

Microbiological Control Pharma QC Applications (Sales Training eBook) Simplifying Progress

SARTURIUS

Reliability

Intelligent Tools for Microbiological Quality Control

Working in pharmaceutical manufacturing quality control is a big responsibility, customers are concerned for the patient's wellbeing. We understand that ensuring safety and compliance for microbiological processes is critical.

Our microbiological QC portfolio is designed to give the best tools, ensuring results meet the required levels of safety and compliance. We offer intelligent solutions for unmet needs.









Efficiency

Sterility Testing

Air Monitoring

Rapid Testing



Microbiological QC Solutions (all solutions for Pharma QC)



Short Introduction to Quality Control in the Biopharmaceutical Industry Video (slide show)

English



Guide to Pharmaceutical QC for Microbiology

English

English

French



Short Explanation on Controlled Environments and Clean Room Classes Video (slide show)

English









Microsart® e.motion Dispenser



Microsart® filtration Manifolds



Microsart® @filter & @media

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

Key Benefits & Features

- Convenience

+ Safety



Rapid Testing





Sterility Testing

Air Monitoring

Rapid Testing



Data Sheet Microsart® @filter



Val Mid Mid

Validation Guide Microsart® @filter Microsart® @media

English



Data Sheet Microsart® @media





Microsart® @media Product Overview Training Video

English



Microsart® @filter and @media Full Workflow Training Video

English

Back to @filter @media



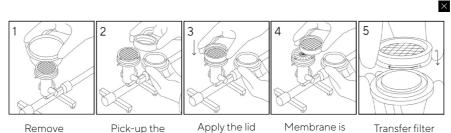
Microsa

Our Microsart® @filt unique system which plate. With only a tur risk of contamination

Key Benefits & Feat

Convenience

Safety



transferred

on @media

Touch-Free Membrane Transfer

plate lid

the funnel

Microsart® @media's innovative, adhesive lid transfers the filter and positions it precisely onto the agar plate to allow touch-free transfer of the membranes.

on filter



Easy Colony Enumeration

Microsart® @media's convenient, liftable interior lid provides easy access to colonies after incubation.



Marketing Resor



Microsart® @filter & @media

Our Microsart® @filter combin unique system which effortless plate. With only a turn, it's lock risk of contamination.

Key Benefits & Features

+ Convenience

+ Safety







Thanks to its small footprint the Microsart® e.motion dispenser saves precious space under the laminar air flow which can be used for samples, media and funnels instead. The membrane filters are released fully automatically, at the touch of a button or hands-free or by foot switch!

Key Benefits & Features

+

Convenience



Performance







Air Monitoring

Rapid Testing



Back to Microsart® e.motion





Microsart® e.motion Dispenser Manual



Data Sheet Microsart® e.motion Membrane Filters



English
German
French
Spanish
Italian
Russian
Japanese
Chinese
Turkish
Polish

Back to Microsart® e.motion



Microsart®

Thanks to its small footpring saves precious space unde for samples, media and fur released fully automaticall or by foot switch!

Key Benefits & Features



Convenience

Performance



Battery Driven

Microsart® e.motion dispenser can be purchased with battery or main power connection. Having no cable inside the laminar flow facilitates handling, cleaning and disinfection

Color code indicates battery state.



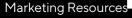
Automatic Dispensing

A sensor detects movements in front of the dispenser when approaching the forceps. The membrane is then released automatically facilitating handling.



Remaining Membranes Info

Users can see any time how many membranes are left in the dispenser, helping streamlining their workflows with no stress







Microsart® e.motion Dispenser

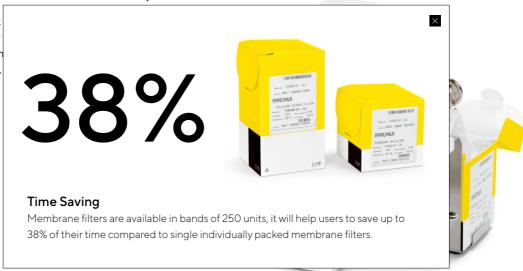
Thanks to its small footprint saves precious space under for samples, media and funn released fully automatically, or by foot switch!

Key Benefits & Features



Convenience

Performance







The user can choose between different sizes of manifolds, from single branch to multi-branch. The different manifold sizes are connectable with each other by quick connection to enable the manifold to adapt to daily workload. Depending on the application and criticality of product to be tested, users can choose between different funnel and filtration units, from complete reusable to single sterile solutions.

Key Benefits & Features

- + Convenience
- + Performance
- + Ergonomics
- + Adaptability







Air Monitoring

Rapid Testing



Microsart® Manifolds Datasheet





Microsart® Manifolds Video

English



Microsart® Manifolds Manual





Microsart® Manifolds Video

English

Back to Microsart® Manifolds



The user can choose betwee branch to multi-branch. Th with each other by quick co to daily workload. Dependi product to be tested, users filtration units, from comple

Key Benefits & Features

- + Convenience
- + Performance
- + Ergonomics
- + Adaptability



Assembly and disassembly

without tools facilitates handling and cleaning and sterilization of the manifolds.



Quick connectors on both sides of the manifolds improve usability and allow positioning the pump on left or right side.



Silicone feet prevent the manifold to slide on the working bench and facilitate overall handling.



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The user can choose between different sizes of manifolds, from single

branch to multi-branch. The d with each other by quick con to daily workload. Depending product to be tested, users co filtration units, from complete

Key Benefits & Features

+ Convenience

Performance

+ Ergonomics

+ Adaptability





The Manifold is made of 100% stainless steel.

The high quality of the stainless-steel material (Stainless Steel 316L - 1.4404) and the consequence in using one material type ensures a long working life of the manifolds





The user can choose between different sizes of manifolds, from single

branch to multi-branch. The diff with each other by quick conneto daily workload. Depending or product to be tested, users can filtration units, from complete re

Key Benefits & Features

- + Convenience
- + Performance
- + Ergonomics
 - Adaptability



Low height ensures efficient and ergonomic operation under the laminar flow, especially when heavy bottles must be repeatedly lifted over the funnel by the technician



Easy to operate valves minimize the risks of strain injuries when numerous samples must be analyzed in a short period of time.



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The user can choose between a branch to multi-branch. The diff with each other by quick connet to daily workload. Depending or product to be tested, users can filtration units, from complete re-

Key Benefits & Features

- + Convenience
- + Performance
- + Ergonomics
- + Adaptability



Depending on the number of daily tests users can choose between 1, 2, 3 or 6-branch manifolds.



The number of filtration positions can be extended easily using the quick connectors. This facilitates the adaptation of the installation to the workload





Microbial Enumeration



Sterisart® Pump



Sterisart® Disposable Canisters



Sterisart® NF

State-of-the-art closed filtration system for lot-release sterility testing of sterile pharmaceuticals. The Sterisart® NF system is easy to use and ensures the maximum reliability of sterility test results. The portfolio includes several devices adapted to specific sterility testing needs and is fully compliant with all pharmacopeial and regulatory requirements.

Key Benefits & Features

+ Convenience

+ Safety

Performance



Rapid Testing





Sterility Testing

Air Monitoring

Rapid Testing



Sterisart® NF Flyer

English

English

English

German



Video of Sterility **Testing Workflow**

English



Datasheet Sterisart® NF



Points to Consider When Validating Sterility Testing Canisters

English Portuguese



Sterisart® NF **Brochure**



Why It Is Important to Have a Secondary Supplier

English Portuguese



Application Note Sterisart® Septum





Sterisart® Validation Guide

English



Sterisart® Sterility Testing eBook

English

Back to Sterisart® NF



Video Sterisart® Why Sartorius?

English

Sterisart® NE

State-of-the-art closed filtra of sterile pharmaceuticals. T and ensures the maximum r portfolio includes several de needs and is fully compliant requirements.

Key Benefits & Features

Convenience

Safety

Performance







The two different color-coded clamps on Sterisart® tubing eliminate the risk of confusion, making it easy for users to identify and fill the canisters with the correct media

The extra-large, grip-optimized filter caps are directly attached to the vent filters. This is practical - and not only that. The caps connected by a band to the vent filters cannot fall off or touch any surfaces of the isolator, so they are safe from contamination.

Instead of being sealed in a separate, difficult-to-open package, the easy-tohandle yellow plugs for closing the canisters are right where users need them: in extra pockets directly inside the primary packaging. This facilitates the workflow and lets technicians stay focused on their core tasks.





Sterisart® NE

State-of-the-art closed filtra of sterile pharmaceuticals. T and ensures the maximum r portfolio includes several de needs and is fully compliant requirements.

Key Benefits & Features

+ Convenience

+ Safety

Performance

1.0

A critical step in sterility testing is sampling from or supplementing the media in a canister. You usually do this by piercing a tube. This conventional method is complicated, involves the hazard of injury and increases the risk of false positive results.

The **septum technology** has been purposebuilt to aseptically draw samples.

The sample will remain safely protected, ensuring a sterile barrier against contamination. At the same time, the simple piercing mechanism minimizes risk of puncture injuries.

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.





Sterisart® N

State-of-the-art closed filtra of sterile pharmaceuticals. T and ensures the maximum r portfolio includes several de needs and is fully compliant requirements.

Key Benefits & Features

Convenience

Safety

Performance

Our gamma-sterilized and gas-impermeable primary packaging enables users to omit the rinsing procedure and proceed right away with testing. This will save not only many steps, but also the additional costs incurred.



Oily substances and emulsions are difficult and take considerable time to filter. Sterisart® CA units with a cellulose acetate membrane deliver the fastest flow rates in customer tests.



The inlet port of the Sterisart® canisters has been designed with an anti-foaming dispensing channel. This facilitates rinsing and minimizes risks of venting filter clogging.



The venting filter is positioned with a safety clearance of 1 inch, or over 2½ cm, to effectively protect from contact with culture medium, even if foaming or the slightest vibration occurs.





Sterisart® Universal Pump

The Sterisart® Universal Pump is available in two versions: as basic version 16419 and as an upgraded version 16420 with display and user software. The pump can be used in clean rooms, integrated into clean benches, or installed countersunk in the working surface of isolators. Its low, compact design has a space-saving footprint – a great benefit for most clean room benchtops and isolators.

Key Benefits & Features

+ Convenience

+ Safety

+ Robustness









Sterisart® Universal Pump Brochure

English German



Sterisart® Universal Pump 16420 Manual

EN | DE French

Russian



Sterisart® Easy Configuration Datasheet

English



Sterisart® Universal **Pumps Equipment Qualification** (IQ|OQ) Datasheet

English German



Sterisart® Universal Pump 16419 Manual

EN | DE



Sterisart® Universal Pumps Preventive Maintenance and Service Contracts

English German



Sterisart® Sterility Testing eBook

English

Back to Sterisart® Pump



Why Sartorius?

Video Sterisart® **English** The Sterisart® Universal Puversion 16419 and as an upg software. The pump can be benches, or installed count Its low, compact design has for most clean room bench

Key Benefits & Features

+

Convenience



Safety



Robustness



Compact and User-friendly

As space is often limited in isolators and clean benches, the Sterisart® Universal pump has been designed with a compact footprint and a low profile. Thanks to its user-friendly construction, **it saves spaces**, ensuring excellent **ergonomic handling**, particularly in the areas in front of and above the pump. Despite the pump's compactness, it is easy to thread the tubing of the Sterisart® sterility test unit into the pump rotor. The special pump head design ensures excellent life of the tubing and, moreover, is easy to access for cleaning and disinfecting.





Sterisart® Universal Pump

The Sterisart® Universal Puversion 16419 and as an upg software. The pump can be benches, or installed count Its low, compact design has for most clean room bench

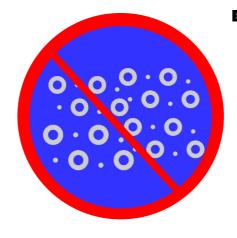
Key Benefits & Features

+ Convenience

+ Safety

Robustness

Zero particle emission



Increased Safety and Reliability

A unique motor principle has resulted in a closed pump chassis design, eliminating the need for ventilation of the motor. Therefore, the pump will not release any particles or microbes into cleanroom or isolator environments or cause turbulence in laminar-flow areas. This results in increased safety and reliability.



Sterisart® Universal Pump

The Sterisart® Universal Puversion 16419 and as an upg software. The pump can be benches, or installed count Its low, compact design has for most clean room bench

Key Benefits & Features

+ Convenience

+ Safety

Robustness



Rugged and Maintenance-Free

As the pump chassis is made of stainless steel, it features excellent chemical compatibility with sterilants used in isolators. This, together with the unique type of motor, makes the pump highly rugged and virtually maintenance-free, considerably reducing service costs.











Microbial Enumeration

MD8 Airscan®

Monitors ambient air in cleanrooms and controlled areas in the (c) GMP environment for viable microorganisms. The MD8 Airscan® provides non-stop active air monitoring for at least 8 hours, using only one single gelatin membrane filter. Convenient, continuous monitoring no one else can offer.

Key Benefits & Features

Convenience

Performance









MD8 Airscan® Datasheet



Multiple



MD8 Airscan® Equipment Qualification (IQ|OQ) Datasheet





MD8 Airscan® Sampling Head Manual



MD8 Airscan® Equipment Qualification (IQ|OQ) Datasheet

English German



MD8 Airscan® Sampling Head Manual





MD8 Airscan® Product Overview Video

English





GMP Annex1 Air-Monitoring Webinar 2021

English

Back to MD8 Airscan®



MD8 Airsca

Monitors ambient air in clea GMP environment for viable provides non-stop active air one single gelatin membran monitoring no one else can

Key Benefits & Features



Convenience Performance



The MD8 Airscan® Command Unit weighs **only 1.2 kg** (2.6 lbs). It includes 2 LEDs for displaying operating status and errors.



The specially designed bayonet connector allows the unit to function as a "stand-alone benchtop version".



Quick connectors allow the command unit to be disconnected from one sampling head and connected to another one



The MD8 Airscan® Command Unit can be connected with a thermal transfer printer.





MD8 Airsca

Monitors ambient air in clea GMP environment for viable provides non-stop active air one single gelatin membran monitoring no one else can

Key Benefits & Features

Convenience

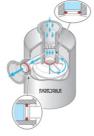
Performance



Stores up to 300 test results from different sampling heads and displays operating status and errors.



Stainless-steel tri-clamp connectors facilitate installation of the MD8 Airscan® as an integrated unit in lab's air-line.



Flow path can be disinfected or sterilized inline with vaporized hydrogen peroxide (VHP).





Gelatin Filters

Gelatin filter disposables are individually packaged, presterilized and ready-to-connect units, each consisting of a gelatin membrane filter and a holder. Gelatin filters in conjunction with the MD8 Airscan® Air Sampler are used for collection of airborne microbes and viruses.

Key Benefits & Features

Convenience

Performance

Compliance









Gelatin Membrane Filters in Biosafe® Bags

English German



Continous Air Monitoring Application Note

English German Japanese



Gelatin Filter Disposables Datasheet

English



Air Monitoring in Cleanroom Environments Cording to EN 17141 and ISO 14698

English



Gelatin Filter Disposables Manual





Gelatin Membrane Filters Product Features and Transfer to Agar Plate Video

English



Biosafe® Bags and Port Product Demonstration Video

English

Back to Gelatin Filters







GMP Annex1 Air-Monitoring Webinar 2021

English

Gelatin Filt

Gelatin filter disposables a ready-to-connect units, ea and a holder. Gelatin filters Sampler are used for collect

Key Benefits & Features

+ Convenience

- Performance

Compliance



Biosafe® Transfer Bags

Gelatin membrane filters (GMF) in Biosafe® Bags are aseptically transferred without any risk of contamination through the Biosafe® Port into the desired critical area, such as an isolator. The solution facilitates collapsing and streamlining of customers processes. (see video in marketing resources page).







Gelatin Filters

Gelatin filter disposables are indivi ready-to-connect units, each cons and a holder. Gelatin filters in coni Sampler are used for collection of

Key Benefits & Features

Convenience

Performance

Compliance

Long Term Monitoring

The MD8 Airscan® provides non-stop active air monitoring for at least 8 hours, using only one single gelatin membrane filter. Published experimental results have been proving the extraordinary performance of Gelatin Membrane Filters (see app. note).



Absolute Retention

of organisms since the filters capture all bacteria laden particles in the sample regardless of particle size.



Residual Moisture

in the filters prevents desiccation of the retained organisms, improving recovery rates











Gelatin Filt

Gelatin filter disposables a ready-to-connect units, ea and a holder. Gelatin filters Sampler are used for collect

Key Benefits & Features

+

Convenience



Performance



Compliance







Regulatory Compliance

Biocontamination control strategies are a key requirement of recent standards and guidelines, such as the EN 17141 and the revision of the EU GMP Annex 1. The EN 17141, published in 2020, has been adopted in the European Union and United Kingdom, replacing the ISO 14698. The Annex E chapter of EN 17141 details guidance on culture-based microbiological monitoring methods and sampler verification. We have demonstrated that microbial air monitoring by Gelatin Membrane Filtration meets the requirements of the EN 17141 and the ISO 14698, which remains the standard outside the EU and the United Kingdom. (see application note).











Microsart® Mycoplasma



Microsart® ATMP Sterile Release



Microsart® Mycoplasma

Viable but non-culturable (VBNC) Mycoplasma can go undetected when using the traditional method of mycoplasma culturing, risking false-negative results. Our Microsart® qPCR kits offer a method for early detection of mycoplasma contamination. These kits are fast, highly specific, sensitive, and compliant with international guidelines.

Key Benefits & Features

+ Convenience

+ Performance

+ Compliance







Sterility Testing

Air Monitoring

Rapid Testing



Microsart® AMP Mycoplasma Datasheet

English



Correlation Between Colony Forming Units and Genome Copies of 9 Mycoplasma Species – App. Note

English



Mycoplasma Assays for qPCR - The New Gold Standard - Flyer

English



Minimize the Risk of Mycoplasma Contamination in Your Cell Cultures - App. Note

English



Battle Card Microsart® Mycoplasma PCR Kits

English



Benchmarking of Two Mycoplasma Real-time PCR Kits According EP 2.6.7

English



Digital Tool – ATMP Sterile Release and Mycoplasma Testing

English

Back to Microsart® Mycoplasma



Microsart®

Viable but non-culturable when using the traditional false-negative results. Our early detection of mycopla highly specific, sensitive, as

Key Benefits & Features



Performance





Reduced Pipetting Steps

with Our Master Mix The ready-to-use master mix has the DNA for internal control already included. It mitigates the risks of false-negative results and minimizes the number of reactions to run



Testing Right Away

Microsart® Mycoplasma qPCR kits can be used with any qPCR cycler able to detect the fluorescent dyes FAM® and ROX®.



Our clear, color-coded reagents guide the user through the short and simple protocol.





Microsart® Mucanhama

Viable but non-culturable (VBN when using the traditional meth false-negative results. Our Micrearly detection of mycoplasma highly specific, sensitive, and co

Key Benefits & Features

Microbial Enumeration

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Convenience



Performance Compliance



Reliable Results Within 3 Hours

Users will avoid lengthy 28-day cultivation protocols when choosing Microsart® Mycoplasma qPCR Kits.



TaqMan® probes ensure the highest qPCR **specificity** without the need for a melting-curve analysis.



Lyophilized reagents ensure consistent quality without the need for freezer storage.



Validation standards for required mycoplasma species in Microsart® Mycoplasma qPCR kits are lyophilized to render them **non-in-fectious**

Marketing Resources





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Rapid Testing

Microsart® Mucanhama

Viable but non-culturable (VBN when using the traditional meth false-negative results. Our Micr early detection of mycoplasma highly specific, sensitive, and co

Key Benefits & Features

+ Convenience

+ Performance

Compliance



Validated Test Results in Compliance With International Standards

Microsart® AMP and ATMP Mycoplasma Kits are validated according to EP 2.6.7 for sensitivity, specificity, and robustness. They also fulfill the criteria of international authorities, such as USP and JP.

Marketing Resources





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Microsart® ATMP Sterile Release

Detection of bacterial and fungal contamination within 3 hours using the proven real-time PCR with our Microsart® ATMP Sterile Release Kit, a combination of Microsart® ATMP Bacteria and of Microsart® ATMP Fungi.

Key Benefits & Features

+ Convenience

+ Performance

Compliance







Sterility Testing

Air Monitoring

Rapid Testing



Microsart® ATMP Bacteria | Fungi | Sterile Release Microsart® Research

Bacteria | Fungi

English



Detection of Microbial Contaminations in High Cell Density Jurkat-, HPBMC and CHO-Cultures - App. Note

English



Short Introduction of Rapid Sterility and ATMP Video (Slide Show)

English



Equivalency of PCR-Based Rapid Sterility Testing and the Compendial Culture Method - App Note

English



Microsart® ATMP Bacteria Tutorial Video

English



Digital Tool - ATMP Sterile Release and Mycoplasma Testing English

Back to Microsart® ATMP Sterile Release



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Microsart®

Detection of bacterial and the proven real-time PCR Kit, a combination of Micro ATMP Fungi.

Key Benefits & Features

Convenience

Performance

Compliance



Reduced Pipetting Steps

with Our Master Mix

The ready-to-use master mix has the DNA for internal control already included. It mitigates the risks of false-negative results and minimizes the number of reactions to run.



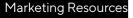
Testing Right Away

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Microsart® A

Detection of bacterial and fung the proven real-time PCR with of Kit, a combination of Microsart(ATMP Fungi.

Key Benefits & Features

+ Convenience

Performance

Compliance



Reliable Results Within 3 Hours

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Lyophilized reagents ensure consistent quality without the need for freezer storage.



Validation standards for required bacterial and fungal species in Microsart® ATMP Sterile Release are lyophilized to render them **non-infectious**.





Microsart® A

Detection of bacterial and fung the proven real-time PCR with (Kit, a combination of Microsart(ATMP Fungi.

Key Benefits & Features

+ Convenience

+ Performance

Compliance







Validated Test Results in Compliance With International Standards

Microsart® ATMP Sterile Release kits were developed in close cooperation with authorities and are validated according to EP 5.1.6 and USP <1223> for sensitivity, specificity, and robustness.

This test is not a replacement for the classic sterility test according to USP<71> or FP 2.6.1



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