MEDCER

spineserv GmbH & Co. KG

Need support with Clinical Evaluation or Clinical Studies?

Contact us

www.medcer.com.tr | info@medcer.com.tr

www.spineserv.com | experts@spineserv.de

Who We Are?

MEDCER

MEDCER is founded in 2015 by Mehmet Fatih Örmeci. MEDCER is accredited on ISO 13485 as a certification body from 2016 to 2020. MEDCER continues to activities on ISO 13485:2016 certification as 3rd party certification body together with partners. In addition to this, MEDCER provide supplier audits and internal audits according to ISO 13486, 2017/MDR and 21 CFR 820 for their clients.

MEDCER also provides consultancy services to clients for technical documentation on legal requirements and quality management systems. These covers design dossier and technical file preparation for EU legal requirements and 510(k) submission file preparation for US legal requirements.

MEDCER also supporting medical device industry for post market surveillance activities and clinical evaluation consultancy.

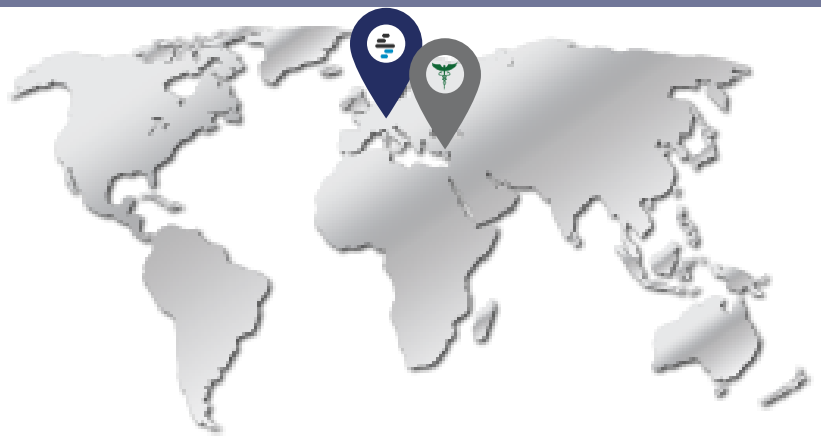
spineserv GmbH & Co. KG

SpineServ is a spin-off company of the research group of Prof. Dr. Hans-Joachim Wilke (Institute of Orthopaedic Research, University of Ulm, www.biomechanics.de). It was founded in 2007 and is specialized in providing a broad variety of mechanical testing services for medical devices. For this purpose SpineServ is accredited according to DIN EN ISO/IEC 17025:2018.

Spinal implants, osteosynthesis implants, endoprostheses and dental implants, surgical instruments, implant materials and biomaterials undergo static testing, dynamic fatigue testing, wear testing or corrosion testing either according to standards (ASTM, ISO) or following custom testing procedures.

Due to our expertise in biomechancis, medicine and biology we also offer our know-how to answer questions regarding the mechanical safety and effectiviness of medical devices through scientific consulting, expert opinion and literature reviews.

Contact - Our Location in Turkey and Germany



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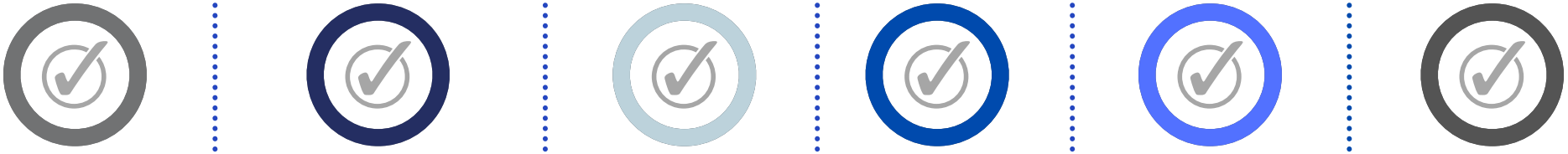
OUR SERVICES



Literature Search

Benchmark device clinical experience research

Pre-Clinical Testing

Clinical Trial

Post Market Clinical Follow-Up

Post Market Surveillance

Contact us

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Literature Search

With our expert team, we have services for the systematic scanning, selection and evaluation of literature-based clinical data, as well as the retrospective or prospective evaluation of clinical data consisting of medical devices whose suitability has been evaluated, and even the creation of clinical research protocols in accordance with the legislation.

Benchmark device clinical experience research

Data for the state of the art which may relate directly to the device in question and/or to equivalent devices, benchmark devices and similar devices and technologies as well as to the medical alternatives available to the intended patient population.

If a manufacturer possesses its own clinical data for the device, this is a definite plus. The literature is then considered together with the data to enable a consistent appraisal and overall analysis.

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PRE-CLINICAL TESTING

The preclinical medical device testing is conducted to determine the performance and safety based on the benchmark values.

SpineServ performs the mechanical tests, which are among the preclinical performance data.

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Medical Device Testing and Services

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Medical Device Testing and Services

Device Categories and Testing Facilities

Spinal implants

- internal fixators
- Plates
- Intervertebral body fusion devices
- Vertebral body replacement implants
- Intervertebral disc prostheses
- Nucleus replacement implants
- Extradiscal motion preserving implants

Endoprostheses

- Total and partial hip joint replacement implants
- Total and partial knee joint replacement implants
- Anatomical and reverse shoulder prostheses
- Ankle joint replacement implants
- Small joint replacement implants

Osteosynthesis

- Plates and screws
- External fixators
- Intramedullary systems
- Gliding nails
- Staples, wires, etc.

Others

- Dental implants
- Catheters
- Implant materials
- Surgical instruments

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CLINICAL TRIALS

What kind of services can we offer you for clinical trials?

- **Documenting Clinical Investigation Protocol**
- **Review and Feedback of Clinical Investigator's Brochure**
- **Carry Out Clinical Investigation Application To Competent Authority**
- **Carry Out Clinical Investigation In Accordance With Existing Clinical Investigation Protocol**

The innovations in the EU Medical Device Regulation (EU MDR 2017/745) could, if implemented strictly, result in the fact that equivalence of comparable products will no longer be recognised. In this case, own clinical investigations must be carried out before placing the product on the market.

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Post Market Clinical Follow-Up

What can we do for you?

- Documenting PMCF Protocol
- Carry Out PMCF Study Application To Competent Authority
- Carry Out PMCF Study In Accordance With Existing PMCF Protocol

We can carry out your PMCF studies in Turkey with our medical team from every branch.

Contact us

Post Market Surveillance

Our post-market surveillance activities services:

- Documenting PMS Plan
- Documenting Post Market Surveillance Report or Periodic Safety Update Report
- Carry Out Post Market Surveillance Activities and Updating Technical Documentation In Accordance

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