the following scopes:

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 1402 | Devices utilising non-ionising radiation |
| MD 1403 | Devices for hyperthermia/hypothermia |