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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Medical Devices

Processing / Reprocessing of Medical Devices

Processing / Reprocessing of medical devices is essential to ensure that reusable instruments are free from contamination before each use, eliminating any risk of infection for patients.
Regulations and standards such as the EU Medical Device Regulation (MDR 2017/745), ISO 17664, FDA's *Reprocessing of Reusable Medical Devices* guidance as well as ANSI/AAMI ST98 require manufacturers to provide a validated processing / reprocessing procedure, ensuring patient safety and full compliance.

Ready-to-Use Test Packages

Basic FDA Monitoring-Readiness

	Medical Device Categorization		
	Non-critical	**Semi-critcal**	**Critical**
Processing / Reprocessing validations (ISO 17664)			
Preparatory cleaning/sterilization to remove residues (e.g. from transport)	★	★	★
Efficiency control of cleaning (ANSI / AAMI ST98) 6 Simulated Use cycles incl. visual evaluation of residual moisture after cleaning + disinfection	★ Endpoints: visual + protein if applicable	★ Endpoints: visual + Protein + TOC	★ Endpoints: visual + Protein + TOC
Efficiency control of disinfection (AAMI TIR 12)	★	★ (not necessary if sterilization is the last step)	★
Efficiency control of sterilization (ISO 17665) incl. visual evaluation of residual moisture	★	★ (recommended)	★
Rinsing Validation (after 1 cycle of complete reprocessing)			
Preparatory cleaning / disinfection / sterilization	★	★	★
e.g. cytotoxicity test	★	★	★
TAT estimated*	11 - 17 weeks	11 - 17 weeks	11 - 17 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 11 weeks after sample receipt.**

★ Initial & Revalidation ★ Mandatory ★ Advisable

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Medical Devices

Basic MDR ReUse-Readiness

	Medical Device Categorization		
	Non-critical	Semi-critcal	Critical
Reprocessing validations (ISO 17664)			
Preparatory cleaning/sterilization to remove residues (e.g. from transport)	★	★	★
Efficiency control of cleaning & desinfection Can be validated at the same time, microbiological method	★	★	★
Efficiency control of sterilization (ISO 17665)	★	★ (recommended)	★
Non-detraction of biocompatibility after 1 x reprocessing			
Preparatory cleaning / disinfection / sterilization	★	★	★
e.g. Cytotoxicity test	★	★	★
TAT estimated*	9 - 10 weeks	14 - 15 weeks	14 - 15 weeks
„End of Life "-Testing (Non-detraction of biocompatibility, functionality, reprocessability)			
Repeated processing (performance in blocks of 10 cycles)	★	★	★
e.g. Cytotoxicity test	★	★	★
e.g. Chemical analysis	★	★	★
e.g. Processing / Reprocessing validation - depending on the specific product	★	★	★
Functionality tests	★	★	★
TAT estimated* 1 block (10 cycles) of repeated processing Cytotoxicity test	2-3 weeks	2-3 weeks	2-3 weeks

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★ Initial & Revalidation ★ Mandatory ★ Advisable ★ Performance by the manufacturer

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*
Non-critical (FDA)	• Preparatory Cleaning / Sterilization ▸ 1 test • Efficiency Control of Cleaning including Simulated Use Cycles ▸ Endpoints: visual + protein ▸ 1 test • Efficiency control of disinfection ▸ 1 pooled test • Rinsing validation ▸ 1 test	11 weeks
Non-critical (MDR)	• Preparatory Cleaning / Sterilization ▸ 1 test • Efficiency Control of Cleaning and Disinfection ▸ 1 test • Cytotoxicity test after 1 processing cycle ▸ 1 test • Repeated Processing ▸ 10 cycles of processing + cytotoxicity test ▸ 1 test	11 weeks
Semi-critical (FDA)	• Preparatory Cleaning / Sterilization ▸ 1 test • Efficiency Control of Cleaning including Simulated Use Cycles ▸ Endpoints: visual + protein + TOC ▸ 1 test • Efficiency Control of Sterilization ▸ 1 test • Rinsing validation ▸ 1 test	11 weeks
Semi-critical (MDR)	• Preparatory Cleaning / Sterilization ▸ 1 test • Efficiency Control of Cleaning and Disinfection ▸ 1 test • Cytotoxicity test after 1 processing cycle ▸ 1 test • Repeated Processing ▸ 10 cycles of processing + cytotoxicity test ▸ 1 test	16 weeks
Critical (FDA)	• Preparatory Cleaning / Sterilization ▸ 1 test • Efficiency Control of Cleaning including Simulated Use Cycles ▸ Endpoints: visual + protein + TOC ▸ 1 test • Efficiency Control of Sterilization ▸ 1 test • Rinsing validation ▸ 1 test	11 weeks
Critical (MDR)	• Preparatory Cleaning / Sterilization ▸ 1 test • Efficiency Control of Cleaning and Disinfection ▸ 1 test • Cytotoxicity test after 1 processing cycle ▸ 1 test • Repeated Processing ▸ 10 cycles of processing + cytotoxicity test ▸ 1 test	16 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 11 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

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