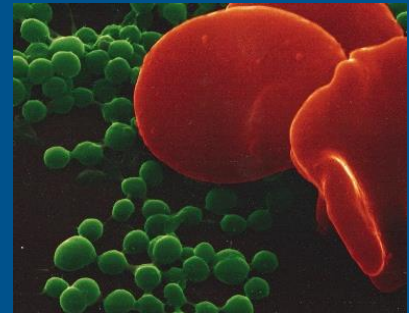


# Biocompatibility testing

## Aim

Tests based on the DIN EN ISO 10993 series of standards (mandatory for medical devices) can be used to assess the product in terms of its compatibility with the skin, mucous membrane and the immune system.



## Customer benefit

- Biocompatibility analysis to confirm that your product has no negative impact on living tissue
- Knowledge of the product, assessment and evaluation of its toxicological potential
- Testing by an accredited laboratory using state-of-the-art animal-free methods
- Consumer safety through testing by a neutral institute
- Avoidance of complaints
- If the tests are passed, the label “Medically tested” can be awarded for the product



## The tests are particularly suitable for

- Bedding
- Yarns
- Clothing worn close to the body
- Textiles for allergy sufferers or sensitive target groups
- Jewelry and accessories



## Tests

- Cytotoxicity test according to DIN EN ISO 10993-5 to exclude a cell-damaging effect
- Cytotoxicity test for elastane-containing materials according to DIN EN ISO 10993-5 in combination with Wiegand, C. et al. (2017)\*
- In vitro skin sensitization test (screening method), for the assessment of the risk potential of the tested product to cause allergies
- Irritation test with the reconstructed human epidermis model (RhE model) according to DIN EN ISO 10993-23
- HET-CAM according to DB-ALM Method Summary n° 96, recognized alternative to the Draize test (rabbit eye test), for the exclusion of a chemical irritation
- Test for harmful substances according to the STANDARD 100 by OEKO-TEX® standard



\*Optimized protocol for the biocompatibility testing of compression stockings and similar products with close skin contact in vitro. *The journal of the textile institute*, Vol. 109, No. 7, 891-902.



## Test sample requirements

### General

- For ready-made samples, send the complete product
- In the event of complaints, provide the product in question for testing, if possible (please do not provide retain samples)
- Test samples must be packed individually to avoid contamination during transport, i.e. pack them separately e.g. in plastic bags
- Provide sufficiently precise designations of the test sample (material composition, item number, etc.)

### Quantity of material

- At least 40 g of the test sample (for each individual test)

### Test duration

- Usually 10-15 working days (per individual test); date confirmation after receipt of test sample