Add value.
Inspire trust.

ISO 10993 - Biocompatibility testing of medical devices

Biological and chemical testing of medical devices

Your challenges

To be accepted on the global marketplace, a medical device or material that will have contact with the human body must not expose patients or end-users to unnecessary risks. A manufacturer must therefore ensure that new and existing medical devices, which have undergone modification, are tested for biocompatibility and comply with the internationally accepted requirements of the ISO 10993 series.

However, the compliance process is complicated as test specifications depend upon a complex combination of the type of medical device or material and its intended use, alongside the nature and duration of contact between the medical device and the body. The wide range of tests for the assessment of biological effects include chemical characterisation of the medical device, cytotoxicity, sensitisation, irritation or intracutaneous reactivity, systemic toxicity (acute, subacute, subchronic, chronic), , material-mediated pyrogenicity, genotoxicity, implantation and haemocompatibility. Not only must manufacturers identify the correct testing procedure, they must also fully understand how to interpret test outcomes. This must all be achieved within timescales that cost effectively minimise time-to-market.

What is ISO 10993?

The ISO 10993 series of standards address the biological evaluation, or biocompatibility, of medical devices based on material, contact type and duration. These standards cover a range of biological safety scenarios and stipulate what specific evaluations must be completed. Biocompatibility testing must be conducted in compliance with Principles of Good Laboratory Practice (GLP) and/or ISO/IEC 17025.

Why is ISO 10993 important to your business?

The primary purpose of a device biocompatibility assessment, as required by ISO 10993, is to protect patients from potential biological risks. Compliance with ISO 10993 establishes biocompatibility of a medical

device, confirming that it is safe for patient contact or implant and will perform its intended function without any adverse patient effects.

How can we help you?

TÜV SÜD offers a comprehensive range of ISO 17025 & GLP-compliant testing services according to the ISO 10993 series of standards, including biocompatibility studies and chemical-related testing services. Our worldwide network of experts delivers global expertise with local support.

Our services at a glance

TÜV SÜD provides the following biological risk assessment tests to help manufacturers meet biocompatibility testing requirements of the International Organisation for Standardisation (ISO), U.S. Food and Drug Administration (FDA) and American Society for Testing and Materials (ASTM).

- **Cytotoxicity - ISO 10993-5:** Cytotoxicity tests are conducted to evaluate the general toxicity level of the medical device or material on cell culture through in vitro elution and agarose overlay methods.

- **Genotoxicity - ISO 10993-3 & FDA**: Genotoxicity tests are required to identify the presence of toxins that can impact the genetic material of cells. Following the ISO requirements, we examine gene mutation, chromosomal damages and DNA damage through various assay.

- **Hemocompatibility - ISO 10993-4 & ASTM:** Hemocompatibility tests help evaluate the effects blood-contacting medical devices have on blood and blood components through hematology and thrombosis tests.

- **Irritation and Sensitisation - ISO 10993-10:** Irritation testing assesses the medical device for skin irritability through i.e. primary skin, ocular and intracutaneous reactivity tests and in vitro skin irritation tests. Sensitisation tests are conducted to evaluate possible adverse cutaneous reactions of the immune system to the medical device through in vivo and in vitro testing methods.

- **Systemic Effects of Systemic Toxicity and Pyrogenicity - ISO 10993-11 and ASTM:** Acute to chronic systemic toxicity tests assess effects of

medical devices in vivo. Pyrogenicity tests are carried out to test for material-mediated fever-causing compounds called pyrogens that impact patients when they come in contact with the medical device.

- **Implantation - ISO 10993-6:** Implantation tests evaluate the effects of medical devices on the surrounding living tissue at both macroscopic and microscopic levels.

- **Chemical Characterisation - ISO 10993-18:** Chemical characterisation is required to identify the quantities of extractables and leachables that migrate from a medical device when it is used or challenged.

- **Toxicological Risk Assessment - ISO 10993-17:** A toxicological risk assessment of extractables and leachables help quantify associated risks based on exposure and safe intake dose.

- **Sterility Testing - ISO 11737 series:** Bioburden testing, as part of sterility testing, helps to determine the population of microorganisms on a medical device that has not been sterilised.

- **Sterile Barrier System - ISO 11607 & EN 868 series:** Sterile barrier tests are required for the validation of a medical device's packaging system to ensure the device maintains its sterility and aseptic quality before use.

- **Biological Evaluation Plan (BEP)**: It is an important document which provides information on product safety and about the strategy implemented in order

to evaluate safety of device in compliance with available standards and guidelines. BEP should demonstrate risk management activity according to ISO 14971.

- **Biological Evaluation Report (BER)** : A biological evaluation report (BER) is a collective summary of all the data generated and /or gathered based on BEP and is used to support biological safety of medical device during clinical use of the device.

Your business benefits

- **Minimise risk and increase market confidence** – our knowledge of complex regulations, as well as our ability to tailor processes, will meet your specific business requirements.
- **Save time and money** – beyond the biological testing of medical devices, our single-source solutions will cover all your testing requirements, including software validation, EMC, functional and electrical safety.
- **Expert partnership** – our extensive record of medical device technical and regulatory expertise means that we are a trusted partner for a wide range of organisations, including global manufacturers and local research and development firms.

Why choose TÜV SÜD?

TÜV SÜD is globally recognised for its quality and safety as a third party one-stop testing provider. We offer a suite of testing services required for medical devices and help manufacturers and suppliers to independently meet global regulatory standards. Our global network of medical health and services professionals are well recognised in their fields. Their collective expertise makes TÜV SÜD a trusted partner of choice for manufacturers seeking accreditations in line with medical device regulations.

TÜV SÜD is one of the largest EU notified bodies in the world. Our technical professionals are actively involved in medical device standards development and participate in many key standards committees. TÜV SÜD is also a member of Team NB, the European Association for Medical Devices of Notified Bodies, which facilitates the exchange of information on standards and regulations applicable to medical devices.

Add value. Inspire trust.

TÜV SÜD is a trusted partner of choice for safety, security and sustainability solutions. It specialises in testing, certification and auditing. Since 1866, the company has remained committed to its purpose of enabling progress by protecting people, the environment and assets from technology-related risks. Through more than 25,000 employees across over 1,000 locations, it adds value to customers and partners by enabling market access and managing risks. By anticipating technological developments and facilitating change, TÜV SÜD inspires trust in a physical and digital world to create a safer and more sustainable future.

Related services

TÜV SÜD provides the following related services:

- Microbiological Testing
- Environmental Simulation
- Transportation Simulation & Packaging
- Electrical Safety
- Functional Safety / Single Fault Safety
- Electromagnetic Compatibility (EMC)
- Battery Testing
- Cyber Security & Software
- Radio Equipment – Testing & Global Market Access
- MRI Safety Testing

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