A member of GBA Group

GBA MDS
MEDICAL DEVICE SERVICES

Testing Solutions for US Medical Device Manufacturers

Streamlined Lab Packages for Regulatory Submissions

We offer standardized and customizable biocompatibility testing and evaluation packages according to ISO 10993 series and FDA Guidance for the Use of International Standard ISO 10993-1 (2023) including chemical characterization, biological testing, toxicological risk assessments of extractables/leachables and biological evaluation reports tailored for medical device manufacturers preparing for regulatory submissions.

Our **laboratory in Germany** combines over 30 years of expertise in medical device testing **with ISO/IEC 17025 accreditation** and **GLP certification** for a broad range of methods.

Worldwide laboratory network and service

Strategic partnerships & personal contact

Scientific & technical know-how

About GBA Medical Device Services

GBA Medical Device Services was founded in 1994 in Gilching near Munich and is one of the leading providers for the qualification and evaluation of medical devices in Europe. With over 50 highly qualified employees, laboratory analyses and other services for the medical device industry are carried out in a state-of-the-art and lean-optimized building with over 1,200 sqm of laboratory space.
GBA Medical Device Services distinguishes itself through its outstanding quality standards, the know-how of its employees built up over years, capacities available at short notice with fast processing times and a technical exchange at eye level.
The test laboratory is accredited according to DIN EN ISO 17025 and certified according to GLP.

About GBA Group

GBA Group is an international life science services company with over 3,000 employees in 14 countries and a wide range of testing and consulting services in the fields of pharmaceuticals, medical devices, cosmetics, chemicals, food, drinking water and the environment. The group stands for outstanding technical expertise, efficient processes and focus on customer benefits.

GBAGROUP

GBA Medical Device Services GmbH
Dornierstr. 19 • 82205 Gilching
Tel +49 8105 77835-0
contact@mdservices.de

gba-group.com/medical-devices

GBA MDS
MEDICAL DEVICE SERVICES

Medical Devices

Biological (biocompatibility) evaluation on medical devices

Biological evaluation of a medical device shall be conducted within a risk management process acc. to ISO 14971. This involves the identification of biological hazards, the estimation of the associated biological risks, the determination of their acceptability and the implementation of risk control measures (ISO/FDIS 10993-1:2025). Biological evaluation shall consider both the biological safety of the finished device in first use, and the significance of any changes to the medical device which can occur throughout the life cycle.

Ready-to-Use Test Packages

Basic FDA Biocompatibility-Readiness

Biocompatibility Testing Services	
Cytotoxicity ISO 10993-5	Quantitative testing under ISO/IEC 17025 accreditation and GLP certification: • MTT Assay, TAT estimated* 4-5 weeks Qualitative testing: • MEM Elution Test, TAT 4-5 weeks
Sensitization ISO 10993-10, ASTM F2148	*In vivo* testing under ISO/IEC 17025 accreditation and GLP certification: • maximization test for delayed-type hypersensitivity[1], TAT estimated* 8-9 weeks • local lymph node assay[1] (LLNA), TAT estimated* 12-13 weeks
Irritation ISO 10993-23	*In vivo* testing under ISO/IEC 17025 accreditation and GLP certification: • intracutaneous irritation test[1], TAT estimated* 6-7 weeks • dermal irritation test[1], TAT estimated* 6-7 weeks • further *in vivo* irritation tests[1] (e.g. oral mucosa, ocular) on request
Systemic toxicity ISO 10993-11	*In vivo* testing under ISO/IEC 17025 accreditation and GLP certification: • acute systemic toxicity test[1], TAT estimated* 6-7 weeks • further systemic toxicity tests[1] (subacute, subchronic) on request • material-mediated pyrogenicity test (rabbit)[1], TAT estimated* 6-7 weeks
Genotoxicity ISO 10993-3	*In vitro* testing under ISO/IEC 17025 accreditation and GLP certification: • Ames test, point mutation[1], TAT estimated* 3-4 months • chromosomal aberration test in human lymphocytes or V79 cells[1], TAT estimated* 6-7 months • micronucleus test in human lymphocytes or in V79 cells[1], TAT estimated*6-7 months • gene mutation test in mammalian cells[1], HPRT test, point mutation, TAT estimated* 4 5 months • gene mutation in mammalian cells[1], mouse lymphoma assay, microtiter plate method, TAT estimated* 4-5 months *In vivo* testing under ISO/IEC 17025 accreditation and GLP certification: • chromosomal aberration assay in mammalian bone marrow[1], TAT estimated* 12 months
Chemical characterization ISO 10993-18	Chemical characterization under ISO/IEC 17025 accreditation: • volatile, semi-volatile and non-volatile organic E&L characterization: HS-GC-FID/-MS, GC-FID/-MS, LC-MS[1]; TAT estimated* 4-8 weeks • sum parameter testing: TOC[1], THC[1], NVR[1], TAT estimated* 4 weeks • inorganic E&L: ICP-MS/-OES, TAT estimated* 5 weeks • further analytical techniques: FTIR[1], REM-EDX[1], TAT estimated* on request
Degradation products from metals and alloys ISO 10993-15	Electrochemical corrosion testing under ISO/IEC 17025 accreditation, TAT estimated* 6-8 weeks: • potentiodynamic test • potentiostatic test • immersion test

*** Estimated turnaround time (TAT) from receipt of the samples at the laboratory depending on medical device category. Individual test results are provided progressively. Additional services such as GLP documentation require one additional week.**

[1] Testing is performed under our coordination at GBA sister or partner laboratories under ISO/IEC 17025 accreditation and GLP certification.

GBA MDS
MEDICAL DEVICE SERVICES

Medical Devices

Basic MDR Biocompatibility-Readiness

Biocompatibility Testing Services	
Cytotoxicity ISO 10993-5	Quantitative testing under ISO/IEC 17025 accreditation and GLP certification: • MTT Assay, TAT estimated* 4-5 weeks Qualitative testing: • MEM Elution Test, TAT 4-5 weeks
Bloodcompatibility ISO 10993-4	*In vitro* testing under ISO/IEC 17025 accreditation and GLP certification: • hemolysis test, extraction and direct contact method, use of human erythrocytes concentrate, TAT estimated* 2-4 weeks • thrombogenicity test, use of fresh human blood, TAT estimated* 5 weeks
Chemical characterization ISO 10993-18	Chemical characterization under ISO/IEC 17025 accreditation: • volatile, semi-volatile and non-volatile organic E&L characterization: HS-GC-FID/-MS, GC-FID/-MS, LC-MS[1]; TAT estimated* 4-8 weeks • sum parameter testing: TOC[1], THC[1], NVR[1], TAT estimated* 4 weeks • inorganic E&L: ICP-MS/-OES, TAT estimated* 5 weeks • further analytical techniques: FTIR[1], REM-EDX[1], TAT estimated* on request
Degradation products from metals and alloys ISO 10993-15	Electrochemical corrosion testing under ISO/IEC 17025 accreditation, TAT estimated* 6-8 weeks: • potentiodynamic test • potentiostatic test • immersion test
Sensitization ISO 10993-10, ASTM F2148 OECD 442D, 442E	*In vivo* testing under ISO/IEC 17025 accreditation and GLP certification: • local lymph node assay[1] (LLNA), TAT estimated* 12-13 weeks • maximization test for delayed-type hypersensitivity[1], TAT estimated* 8-9 weeks *In vitro* testing under ISO/IEC 17025 accreditation and GLP certification: • LuSens Assay[1], TAT estimated* 4-5 months • h-CLAT Assay[1], TAT estimated* 4-5 months
Irritation ISO 10993-23	*In vitro* testing under ISO/IEC 17025 accreditation and GLP certification: • skin irritation test[1], Reconstructed Human Epidermis Test method (RhE) test, TAT estimated* 12-15 weeks *In vivo* testing under ISO/IEC 17025 accreditation and GLP certification: • intracutaneous irritation test[1], TAT estimated* 6-7 weeks • dermal irritation test[1], TAT estimated* 6-7 weeks • further *in vivo* irritation tests[1] (e.g. oral mucosa, ocular) on request
Systemic toxicity ISO 10993-11	*In vivo* testing under ISO/IEC 17025 accreditation and GLP certification: • acute systemic toxicity test[1], TAT estimated* 6-7 weeks • further systemic toxicity tests[1] (subacute, subchronic) on request • material-mediated pyrogenicity test (rabbit)[1], TAT estimated* 6-7 weeks
Genotoxicity ISO 10993-3	*In vitro* testing under ISO/IEC 17025 accreditation and GLP certification: • Ames test, point mutation[1], TAT estimated* 3-4 months • chromosomal aberration test in human lymphocytes or V79 cells[1], TAT estimated* 6-7 months • micronucleus test in human lymphocytes or in V79 cells[1], TAT estimated* 6-7 months • gene mutation test in mammalian cells[1], HPRT test, point mutation, TAT estimated* 4-5 months • gene mutation in mammalian cells[1], mouse lymphoma assay, microtiter plate method, TAT estimated* 4-5 months *In vivo* testing under ISO/IEC 17025 accreditation and GLP certification: • chromosomal aberration assay in mammalian bone marrow[1], TAT estimated* 12 months

*** Estimated turnaround time (TAT) from receipt of the samples at the laboratory depending on medical device category. Individual test results are provided progressively. Additional services such as GLP documentation require one additional week .**

[1] Testing is performed under our coordination at GBA sister or partner laboratories under ISO/IEC 17025 accreditation and GLP certification.

Why work with us?

- **FDA/MDR-Relevant Data:** All required tests in one hand
- **International Credibility:** ISO 17025 accredited & GLP certified
- **Budget Control:** Competitive pricing vs. US labs
- **Fast Turnaround:** Reliable timelines
- **Low Administrative Burden:** End-to-end logistics handled

Who we serve

- Small to mid-sized medtech companies
- Large device manufacturers seeking cost-effective alternatives
- Companies preparing for FDA/MDR submissions
- Startups needing fast, compliant, and affordable testing

Simple Sample Logistics* for US Clients

We take the hassle out of international shipping:

- You send your samples to our US-based affiliate
- We handle international shipping, customs, and documentation
- You receive direct communication and reporting
- Results delivered digitally
- Minimal effort – Maximum compliance

*** Available upon request – additional fees may apply**

GBA MDS
MEDICAL DEVICE SERVICES

Medical Devices

Examples of Packages

Overview of test package and estimated turnaround times.

Package Type	Package Contents	TAT estimated**
Single-use sterile device made of plastics and stainless steel with limited contact (< 24 h) with intact mucosal membrane[1]	• cytotoxicity, MTT Assay • chemical characterization, organic extractables, 2 extraction vehicles, AET considered, GC-FID/-MS • optional[2]: chemical characterization, inorganic extractables, ICP-MS screening • optional[3]: sensitization and intracutaneous irritation	4-5 weeks 4-5 weeks 5 weeks 8-9 weeks (Sens.), 6-7 weeks (Irrit.)
Single-use sterile device made of plastics and stainless steel with limited direct contact (< 24 h) with circulating blood[1]	• cytotoxicity, MTT Assay • hemolysis, extract method • thrombogenicity • chemical characterization, organic extractables, 2 extraction vehicles, AET considered, GC-FID/-MS • optional[2]: chemical characterization, inorganic extractables, ICP-MS screening • optional[3]: sensitization, intracutaneous irritation, acute systemic toxicity (AST), material-mediated pyrogenicity (MMP)	4-5 weeks 2-4 weeks 5 weeks 4 weeks 5 weeks 8-9 weeks (Sens.), 6-7 weeks (Irrit.), 6-7 weeks (AST), 6-7 weeks (MMP)
Single-use sterile surgical implant made of Ti6Al4V ELI alloy with permanent contact (> 30 days) with tissue and bone[1]	• cytotoxicity, MTT Assay • chemical characterization, organic extractables, exhaustive extraction, 3 extraction vehicles, AET considered, HS-GC-MS, TOC/THC applied for proof of exhaustive extraction, GC-MS, LC-MS • electrochemical corrosion testing • chemical characterization, exhaustive extraction, inorganic extractables, ICP-MS screening • optional[3]: sensitization, intracutaneous irritation, acute systemic toxicity (AST), material-mediated pyrogenicity (MMP)	4-5 weeks 6-8 weeks 6-8 weeks 5-8 weeks 8-9 weeks (Sens.), 6-7 weeks (Irrit.), 6-7 weeks (AST), 6-7 weeks (MMP)

*** Estimated turnaround time (TAT) from receipt of the samples at the laboratory depending on medical device category. Individual test results are provided progressively. Additional services such as GLP documentation require one further week.**

[1] The example packages consider the biological safety of the finished device after manufacturing (at the beginning of the device's life cycle), testing at the end of the device's life cycle is not considered (further information on testing at the device's end of life as well as performance of accelerated ageing in our climate chambers or of repeated processing (automated cleaning/disinfection, steam sterilization) on request).

[2] Testing for inorganic extractables will become necessary for medical devices with limited patient contact if the stainless steel is not standardized for the use in medical devices and/or if cytotoxicity test results indicate corrosion of the stainless steel device component(s).

[3] The decision if in vivo biological testing acc. to ISO 10993-10, -11 and -23 or alternatively available in vitro testing methods according to ISO 10993-23 have to be performed for biological evaluation of the medical device requires consideration of existing data sets first and only if these are insufficient for biological risk assessment should additional testing be considered.

[4] The final price of chemical characterization, organic extractables depends on several aspects, e.g. if extract concentration has additionally to be performed to achieve the Analytical Evaluation Threshold (AET) as reporting threshold, the number of extractables detected above AET and therefore to be identified, if additional analytical techniques (e.g. LC-MS/MS) have to be used for adequate extractables identification and if further extraction steps have to be performed in addition to the generally performed 3 x 24 h extraction steps to achieve exhaustive extraction.

Custom Packages available

Single tests or tailored solutions upon request.

Additional Services (Optional)

Additional Service	Description	TAT estimated
GLP Documentation for Cytotoxicity, Hemolysis and Thrombogenicity Testing[1]	Full GLP-compliant reporting	plus 1 week
Additional Effort	e.g. consulting, repeat testing, pooled samples	

[1] GLP costs for in vitro/in vivo sensitization, irritation, systemic toxicity and genotoxicity are already included in final testing prices.

*** A time expenditure < 30 minutes will not be charged.**