

DOMINIQUE DUTSCHER SAS

Microbiological QC Solutions

Performance You Deserve,
with the Compliance You Expect

Simplifying Progress

SARTORIUS

Intelligent Tools for Microbiological Quality Control

Working in pharmaceutical manufacturing quality control is a big responsibility, and you are understandably concerned for the patient's wellbeing. We understand that ensuring safety and compliance for your sampling detection and microbiological processes is critical to you and your company. Our microbiological QC portfolio is designed to give you the best tools to meet the challenges you face every day, ensuring your results meet the required levels of safety and compliance. We offer intelligent solutions for unmet needs.

DOMINIQUE DUTSCHER SAS

Compliance

Reliability

Safety

Microbial Enumeration

USP <61>, <62> and <1231>, EP 2.6.12, EP 2.6.13, EP Monograph 0008 and 0169

Count the number of microbes in your sample using touch-free membrane transfer to agar.



Rapid Microbial Detection

USP<63> I EP 2.6.7 I USP<1071>

Detect mycoplasma as well as total bacteria and fungi within 3 hours (instead of 14 or 28 days) by qPCR.



Sterility Testing

USP <71> | EP 2.6.1 | JP 4.06

Determine whether your sample is sterile. Use aseptic sampling for further quality assurance.



Microbial Air Monitoring

USP <1116> EU GMP Annex 1

Employ non-stop clean room monitoring for up to 8 hours.



Efficiency

Forceps-Free & Effortless Membrane Transfer

Microsart® @filter & @media
Do you want to transfer your membrane after the filtration without risking contamination to the agar media?

Membrane filtration is the regulatory-preferred method for microbial enumeration testing. However, transferring the membrane filter to the microbiological medium is one of the most common sources of contamination and false-positive results.

Our Microsart® @filter combined with the Microsart® @media is a unique system which effortlessly positions the Cellulose Nitrate membrane on the agar plate. With only a turn, it's locked and ready to incubate, reducing the risk of contamination.

DOMINIQUE DUTSCHER SAS

Your Benefits

- Touch-Free Membrane Transfer
  Microsart® @media's innovative, patented, adhesive lid transfers the filter and positions it precisely onto the agar plate to allow touch-free transfer of the membrane.
- Minimized Risk of Cross-Contamination
  The integrated venting function of the new Microsart® Manifold minimizes the risk of cross-contamination during filtration.
- Easy Colony Enumeration
  Microsart® @media's convenient, liftable interior lid provides easy access to colonies after incubation.
- Easy Connectors Allow Removal Without Cracking
  The bayonet closure allows easy adjustments onto and removal from the stainless-steel manifold.

For more information about Microsart® @filter & @media, visit us at www.sartorius.com/microbio-qc



The Gold Standard for Mycoplasma Detection

Microsart® Mycoplasma qPCR Detection Kits
Would you rather know in 3 hours or wait 28 days?

Mycoplasma testing per USP <63> and EP 2.6.7 can take 28 days. Avoid this lengthy cultivation method with our Microsart® Mycoplasma qPCR detection kits. These kits are fast, highly specific, sensitive, and compliant with international regulations.

Sartorius qPCR experts provide step-by-step support during your matrix-specific validation and beyond.

DOWNLOADED BY CHER SAS



Your Benefits

- Don´t worry about false positives due to highly specific TaqMan probes
- Let the Master Mix do the internal control and reduce tedious pipetting steps
- Eliminate contamination risks by using the only non-infectious CFU-standards

For more information about microbial detection, visit us at www.sartorius.com/microbio-qc

Rapid Sterility: Rapid Detection of Bacteria and Fungi in Only 3 Hours

Microsart® ATMP Sterile Release Kit
Do you want to be sure that your Advanced Therapy Medicinal Products (ATMPs) are contamination-free before treatment?

Detect bacterial and fungial contamination within 3 hours using proven TaqMan™ probes for real-time PCR in our Microsart® ATMP Sterile Release Kit. To ensure patient safety and reduce the need for prophylactic antibiotic treatment, release only contamination free cell therapy products for use.



Your Benefits

- Ensure ATMPs Are Bacteria and Fungi-Free Before Treatment
  Test your ATMPs using qPCR detecting a broad range of gram-positive and gram-negative bacterial and fungal contaminants.
- Get Reliable Results in Only 3 Hours, Without False-Positives
  Avoid lengthy 14-day cultivation protocols and save time. TaqMan® probes ensure the highest level of qPCR specificity. There is no need to perform uncertain melting curve analyses.
- Eliminate Contamination Risks With the Only Kit With Non-Infectious Bacterial and Fungal Validation Standards
  Prequantified validation standards on CFU- and GC-basis are lyophilized and non-infectious. We provide step-by-step, matrix-specific validation guidance from Sartorius qPCR experts. Avoid the risk of cross-contamination with individually packaged, sample-specific vials.

For more information about rapid sterility, visit us at www.sartorius.com/microbio-qc

DOMINIQUE DUTSCHER SAS



Continuous Active Air Monitoring

Active Air Monitoring with MD8 Airscan®
What if you could monitor for viable air during an entire production run using only a single plate?

The MD8 Airscan® command unit utilizes a single, sterile gelatine membrane filter to capture and retain even the smallest airborne microorganisms, even viruses, over an 8 hour period. This USP-approved membrane filter can then be placed on any standard agar plate for routine incubation per your environmental monitoring protocols.

Rule out false test results, ensure the most accurate data, and reserve valuable incubator space for other critical tests.





DOMINIQUE DUTSCHER SAS

Your Benefits

- Non-Stop Active Viable Air Monitoring for at Least 8 Hours With a Reduced Risk of False Positive Results Due to Sampling Errors
  The EU Good Manufacturing Practice (GMP) Annex-1 specifies that “any risk caused by interventions of the monitoring operations is avoided”. Unlike settle plates that need to be changed after 4 hours, an example of an intervention during operation, our unique gelatine membrane affords up to at least 8 hours of uninterrupted sampling. Unlike conventional plates, our agar-free gelatine membrane filters do not dry out, and there is no-risk associated with the prolonged exposure of a nutrient source within your clean room. Given that any recovery of 1 cfu or greater in a grade A clean room requires an investigation according to the Annex-1, you can’t be too careful.

Your Path to EU GMP Annex 1 Compliance

Multiple Configurations Available to Suit Any Microbiology Testing Need
This includes Gelatine Membrane filters in Biosafe® bags for its aseptic transfer, via a Biosafe® port, into isolators, RABS and clean rooms.



* Vaporized Hydrogen Peroxide

DOMINIQUE DUTSCHER SAS



For more information about air monitoring, visit us at www.sartorius.com/en/products/microbiological-testing/environmental-monitoring

Redefine Your Standards for Sterility Testing

Sterisart® NF System & Sterisart® Universal Pump

How certain are you about your sterility testing?

Sterility testing is considered one of the most critical tests conducted by the Microbiology team, and it's common for many to wonder whether the testing was done correctly. Our Sterisart devices are designed to give you confidence in your results. If you are looking to move into rapid microbiology testing, our Sterisart devices are designed to allow you to aseptically sample via a septum while ensuring compliance with global regulations.



Your Benefits

- Safety for You and and Your Sample
  The risk of personal injury and cross contamination, by conventional sampling via the tubing, is high. The Sterisart® Septum ensures a sterile barrier during sampling and supplementation of the growth media and does not compromise the integrity of the closed system.

- Innovative Design
  Our specially designed and patented dual-needle, with its protective shield and built-in venting filter, ensures safe and easy handling even when working with cumbersome isolator gloves. Our canisters also feature an anti-foaming inlet, complete with raised venting filters to prevent accidental clogging and subsequent contamination.

- The Right Equipment
  Redefine your sterility testing standards with our reliable and robust Sterisart® Universal pump, featuring a 316L grade mirror-finish stainless steel design for easy decontamination and long-lasting performance. Go fully paperless with electronic reporting, meeting all regulatory requirements. Experience enhanced workflow efficiency through semi-automation and visual guidance, ensuring precision and minimizing errors.

For more information about sterility testing, visit us at www.sartorius.com/en/products/microbiological-testing/sterility-testing





DOMINIQUE DUTSCHER SAS

Sartorius Service

Ensure Compliance and Quality of Your Results

Working in Quality Control is a big responsibility. Ensuring reproducible and reliable results as well as compliance is critical to you. We at Sartorius are dedicated to providing full lifecycle support, maintaining global regulatory compliance and offer worldwide support for you and your staff.

- Equipment Qualification (IQ | OQ)
  Our IQ | OQ plans and tests follow the "risk-based approach" and focus on critical aspects and functions impacting the product quality.
  Comprehensive documentation of all results coming along with this service can easily be integrated into your quality management systems.

- Preventive Maintenance & Calibration
  To ensure optimal instrument operation, keep your instrument in a qualified state and protect against potential interruptions, regular preventive maintenance and calibration are essential. Our fully documented maintenance & calibration services increase trust in your instrument's performance and long term accuracy of results in your quality control.

- **Trainings for Quality Control Management**
  Sartorius offers a variety of training courses designed to streamline your workflows, making you more efficient, while raising quality awareness.

Want to talk to a Sartorius specialist about our smart solutions in microbiological control?
Request a free trial of our solutions today.
Send questions and requests to: microbio@sartorius.com
We look forward to hearing from you.

www.sartorius.com/microbio-qc

DOMINIQUE DUTSCHER SAS



Supporting Products for Quality Control

Quality Control begins with appropriate sample preparation. See how we can support your routine sample preparation workflow and analytical quality control tests for accurate and reliable results!



Cubis® III Balances
Cubis® III fulfills current and future demands of digital workflow management and pharma compliance. Plug and play connectors offer decreased complexity and simplified IT maintenance. Application conform weighing pans ensure reliability and increase measurement repeatability.





Arium® Ultrapure Water Systems
Arium® ultrapure water systems inspire with their application-oriented design. Whether for analytics, life science, or general purpose, the Arium® water system enables you to perform your workflows more reliably and makes your daily lab work easier.

DOMINIQUE DUTSCHER SAS







DOMINIQUE DUTSCHER SAS

Picus® 2 Electronic Pipettes

The Picus® 2 pipettes ensure reliable and repeatable pipetting results and feature an unbeatable ergonomic design that is kind to your hand. It is as intuitive to use as a mechanical pipette, but also offers more advanced options for experienced users.

Picus® 2 saves you time in the lab with a wide selection of pipetting modes and customizable programs to meet your every need. Safety features like password protection and calibration reminders support compliance requirements in regulated labs. By connecting Picus® 2 to your mobile device, you can use the Sartorius pipetting mobile app to smoothly run sample preparation workflows taking your productivity to the next level.





Octet®

Octet instruments come with an optional GxP compliant 21CFR Part 11 software and compliance tools that include IQOQ and PQ products. They are designed to facilitate analytical method development for biologics lot release and in-process testing.

Germany
Sartorius Lab Instruments GmbH & Co. KG
Otto-Brenner-Strasse 20
37079 Göttingen
Phone +49 551 308 0

USA
Sartorius Corporation
3874 Research Park Drive
Ann Arbor, MI 48108
Phone +1 734 769 1600

For further contacts, visit
www.sartorius.com

DOMINIQUE DUTSCHER SAS

Specifications subject to change without notice.
Copyright Sartorius Lab Instruments GmbH & Co. KG.
Status: 11| 2024