Biological, Biochemical and Chemical Tests of Medical Devices

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Precisely Right.

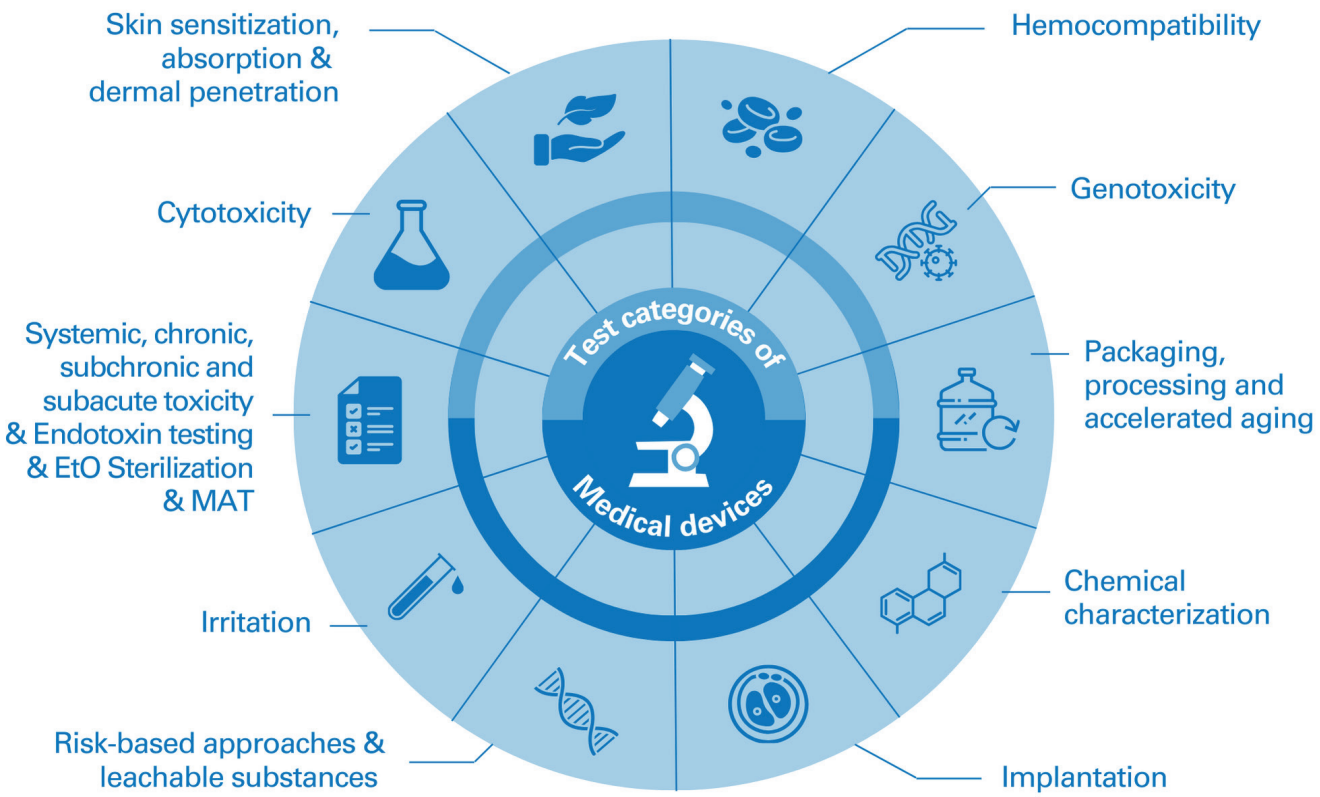
TÜV Rheinland: Your Trusted Testing, Inspection And Certification Partner

> For medical device manufacturers, precise biological, biochemical, and chemical testing is crucial because it provides:
>
> **patient safety, regulatory requirements and brand protection.**

- Daniel Świątko
Regional Business Field Manager, Manager of Medical Devices Certification Section, TÜV Rheinland

For medical device manufacturers, precise biological, biochemical, and chemical testing is crucial because it provides:

- Patient Safety: it ensures that the devices are safe for users and usage.
- Regulatory Requirements: it facilitates meeting stringent legal requirements, and is essential for obtaining certifications and market approval.
- Brand Protection: high-quality testing minimizes the risk of product defects, protecting the manufacturer's reputation.



Risk-based approaches – ISO 10993-1
- Biological Evaluation Plan
- Biological Evaluation Report

Allowable limits for leachable substances – ISO 10993-17
- Toxicological evaluation

Chemical characterization of materials – ISO 10993-18
- Headspace GC-MS
- GC-MS
- LC-MS
- C-MS HRAM
- IPC-MS
- FT-IR direct
- FR-IR extraction
- Exhaustive extraction pre-test
- UV-VIS (3 samples)

Cytotoxicity – ISO 10993-5

- Cytotoxicity MEM Elution
- Cytotoxicity MEM Elution direct contact
- Cytotoxicity Agar diffusion
- Cytotoxicity MTT

Irritation – ISO 10993-10 & ISO 10993-23

- Intracutaneous reactivity
- Irritation (direct product)
- In vitro irritation
- Dermal Irritation (2 extraction vehicles)
- Vaginal irritation (direct product)
- Vaginal irritation (2 extracts)

Skin sensitization – ISO 10993-10

- Sensitization LLNA
- Sensitization GPMT
- Sensitization Buehler (direct contact)

In vitro Skin Absorption and Dermal Penetration Test – OECD 428

Implantation – ISO 10993-6

- Implantation 4 weeks
- Implantation 13 weeks

Hemocompatibility – ISO 10993-4

- Hemocompatibility coagulation
- Hemocompatibility platelet activation
- Hemocompatibility complement activation
- Hemocompatibility hematology

Genotoxicity – ISO 10993-3 & ISO 10993-33

- Genotoxicity AMES (1 extraction vehicle)
- Genotoxicity MLA (1 extraction vehicle)

Systemic toxicity (acute) – ISO 10993-11

- Material mediated pyrogenicity
- Acute systemic toxicity

Endotoxin testing – ISO 10993-11 & ISO 11737-3

- Endotoxin LAL with method validation
- Endotoxin LAL

Chronic toxicity – ISO 10993-11

Subacute and subchronic toxicity – ISO 10993-11

- Subacute toxicity
- Subchronic toxicity

EtO Sterilization – ISO 10993-7

- EO/ECH residual
- EO/ECH exhaustive extraction

Monocyte Activation Test (MAT) – Eur. Pharm.

Packaging for terminally sterilized medical devices – ISO 11607

- Package validation bubble emission
- Package validation dye migration
- Package validation burst pressure
- Package validation seal strength

Processing of products – ISO 17664

- Cleaning validation manual
- Cleaning validation automated
- Disinfection validation

Accelerated aging – ASTM F1980

- Visual inspection ASTM
- Package validation accelerated aging

Do you have any questions? We have the answers!

TÜV Rheinland offers comprehensive services related to the IEC 10993 and many other series of standards and other required tests. Benefit from our many years of experience and our expertise! We will support you throughout the entire process.

Please contact us about specific questions or issues. We will be happy to assist you and be part of your course to success!

CONTACT US

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