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 test packages 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

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GBA MDS
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Medical Devices

Monitoring of Medical Devices

In order to demonstrate that the implemented quality is being maintained, monitoring of the product or components are necessary. The monitoring program is based on the various manufacturing processes and the associated risks of contamination of the product or components. Monitoring ensures that patients, users, and third parties are provided with safely usable medical devices.

Ready-to-Use Test Packages

Basic FDA Monitoring-Readiness

Bioburden (EN ISO 11737-1 (USP [61], EP 2.6.12))	
Bioburden determination ★ Bioburden – Validation of recovery ★ Germ differentiation (MALDI-TOF) ★	
LAL endotoxin test (ISO 11737-3 (ANSI/AAMI ST72, USP [85], EP 2.6.14)	
LAL endotoxin test ★*	
TAT estimated**	2 - 3 weeks

* manufacturing- and application-dependent
** From receipt of the samples at the laboratory until all test reports are provided. Individual test results are provided progressively. First reports available approximately 1 - 2 weeks after sample receipt.

Optional Test

Particle test (USP [788] (AAMI TIR42)	
Particle test ★	
Cytotoxicity test (EN ISO 10993-5, -12)	
Cytotoxicity test (BCA/MTT test method) ★	
Chemical analysis – characterization of organic substances (polar, semi-polar, non-polar) (EN ISO 10993-1, -12, -18)	
Chemical analysis by TOC/THC ★ (USP [643], ASTM F2847/ ASTM D7066, ASTM F2847)	
TAT estimated*	3 - 4 weeks

* From receipt of the samples at the laboratory until all test reports are provided. Individual test results are provided progressively. First reports available approximately 1 - 2 weeks after sample receipt.

★ Initial & Revalidation ★ Mandatory ★ Advisable

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Medical Devices

Basic MDR (& FDA) Monitoring-Readiness

Bioburden (EN ISO 11737-1 (USP [61], EP 2.6.12))	
Bioburden determination ★ Bioburden – Validation of recovery ★ Germ differentiation (MALDI-TOF) ★	
LAL endotoxin test (ISO 11737-3 (ANSI/AAMI ST72, USP [85], EP 2.6.14)	
LAL endotoxin test ★*	
TAT estimated**	2 - 3 weeks

* manufacturing- and application-dependent
** From receipt of the samples at the laboratory until all test reports are provided. Individual test results are provided progressively. First reports available approximately 1 - 2 weeks after sample receipt.

Optional Test

Particle test (USP [788] (AAMI TIR42)	
Particle test ★	
Cytotoxicity test (EN ISO 10993-5, -12)	
Cytotoxicity test (BCA/MTT test method) ★	
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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

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Medical Devices

Examples of Packages

Overview of test package and estimated turnaround times.

Package Type	Package Contents	TAT estimated**
Simple FDA	• Bioburden determination ‣ 1 pooled test • Bioburden – Validation of recovery ‣ 1 test • LAL endotoxin test ‣ 1 pooled test	2 – 3 weeks
Simple MDR (& FDA)	• Bioburden determination ‣ 10 tests • Bioburden – Validation of recovery ‣ 1 test • LAL endotoxin test ‣ 10 tests	2 – 3 weeks
Premium FDA	• Bioburden determination ‣ 1 pooled test • Bioburden – Validation of recovery ‣ 1 test • LAL endotoxin test ‣ 1 pooled test • Particle test ‣ 10 tests • Cytotoxicity test (BCA) ‣ 1 test • Chemical analysis by TOC (polar) ‣ 1 test • Chemical analysis by THC (semi-polar) ‣ 1 test • Chemical analysis by THC (non-polar) ‣ 1 test	3 – 4 weeks

*** test scope and costs dependent on manufacturing and clinical application conditions of the product.**
**** From receipt of the samples at the laboratory until all test reports are provided. Individual test results are provided progressively. First reports available approximately 1 - 2 weeks after sample receipt.**

Custom Packages available

Single tests or tailored solutions upon request.

Additional Services (Optional)

Additional Service	Description	TAT estimated
GLP Documentation	Full GLP-compliant reporting*	1 week
Additional Effort	e.g. consulting, repeat testing, pooled samples	From 1 week

*** TOC/THC are performed under ISO/IEC 17025 accreditation.**
**** A time expenditure <30 minutes will not be charged.**