

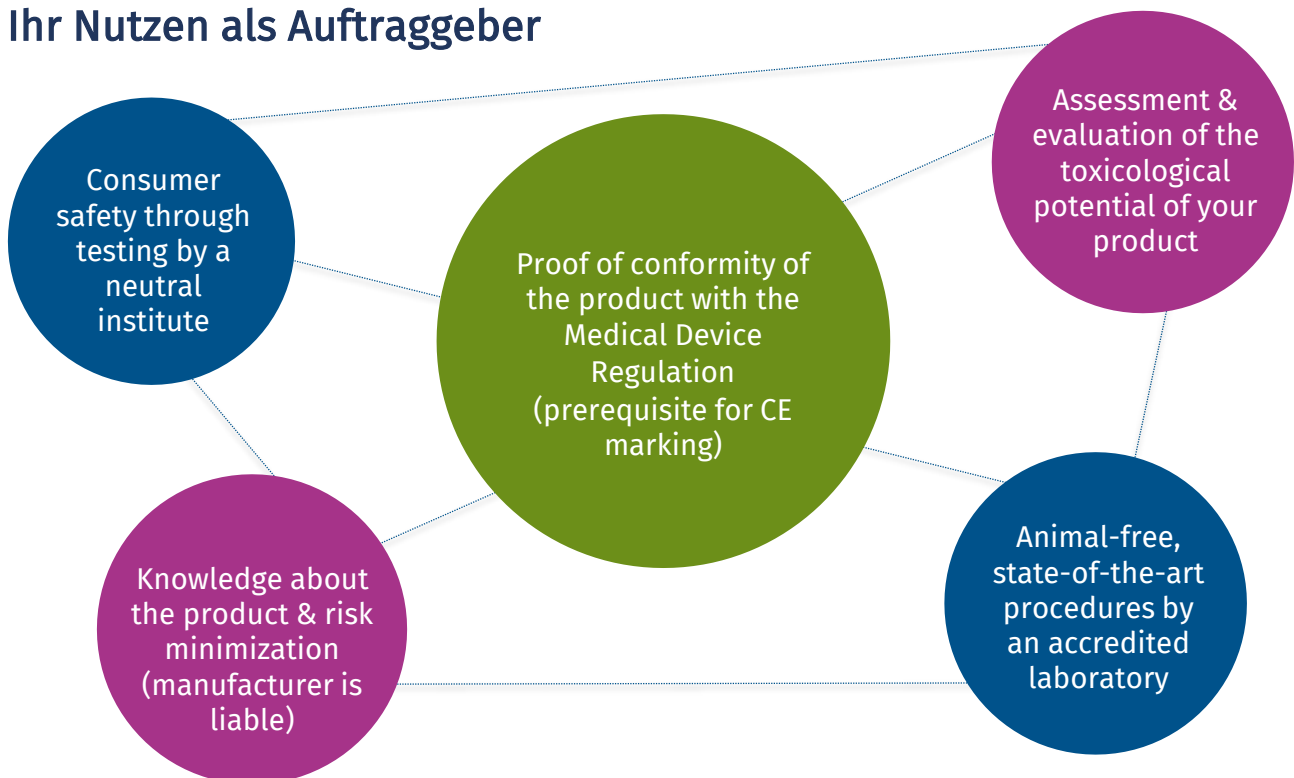
Biocompatibility of medical devices

Objective

The tests of the DIN EN ISO 10993 series of standards are intended to minimize the risk to the user that can arise from a medical device.



Ihr Nutzen als Auftraggeber



Der Test eignet sich besonders für



The basis for the biological assessment of medical devices is the series of standards **DIN EN ISO 10993**. The DIN EN ISO 10993-1 specifies which endpoints you must consider in the biological risk assessment of your product

Tests

- Chemical characterization according to DIN EN ISO 10993-18
 - > Basic information on the toxicological risk of the test sample
- Cytotoxicity according to DIN EN ISO 10993-5
 - > Determination of growth inhibition of skin cells
- Cytotoxicity according to DIN EN ISO 10993-5 in combination with Wiegand, C. et al. (2017)
 - for elastane-containing materials (e.g. medical compression stockings)
- Sensitization
 - Recognized screening test or alternative to the animal tests described in DIN EN ISO 10993-10.
 - Assessment of the risk potential of the tested substances to cause allergies
- HET-CAM according to DB-ALM Method Summary n° 96
 - Recognized alternative to the Draize test and thus to the animal tests described in DIN EN ISO 10993-10
 - Exclusion of chemical irritation
- Test for irritation according to DIN EN ISO 10993-23
 - Determination of the irritation potential with the reconstructed human epidermis model (RHE model)

Test sample requirements

General

- If dyestuffs, auxiliaries or avivages are used in different quantities, always select the articles with the highest input quantity (worst case)
- When sending several samples, ensure that substances contained in the samples are not transferred to other samples, i.e. pack them separately in plastic bags
- Provide sufficiently precise designations of the test sample (material composition, item number, LOT/batch number, etc.)

Quantity of material

- Total product, at least 40 g (for each individual test)

Test duration

- Usually 10-15 working days (per individual test), 4-6 weeks