

## Services for medical device manufacturers

From identification of needs to  
safe application



Medical Center of Excellence

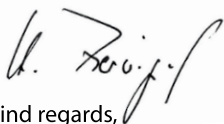
## Services for medical device manufacturers (MDS)

### From identification of needs to safe application

Welcome to Medizin im Grünen, your medical centre of excellence at the gates of Berlin. In our testing laboratory, ideas are turned into safe medical devices: Applications are simulated in a protected testing environment and optimised in confidential dialogue between users and developers. Here you will meet renowned specialists who are committed to safe medical devices by passing on their experiences and skills. Take advantage of the focussed stillness to research and develop without any distractions, surrounded by state-of-the-art medical devices and perfect equipment. Our specialists, partners, suppliers and the Medizin im Grünen team will devote their undivided attention and maximum commitment to you.

*“The only way to make happen what is possible is to persist in chasing the impossible.”*

(Hermann Hesse)



Kind regards,

Dr. Heiko Ziervogel

Owner and Managing Director



## Testing of medical devices – Safe and transparent

The society's expectations regarding more transparency in the use and application of new technologies can only be fulfilled by employing reliable processes for testing the safety and verifying the benefit of medical devices. Medizin im Grünen offers quality-assured processes in compliance with the statutory requirements.

## From idea to prototype

Innovation processes contribute to better understanding the future needs of users in the hospital. Building on this, new ideas can be verified at an early stage in our testing environment. At the end, the application idea is elaborated with specific product features and the technical feasibility is verified. Use our advanced application laboratory to specify and further develop identified needs in preclinical application.

## Development up to marketing authorisation

The requirements for medical device manufacturers include conducting a risk analysis and risk assessment to verify the product's safety as well as conducting a clinical evaluation and investigation to verify the product's performance and efficacy. Together with our investigators, we support you in planning and conducting preclinical and clinical investigations as well as in developing invasive or implantable medical devices.

## Market launch up to reimbursement

The successful use of medical technologies in patient care is the result of a combination of many factors: A first-rate product, experienced specialists and responsibly acting patients. Take advantage of our expertise in training medical device consultants, doctors and assistants. Create with us a solid basis for the safe application of innovative medical devices.

## Market monitoring

Monitoring the safety and performance of medical devices throughout the entire product lifecycle is a central task during the implementation of quality management systems for medical devices. Our testing laboratory is always open to you. It guarantees the quick validation of clinical observations to rule out risks by comparison with validated results and exposure to standardised test conditions.

## First of all – our quality commitment:

Our project plans provide information on the planned and available resources as well as all persons involved. It lays down in detail all technical framework conditions and schedules for the planned test runs. Our test conditions perfectly comply with the requirements set forth in the relevant standards.



### In dialogue with specialists:

Our investigators are experts in their medical specialities. They provide advice and guidance throughout the development cycle of innovative medical devices in daily clinical routine and here in the testing laboratory of our medical centre of excellence.

### Professional variety:

We are in constant professional dialogue with experienced experts from a multitude of medical disciplines, such as anaesthesia, intensive care medicine, trauma surgery, orthopaedic surgery, general surgery, visceral surgery, cardiothoracic surgery, paediatric surgery, neurosurgery, urology, gynaecology, oncology, pneumology, neonatology, paediatric medicine, gastroenterology, plastic surgery, radiology and pathology.

### For individual doctors and entire teams:

The market launch of every new medical device starts with the training of the new diagnostic or therapeutic procedure to support doctors in the confident handling of routine and unexpected situations. Medizin im Grünen is your competent and experienced partner for training interdisciplinary and interprofessional teams.

### Best models instead of patients:

At our centre, the professional medical application of medical devices in diagnosis and treatment starts without a patient. Doctors and skilled nurses work with carefully and responsibly selected models, ranging from computer-based simulations and animal or human specimens to anaesthetised animal models.

### Environment for research and development:

Our facility offers you ten medical functional rooms and four seminar rooms for research, development and training. The modern cafeteria with its spacious terrace provides an inviting place for you to have professional discussions.

### Compliance with statutory provisions:

Professional accreditations, regulatory approvals and certifications by the German regional medical associations have been obtained for all projects. The methods and models are selected carefully and responsibly. Of course, compliance with ethical and legal requirements is ensured.

### Permanent availability:

Our team is at your disposal from Mondays to Sundays between 8.00 am and 6.00 pm. We will give you a warm welcome and guide you with diligence and patience through your innovation and development process, all the way to the marketing authorisation. Contact us in good time to arrange the dates and the necessary resources.

### The proof – your feedback:

Just like you, we want to be among the best. The satisfaction of all involved in the project is the sole benchmark of our activities: Feel free to compare us with similar providers.

### Get in touch with us:

Our experienced team is at your disposal for all questions. Call us on: +49 33679 429810 or contact us by email: [info@medizin-im-gruenen.de](mailto:info@medizin-im-gruenen.de).

**Sandra Fells,**  
Team Leader Project Consultants



**Sybille Kreße,**  
Team Leader OR Staff



## Tested medical devices for safe application

### Testing – Safe and transparent

Medical devices are subjected to extensive technical and clinical testing according to internationally accepted, standardised methods before they are investigated as part of comprehensive clinical trials and used on patients. The society's expectations regarding more transparency in the use and application of new technologies can only be fulfilled by employing reliable processes for testing the safety and verifying the benefit of medical devices. Medizin im Grünen provides for quality-assured processes in compliance with the statutory requirements.

### Practice for new medical devices

Where can you test and investigate a new procedure or innovative product safely and reliably? At our medical centre of excellence. And what's more: Experienced users of medical devices provide support throughout the entire development cycle, all the way to the successful market launch. The doctors and engineers research, develop and test the products in our testing laboratory that resembles a modern hospital with highly specialised operating rooms, intensive care unit and emergency department. You are working on patient models with state-of-the-art technologies and experienced assistance. The testing of your medical devices is performed just as responsibly as in day-to-day practice – always measured on success.

### A wide range of methods and models

At our centre, the professional medical product application in diagnosis and treatment starts without a patient. Before the start of each project, the persons involved will reflect on the current knowledge and evidence base – quickly and concisely. Medical sub-steps or complete procedures are performed with the new product in small teams. The safe and reliable application in clinical practice is tested analytically. All patient features required for the procedure are simulated. Your new medical device is used on carefully and responsibly selected models – from computer-based simulations to animal and human specimens to the anaesthetised animal model. The selection will always be based on what is needed to achieve the agreed testing objectives. Of course, compliance with ethical and legal requirements is ensured. Professional accreditations and regulatory approvals have been obtained for all product applications.

## Superiority through tested innovations

### In dialogue with specialists and engineers

Innovation processes at the beginning of the development of innovative medical devices contribute to better understanding the future needs of users in the hospital. Based on this, new ideas can be verified at an early stage in our testing environment. At the end, the application idea is elaborated with specific product features and the technical feasibility is verified. Use our advanced application laboratory with state-of-the-art medical devices and professional equipment to specify and further develop identified needs in practical application. Our investigators are experts in their medical specialities. They provide advice and guidance throughout the development cycle of innovative medical devices in daily clinical routine and here in the testing laboratory of our medical centre of excellence. We are in regular professional dialogue with experienced experts from a multitude of medical disciplines.

### Focussed stillness

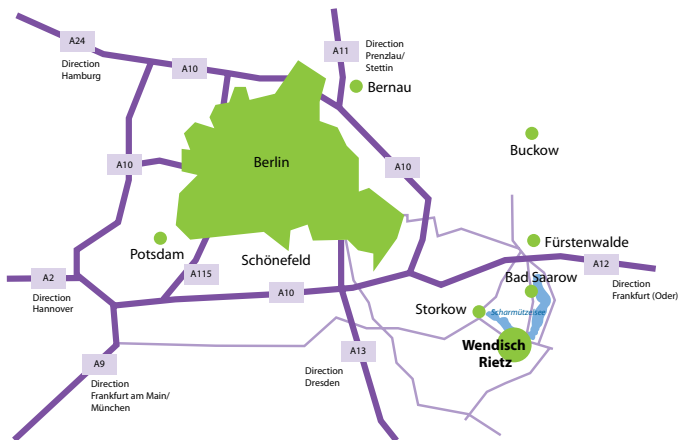
Medizin im Grünen operates a medical centre of excellence for doctors – close to the city life and directly at the Scharmützel Lake. On an area of more than 1,300 square metres, the best conditions for creative research and thorough development are waiting for you. You will find a focussed stillness, enabling you to concentrate on research and work undistractedly. Take advantage of these possibilities and focus on the well-being of patients during the development and application of medical devices.

### Transparency succeeds

For us, maximum transparency is part of quality. Just like you, we are passionate about being among the best. This is why we are dedicated to quality assurance and evaluate every project according to predefined criteria – from identification of needs to planning, all the way to implementation. We provide a detailed description of all project steps. Finally, our clients will always have the opportunity to rate the process, the persons involved and the working environment in our testing laboratory. The company is DIN EN ISO 9001:2008-certified. Feel free to compare us with other providers. The feedback given by participants and lecturers is also available at our Quality Monitor on [www.medizin-im-gruenen.de](http://www.medizin-im-gruenen.de). Simply choose the best offering!

# medizin im grünen

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