At your service

Microbiology Services

The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the U.S. and Canada.

Millipore®

Preparation, Separation, Filtration & Monitoring Products

Microbiology Services

Optimize your QC lab workflow and ensure regulatory compliance

Microbiological monitoring and testing in the pharmaceutical industry is a highly regulated and extremely complex field. With our long history of serving the pharmaceutical industry, we have pioneered and refined ground-breaking solutions, demonstrating the regulatory and technological expertise to share this know-how with our customers to make compliance as simple as possible and help save your valuable resources.

Our services ensure compliance with numerous regulations

- **FDA's Compliance Program Guidance Manual Drug Manufacturing Inspections Pilot Program**
  "A firm in a state of control produces finished drug products."

- **EU GMP vol. 4, 3.41**
  "Measuring, weighing, recording and control equipment should be calibrated and checked at defined intervals by appropriate methods. Adequate records of such tests should be maintained."

- **21 CFR 58.63 (GLP)**
  "Equipment shall be adequately inspected, cleaned, and maintained."

- **FDA Guide to inspections of microbiological pharmaceutical quality control laboratories**
  "Verify that the laboratory has the equipment necessary to perform the tests and that the equipment was available and in good operating condition on the dates of critical testing."

- **USP, 1058**
  "This chapter provides a scientific approach to AIQ and considers AIQ as one of the major components required for generating reliable and consistent data."

  "Use of a validated procedure with qualified analytical instruments provides confidence that the procedure will generate test data of acceptable quality."

Pharmaceutical Microbiological Safety

From sampling to final release, our complete solutions for environmental monitoring, traditional & rapid microbial detection and sterility assurance help you meet the highest quality standards and regulatory demands.

We can support you during the **entire** microbiology method lifecycle.

VALIDATE

2 Validation Protocol

3 Qualification

TRANSFER

4 S.O.P.

QA/QC

DEVELOP

1 Method Development

5 Maintenance & Service Plans

EXTENSIVE USE

6 Training

IMPROVEMENT REQUIREMENTS

Traditional Methods

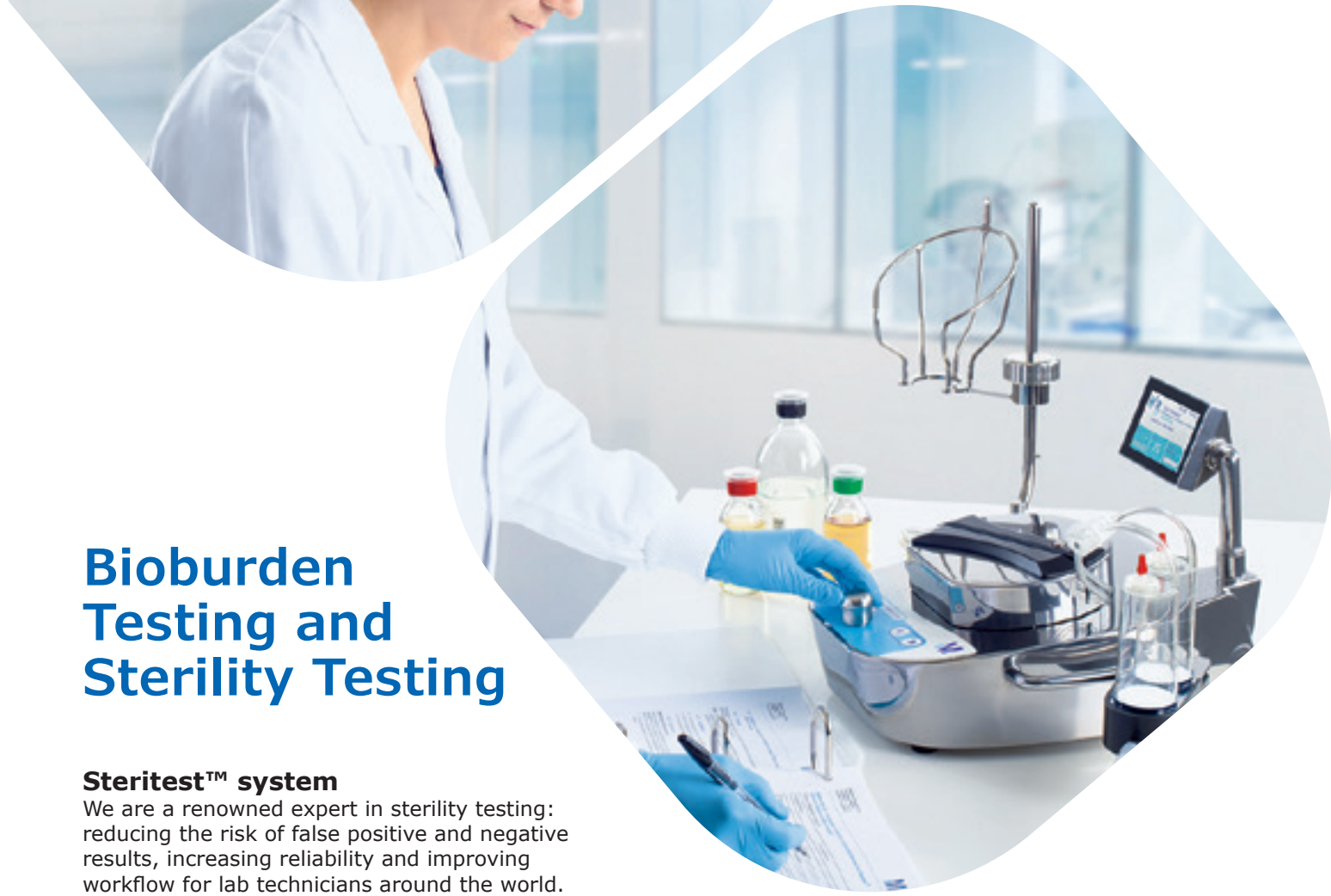
Active Air Monitoring

MAS solution family

Our MAS-100® series is the most complete and accurate system for reliable and easy monitoring of ambient air. To help maintain compliance while enhancing lab productivity and reducing down-time, we offer a full range of services.

What we provide:

- Customer Validation Protocol
  - Ready and easy-to-use GMP compliant
- IQ/OQ
  - Carried out on site
- PQ Consultancy
  - Reduce the workload for your lab team
- Advanced Operator Training
  - Certify your lab staff
- Maintenance and Service Plans
  - Ensure system reliability and increase lifetime
- Environmental Monitoring School
  - Ensure correct interpretation of results



Bioburden Testing and Sterility Testing

Steritest™ system

We are a renowned expert in sterility testing: reducing the risk of false positive and negative results, increasing reliability and improving workflow for lab technicians around the world. We provide an extensive portfolio of quality control products, and services.

Improve efficiency and reduce the workload for your lab team

MerckMillipore.com/ sterility-testing

Milliflex Oasis® filtration system

Milliflex Oasis® filtration system is an integrated solution for bioburden testing giving reliable and accurate results in high throughput production environments. Allow us to help you to streamline your microbial contamination testing workflow and fulfil the necessary regulatory requirements.

Optimize or simplify your method for an easy validation and cost effective testing

What we provide:

- Method Development & Consultancy
  - Optimize your testing method
- Customer Validation Protocol
  - Ready and easy-to-use GMP compliant
- IQ/OQ
  - Carried out on site
- PQ Consultancy
  - Reduce your lab team workload
- Advanced Operator Training
  - Certify your lab staff
- Maintenance and Service Plans
  - Ensure system reliability and increase lifetime
- Requalification protocols & services
  - Maintain regulatory compliance over time
- Milliflex® and Steritest™ Schools
  - Ensure correct interpretation of results

Rapid Methods

What we provide:

- Feasibility Study
  - Check the suitability for your application
- Method Development & Consultancy
  - Customized SOPs
- On-Site Evaluation
  - Try the system under actual conditions of use
- Customer Validation Protocol
  - Ready and easy-to-use GMP compliant
- IQ/OQ
  - Carried out on site
- PQ Consultancy
  - Reduce your lab team workload
- Advanced Operator Training
  - Certify your lab staff
- Maintenance and Service Plans
  - Ensure system reliability and increase lifetime

Rapid microbiological detection solutions for bioburden testing and sterility testing effectively address the diverse contamination issues which face the pharmaceutical and cosmetics industries every day. Innovative rapid technologies provide earlier results, increased assay sensitivity, ease-of-use, excellent accuracy and reliability.

Milliflex® Quantum microbial detection system

The Milliflex® Quantum system is designed for fast, fluorescence-based quantitative detection of microorganisms in the course of bioburden testing in pharmaceutical and cosmetics manufacturing facilities.

We can help you implement a routine rapid testing method

Milliflex® Rapid system

The Milliflex® Rapid System is an automated solution for rapid and accurate detection of microbial contamination in all filterable samples. Based on the detection of adenosine triphosphate with a bioluminescence reaction, this system delivers faster sterility test results than traditional detection methods.

We can help you implement a routine rapid testing method

MerckMillipore.com/ pyromat

PyroMAT™ pyrogen detection kit

Pyrogen contaminations in pharmaceutical products, biotherapeutics, cosmetics and medical devices can induce a life threatening fever, and therefore testing is mandatory for manufacturers. We offer a robust *in vitro* Pyrogen test in accordance with the European Pharmacopoeia regulations.

We can help you implement a routine rapid testing method

What we provide:

- Pyrogen Testing School
  - Understand regulations and ensure optimal usage of the kit
- Feasibility Study
  - Check the suitability for your application
- Method Development & Consultancy
  - Customized SOPs
- Product Specific Validation Consultancy Service
  - Speed up the implementation of your new method
- Software Data Analysis for PSV
  - Ensure proper data interpretation for validation
- Advanced Operator Training
  - Certify your lab staff
- Software Data Analysis Service
  - Reduce the workload for your team

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Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

MerckMillipore.com

To place an order or receive technical assistance

In Europe, please call Customer Service:

France: 0825 045 645
Germany: 069 86798021
Italy: 848 845 645
Spain: 901 516 645 Option 1
Switzerland: 0848 645 645
United Kingdom: 0870 900 4645

For other countries across Europe,
please call: +44 (0) 115 943 0840

Or visit: MerckMillipore.com/offices

For Technical Service visit:
MerckMillipore.com/techservice

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