Characterization of medical devices

Have your materials tested quickly and comprehensively in accordance with DIN EN ISO 10993-18

FAST AND COMPREHENSIVE CHEMICAL CHARACTERIZATION OF MEDICAL DEVICE MATERIALS ACCORDING TO DIN EN ISO 10993-18

To ensure the safety and performance of medical devices, manufacturers must conduct a comprehensive assessment of the biological compatibility of their products.

TÜV Rheinland now offers the chemical characterization of medical device materials in the context of a risk management process. This test is essential to ensure biocompatibility and to meet the high safety standards of the MDR.

The implementation of ISO 10993-18 presents manufacturers with many challenges, in particular with:

- Selecting and developing suitable analytical methods that meet the specific requirements of the medical devices and their applications
- The complexity of materials and the variety of products, which make standardized procedures difficult
- Interpreting the data to gain a thorough understanding of the toxicology and the possible interactions between the chemical substances and the patient's body when the device is in use

OUR CUSTOMIZED SOLUTIONS

Implementation of ISO 10993-18 begins with determining the configuration of the medical device and its material composition in order to select suitable analytical methods, with the precision of the methods being of particular importance.

The standard specifies how samples are to be prepared, stored, and analyzed to ensure reliable and reproducible results.

There are several steps in the characterization process. The materials and substances used are first determined by means of a document check. This is followed by a quantitative analysis to determine the concentrations of these components. Finally, the results must be interpreted within the context of the biological safety assessment, taking into account toxicological data and exposure scenarios.

OUR SERVICES

The chemical characterization according to DIN EN ISO 10993-18 includes the identification and quantification of raw materials, additives, impurities, auxiliary materials used in production, degradation products, and soluble and extractable substances, as well as analytical procedures to determine the material composition of the medical devices. It is our goal to ensure that your medical devices are biocompatible and do not cause any reactions in patients.

OUR NEW SERVICE INCLUDES:

- **Coverage of the DIN EN ISO 10993-18 standard – Chemical characterization of medical device materials within a risk management process:** We identify and quantify chemical substances that could be released from your medical devices upon contact with patients and evaluate the potential risks. Based on the TÜV Rheinland laboratory results, you will be able to implement corrections and improvements at an early stage.
- **Basis for risk assessment according to the standard DIN EN ISO 10993-17 – Toxicological risk assessment of medical device constituents:** Our analytical test results from part 18 of the standard form the basis for the toxicological risk assessment according to part 17 of the standard, allowing you to dispense with certain time-consuming and cost-intensive animal testing.
- **Documentation and reporting:** TÜV Rheinland prepares comprehensive reports detailing the tests and analyses performed, which are needed by manufacturers for the technical documentation and for the approval of medical devices.
- **Training:** TÜV Rheinland offers training sessions and workshops to educate your employees about the ISO 10993-18 requirements.

YOUR BENEFITS

- **Accurate test results thanks to first-class laboratory equipment:** Our laboratories feature state-of-the-art equipment and ensure precise and reliable results.
- **Many years of experience and chemical expertise:** We offer you comprehensive technical expertise that goes beyond the medical device sector to provide you with the right tests for your products.
- **Basis for risk assessment in accordance with standard DIN EN ISO 10993-17:** Use our test report as a basis for the toxicological risk assessment according to part 17.
- **Expert advice and customized services:** We tailor our services to your specific requirements and offer customized solutions for your product, your application scenarios, and your target patient group.
- **Short testing time:** We have established a fast and effective testing process for you. For products with short-term contact, for example, the pure testing time is only 1 to 2 weeks, so you get results quickly and can bring your products to market without unnecessary delays.
- **Fast comparison testing:** For minimal product changes, we perform focused comparison tests to minimize the time needed in order to ensure that your products continue to meet biocompatibility requirements.

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TÜVRheinland®
Precisely Right.

Choose TÜV Rheinland

Our experts are available to answer your questions and assist you so you can ensure the safety of your medical devices.

Contact us today for a personal consultation and to receive a non-binding quotation.

CONTACT NOW

Why TÜV Rheinland?

INTERNATIONAL BRAND
With over 150 years of experience in testing, inspection and certification, we are a long respected and recognized company serving major brands around the world.

ONE TEAM
Our highly experienced experts have practical knowledge of the entire product development cycle as well as testing and certification requirements.

EFFICIENT AND RELIABLE SOLUTIONS
Our international team of qualified experts provides clarity on the regulations specific to your product and simplifies the review process for access to multiple markets.

PARTNER FOR QUALITY
Our global network of accredited laboratories offers our customers access to a comprehensive range of services with additional support in key production and target markets.

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