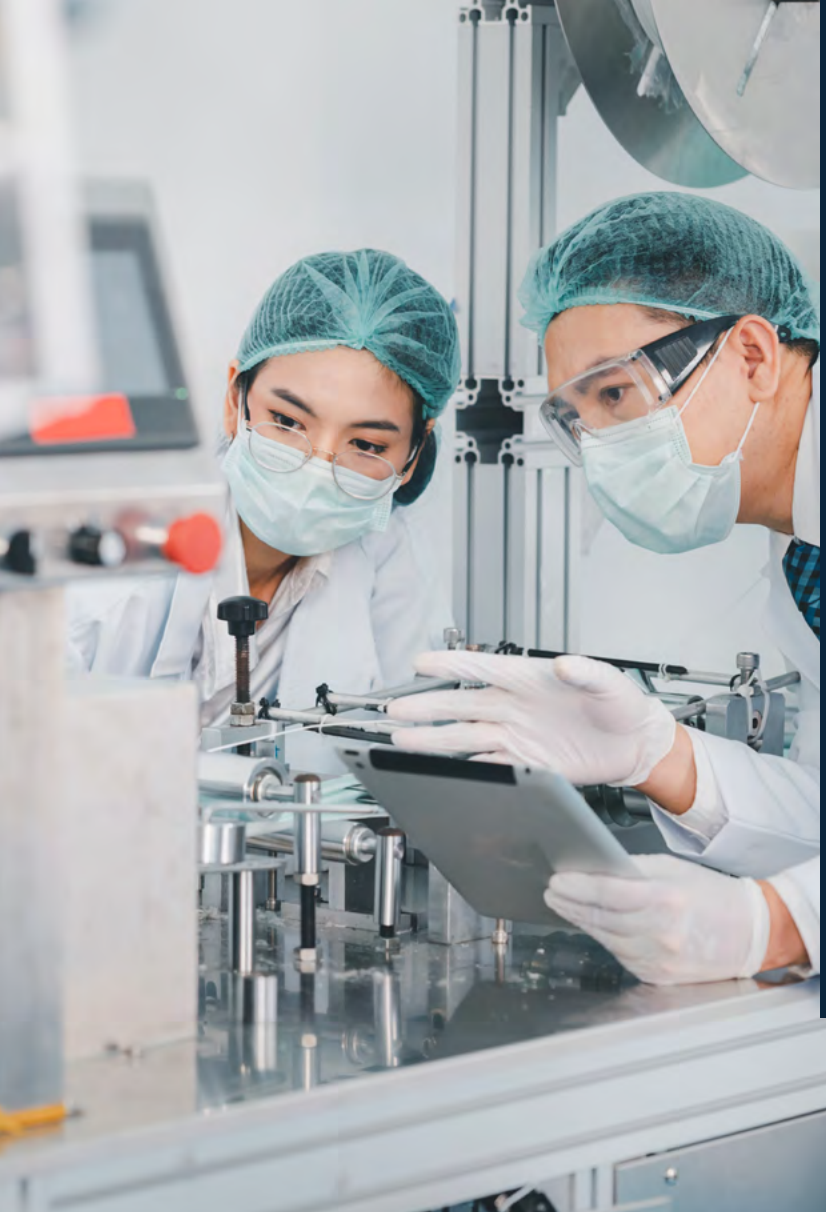

ISO 10993 - Biocompatibility testing of medical devices

Add value.
Inspire trust.

Biological and chemical testing of medical devices

Your challenges
Before they can be accepted for sale on the global marketplace, medical devices or materials that have contact with the human body must comply with the internationally accepted requirements of the ISO 10993 series. The standards cover a wide range of tests and evaluations to ensure that medical devices are safe for human use. Challenges faced by manufacturers include:

Complex compliance process
Test specifications depend upon:
- Type of medical device or material
- Its intended use
- Nature and duration of medical device contact with the human body

Wide range of tests
Including:
- Chemical characterisation
- Cytotoxicity
- Sensitisation
- Irritation
- Systemic toxicity
- Hemocompatibility
- Genotoxicity

Laboratory support
Manufacturers must
- Identify the correct testing strategy & procedure
- Fully understand how to interpret test outcomes

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. We help manufacturers meet the biocompatibility testing requirements of the International Organization for Standardisation (ISO), U.S. Food and Drug Administration (FDA) and American Society for Testing and Materials (ASTM).

Our worldwide network of experts and laboratories delivers global expertise with local support, helping you to minimise time to market. Your single point of contact within TÜV SÜD supports you throughout the process, helping you to successfully navigate global regulatory requirements.

How to determine the most appropriate biocompatibility tests
Determining the type of biocompatibility testing required for a medical device can be complex, and device safety depends on getting it right. The ISO 10993 matrix helps manufacturers determine the specific biological tests required for their medical device based on its nature, duration of contact with the body, and the type of body contact.

It is important to keep in mind that regulatory agencies have distinct requirements. Familiarity with the specific requirements of the agency where the device will be marketed is therefore vital. To ensure that testing is performed to the highest standards, it is also important to ensure that the laboratory has the appropriate certifications and accreditations, such as ISO 17025 and/or GLP.

ISO 10993 matrix

Medical device categorization by			Endpoints of biological evaluation														
Nature of body contact		Contact Duration	Physical and/or chemical information	Cytotoxicity	Sensitisation	Irritation or intracutaneous reactivity	Material medicated pyrogenicity	Acute systemic toxicity	Sub-acute toxicity	Sub-chronic toxicity	Chronic toxicity	Implantation effects	Hemocompatibility	Genotoxicity	Carcinogenicity	Reproductive / development toxicity*	Degradation
Category	Contact	A - Limited (≤24h) B - prolonged (>24h to 30d) C - Long term (>30d)															
Surface medical device	Intact skin	A	■	■	■	■											
		B	■	■	■	■											
		C	■	■	■	■											
	Mucosal membrane	A	■	■	■	■	■	■									
		B	■	■	■	■	■	■	■			■					
		C	■	■	■	■	■	■	■	■	■	■		■			
	Breached or compromised surface	A	■	■	■	■	■	■									
		B	■	■	■	■	■	■	■			■					
		C	■	■	■	■	■	■	■	■	■	■		■	■		
Externally communication medical device	Blood path, indirect	A	■	■	■	■	■	■					■				
		B	■	■	■	■	■	■	■			■	■				
		C	■	■	■	■	■	■	■	■	■	■	■	■	■		
	Tissue/bone/dentin	A	■	■	■	■	■	■									
		B	■	■	■	■	■	■	■			■		■			
		C	■	■	■	■	■	■	■	■	■	■		■	■		
	Circulating blood	A	■	■	■	■	■	■					■	■			
		B	■	■	■	■	■	■	■			■	■	■			
		C	■	■	■	■	■	■	■	■	■	■	■	■	■		
Implant medical device	Tissue/bone	A	■	■	■	■	■	■									
		B	■	■	■	■	■	■	■			■		■			
		C	■	■	■	■	■	■	■	■	■	■		■	■		
	Blood	A	■	■	■	■	■	■					■	■			
		B	■	■	■	■	■	■	■			■	■	■			
		C	■	■	■	■	■	■	■	■	■	■	■	■	■		

■ Information required ■ Endpoint needs to be addressed

Your business benefits

TÜV SÜD's market access solutions and regulatory expertise

Optimise time to market
- Single-source solutions cover comprehensive testing requirement
- A wide range of testing services
- Microbiology & sterilisation validation, packaging validation, MRI safety, electrical safety, EMC & cybersecurity etc.

Minimise risk & increase market confidence
- Extensive knowledge of global regulations
- A single point of contact supports you
- Processes are tailored to meet specific business requirements

Expert global partnership
- Global network of experts & laboratories
- Trusted partner for a wide range of organisations
- Excellent customer service is our standard

Why choose TÜV SÜD?
TÜV SÜD is globally recognised as an independent third-party with a comprehensive service portfolio along the entire value chain. Our suite of medical device testing services helps manufacturers and suppliers to meet global regulatory standards and optimise time to market. The collective expertise of our global network of professionals makes TÜV SÜD a trusted partner of choice for manufacturers seeking accreditations in line with medical device regulations on a worldwide scale.

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. Our extensive certification expertise also provides a sense of clarity to our customers.

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.

Contact us now

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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