

## CONTACT US!



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MIK's holistic approach accompanies you along the innovative pathway from the initial idea to the certification of your innovative products. Where established analytical and testing methods are lacking, we develop new methods tailored to your needs. Our experts are also available to assist you with the evaluation and interpretation of the results after comprehensive testing.



## ABOUT THE NMI

The NMI is a non-university research institution and conducts application-oriented research in the bio- and material sciences. It has an interdisciplinary range of expertise for R&D and services for companies in the healthcare, vehicle, mechanical engineering and toolmaking industries. In research, the NMI cooperates with many top-class institutions. It is supported by the Baden-Württemberg Ministry of Economic Affairs and is a member of innBW.

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## MIK COMPETENCE CENTER

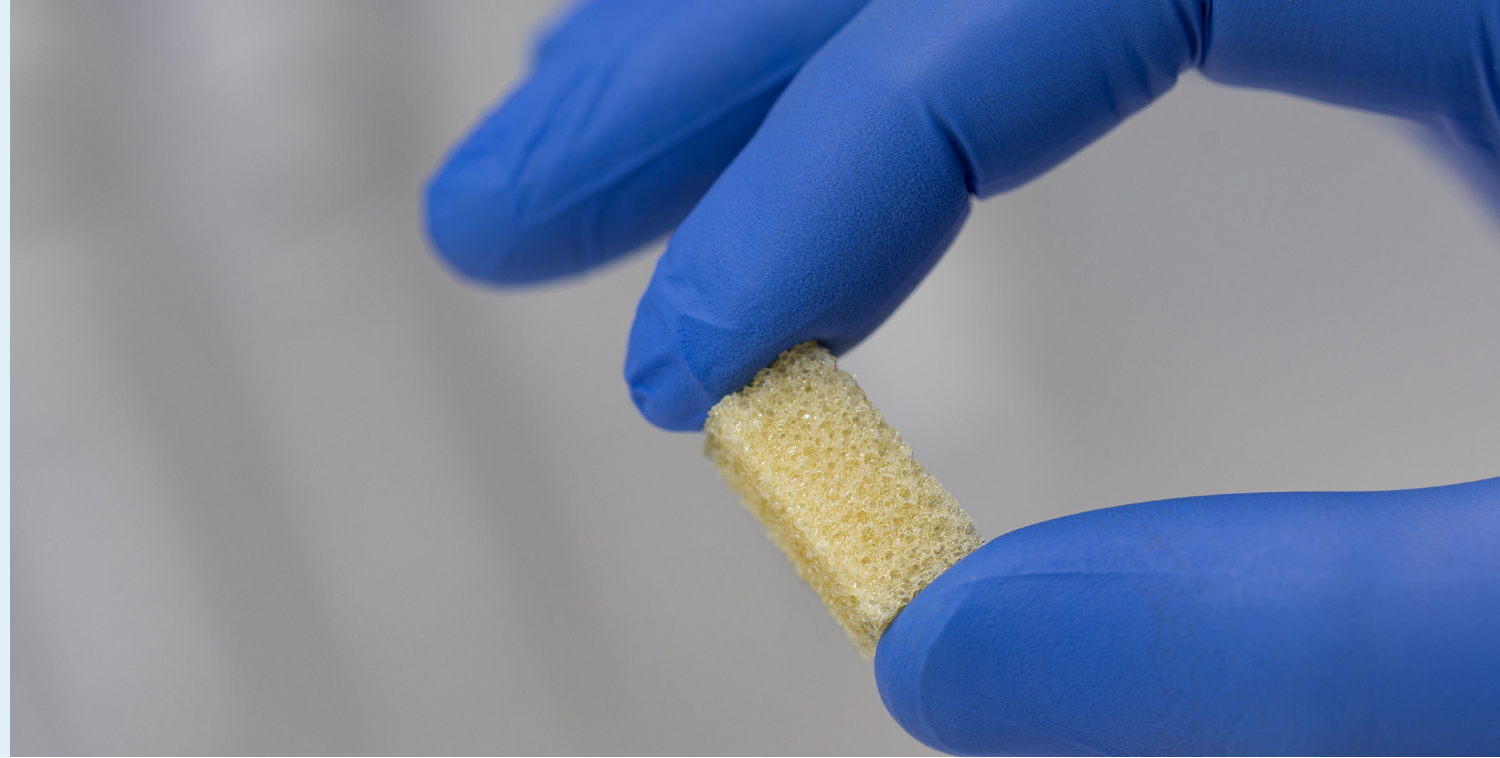
### Concept to final product



## MDR & IVDR

**The strict regulations on medical devices (MDR) and in vitro diagnostics (IVDR) pose major challenges for the healthcare industry.**

**As a competence center, MIK offers consulting and development services tailored to the needs and requirements of the industries concerned.**



### Services

- Reviewing regulatory requirements
- Evaluating biological and technical data
- Designing test plans
- Evaluating and reviewing clinical data
- Establishing risk management in accordance with DIN EN ISO 14971

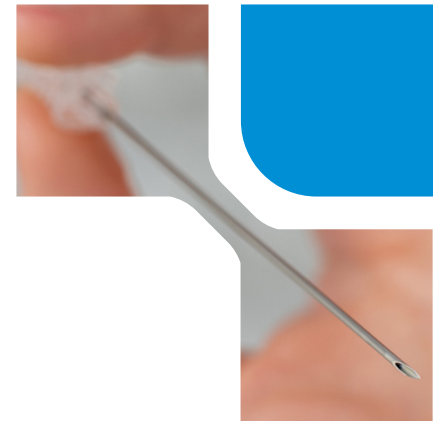


### Biological assessment

- In vitro cytotoxicity based on ISO 10993-5
- Immune response to biomaterials
- In vitro degradation tests
- Detection of degradation products based on ISO 10993-13, -15
- Antibacterial efficacy based on ISO 22196, 20743
- Pyrogenicity according to Ph.eur. 2.6.14

### Surface analysis

- Coating analysis
- Topography
- Chemical characterization
- Surface wettability
- Cleanliness testing



MDR- & IVDR-  
Kompetenzzentrum

supported by BIOPRO Baden-Württemberg