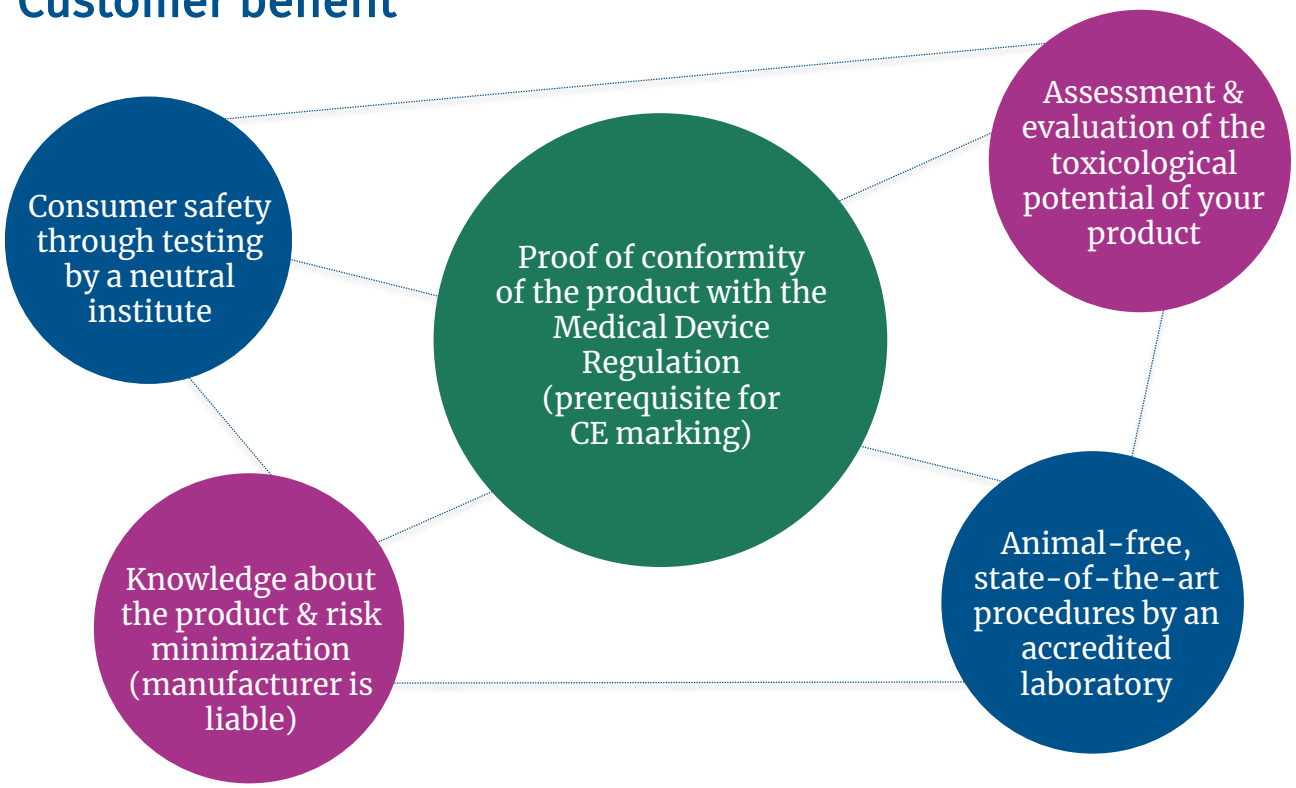
HOHENSTEIN

Biocompatibility of medical devices

Aim

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.

Customer benefit



The tests are particularly suitable for

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 for irritation test according to 10993-23; date confirmation after receipt of test sample