HOHENSTEIN

Chemical characterisation

according to DIN EN ISO 10993-18

Objective

The chemical characterisation of materials for medical devices records substances that can be released from the product. The test thus provides data for the biological assessment and the evaluation of the toxicological hazard potential within the risk management process.

Your benefit as a customer

- Assessment and evaluation of the toxicological potential of your product
- Analysis of biocompatibility to prove the conformity of the medical device with the Medical Device Regulation (prerequisite for CE marking)
- Consumer safety through testing by a neutral institute
- Knowledge about the product and risk minimisation, as the manufacturer is liable

The test is particularly suitable for

- Medical devices of all materials
- Textiles in the healthcare sector

Description

The chemical characterisation according to **DIN EN ISO 10993-18 i**s part of the tests for biocompatibility of the DIN EN ISO 10993 standardseries and is accredited at Hohenstein Laboratories by DAkkS. It provides data for the biological assessment and the evaluation of the toxicological risk of a medical device.

For this test, the sample is extracted at 37 °C for 24 h in methanol as well as in hexane. The chemical substances are determined by gas chromatography (GC/MS).

For the qualitative analysis of the detected substances, they are identified using a combination of calibrated data and a database (NIST) in which the mass spectra of over 180,000 different organic substances are stored.

The semi-quantitative determination of the chemical substances is carried out using a reference substance (toluene). The Analytical Evaluation Threshold (AET) is determined via the estimated exposure to the chemical substances under clinical conditions.

Test sample requirements

General

- If dyes or auxiliaries or additives are used in different quantities, always select the articles with the highest quantity (worst case).
- In the case of ready-made samples, send the complete product.
- In the event of a complaint, please provide the claimed textile (not a reserve sample) for inspection.
- When sending several samples, make sure that ingredients are not transferred to other samples, i.e. pack them separately in plastic bags.
- Provide sufficiently precise descriptions (material composition, item number, etc.) of the test sample.

Quantity of material

- at least 40 g of the test sample

Duration of test

- in general 20 working days; confirmation of date after receipt of test sample

The test report contains the

- calculation of the AET (Analytical Evaluation Threshold) depending on the application of the product.
- listing of extractable chemical substances above the AET.