

SERVICE RANGE FOR MEDICAL DEVICES



Storage stability/ Shelf-life

Accelerated aging, real-time storage

Surface analysis

Morphology Damage characteristics Abrasion (SEM, EDX)

Surface analysis Quantification of bioactive coatings

Cleanliness/ Hygiene

Hygiene monitoring in production

Biocompatibility

Cytotoxicity (DIN EN ISO 10993-5)

Biocompatibility

Irritation (DIN EN ISO 10993-23) **Mucous irritation**

Wearables

- Fitting
- Body size data
- 3D scanning

Biocompatibility

Chemical characterization (DIN EN ISO 10993-18)

MUST-HAVES FOR MEDICAL **DEVICES**

Biocompatibility

Sensitization (in vitro)

Cleanliness/ **Hygiene** Verification of cleaning & sterilizati<u>o</u>n processes

(biomonitors)

Cleanliness/ Hygiene

Microbial load of the product (Bioburden ISO 11737-1)

Chemicals Management

REACH SVHC

Wearables

- Skin and microclimate
- Breathability
- Thermal insulation

Cleanliness/ Hygiene

Barrier properties (microbe penetration)

Effectiveness

Disinfectant test according to EN 14885 and VAH

Odor analysis

Performance of the product vs. sweat, urine, wound odor

Regulatory Affairs

- Risk & Quality Management
- **Biological Evaluation**
- **Clinical Evaluation**

Production Processes

- Quality assurance
- Plant design
- **Process validation**

Product development

- Engineering
- **Quality Management**

OFFERS THROUGH OUR NETWORK