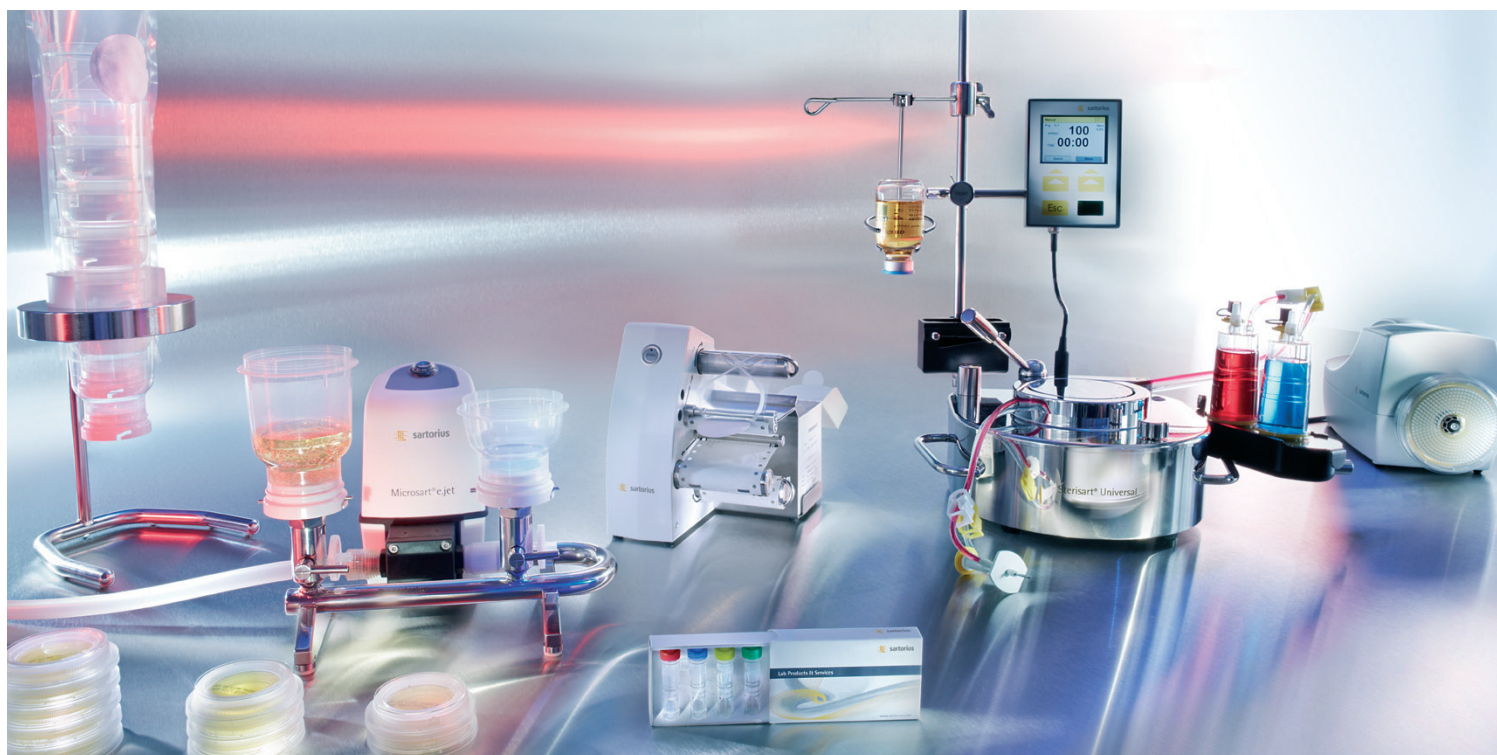# Microbiological QC Solutions:
Performance You Deserve,
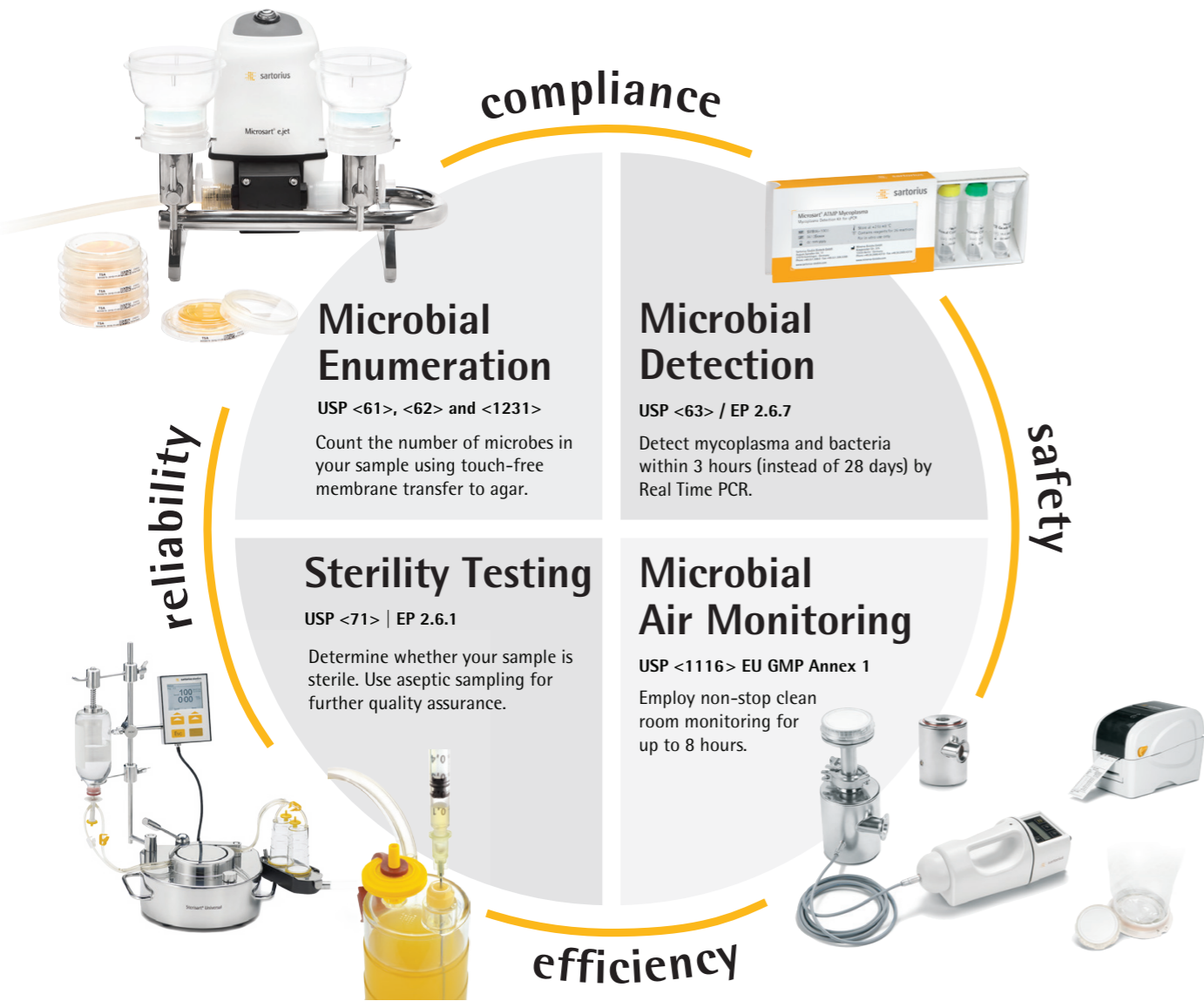# with the Compliance You Expect

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.

compliance

safety

reliability

efficiency

Microbial Enumeration
USP <61>, <62> and <1231>

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

Microbial Detection
USP <63> / EP 2.6.7

Detect mycoplasma and bacteria within 3 hours (instead of 28 days) by Real Time PCR.

Sterility Testing
USP <71> | EP 2.6.1

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.

Forceps-free & Effortless Membrane Transfer

Microsart @filter & @media

Do you want to move your filter during membrane transfer without risking contamination?

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 membrane on the agar plate. With only a turn, it's locked and ready to incubate, reducing the risk of contamination.

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.

Microbial Enumeration | Microbial Detection | Air Monitoring | Sterility Testing | Aseptic Fluid Management | Sartorius Service | Microbiological QC

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

The New 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, matrix-specific validation.

Rapid Bacteria Detection in Only 3 Hours

Microsart® ATMP Bacteria Kit

Do you want to be sure that your Advanced Therapy Medicinal Products (ATMPs) are bacteria-free before treatment?

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

Your Benefits

- **Ensure ATMPs are Bacteria-Free before Treatment**
  Test your ATMPs using qPCR detecting a broad range of gram-positive and gram-negative bacterial 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 Validation Standards**
  Validation standards for required bacterial species in Microsart® Bacteria Kits are lyophilized to render them 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.

Microbial Enumeration | Microbial Detection | Air Monitoring | Sterility Testing | Aseptic Fluid Management | Sartorius Service | Microbiological QC

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

Agar-free, Continuous 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 gelatin membrane filter to capture and retain even the smallest airborne microorganisms 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.

Your Benefits

- **Non-stop Active Viable Air Monitoring for at Least 8 Hours**
  Unique gelatin membrane filters are agar-free: they do not dry out during long-term sampling and do not influence growth.

- **Multiple Configurations Available to Suit any Microbiology Testing Need**

- **Reduced risk of False Test Results Due to Sampling Errors**

Redefine Your Standards for Sterility Testing

Sterisart® NF System & Sterisart® Universal Pump with Canisters

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

- **Experience a Design that is Space-saving, User-friendly, and Modular**
  The Sterisart Universal Pump was specifically designed with a compact footprint and a low profile to take up little space.

- **Double Safety for You and Your Sample**
  Sterisart Septum ensures aseptic sampling and injection when needed for investigational purposes or rapid testing.

- **Clear Test Identification**
  Two color-coded tube clamps differentiate tubes when executing your sterility test.

For more information about air monitoring and sterility testing, visit us at **www.sartorius.com/microbio-qc**

Multiple Ways to Receive Your QC Sample

TAKEONE® Aseptic Sampling System Containers & MYCAP® Bottle Closure Family

Did you know your QC microbiology sample can arrive from production in any configuration you might need?

Our TAKEONE Aseptic Sampling System was designed to make sampling from a production line easier and reduce the risk of contamination. We also had you in mind and made the collection containers available based on your unique testing requirements. Whether it's bags, bottles, syringes or vials, in volumes ranging from 10 mL to 1 L or more, you will receive your microbiology sample in a way that best minimizes cross-contamination and simplifies your testing.

Transfer your samples quickly and without worry of contamination with MYCAP bottle closures. MYCAP closures are one-piece, ready-to-use, and single-use aseptic fluid transfer systems for bottles. Given the wide range of configurations, you have the freedom to transfer your sample while minimizing cross-contamination and saving time and money.

MYCAP® allows for fluid transfer into and out of bottles

QUICKSEAL® for trouble-free aseptic disconnection

Your Benefits

- **Pre-assembled for Quick Installation and Use**

- **Saves Time and Resources**

- **Gamma Irradiated for Sterility Assurance Level (SAL) 10^{-6} or Single-use for Risk-free Handling and Simple Validation**

- **High Performance Resins Suitable for Autoclave Sterilization with Glass Containers**

We Ensure the Quality of Your Results

Services are essential to all pharmaceutical laboratories. Having access to the right resources will ensure you stay in regulatory compliance. We at Sartorius are dedicated to maintaining global regulatory compliance and offer worldwide support for you and your staff.

- **Equipment Qualification (IQ |OQ)**
  This service includes evaluation and adjustment of key instrument parameters. Results are fully documented and easy to integrate into your Quality Management system.

- **Preventive Maintenance & Calibration**
  To ensure optimal instrument operation and protect against potential downtime, add a maintenance contract to your instrument purchase. Our instrument calibration service ensures compliance with regulatory requirements and long term accuracy of results.

- **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.

Microbial Enumeration	Microbial Detection	Air Monitoring	Sterility Testing	Aseptic Fluid Management	Sartorius Service	Microbiological QC

For more information about TAKEONE®, MYCAP® and Service, visit us at **www.sartorius.com/microbio-qc**

Related Products

Cubis® II Balances

The Cubis II is a completely configurable, high performance portfolio of balance hardware and software that will align with your unique demands and compliance requirements to maximize operational efficiency.
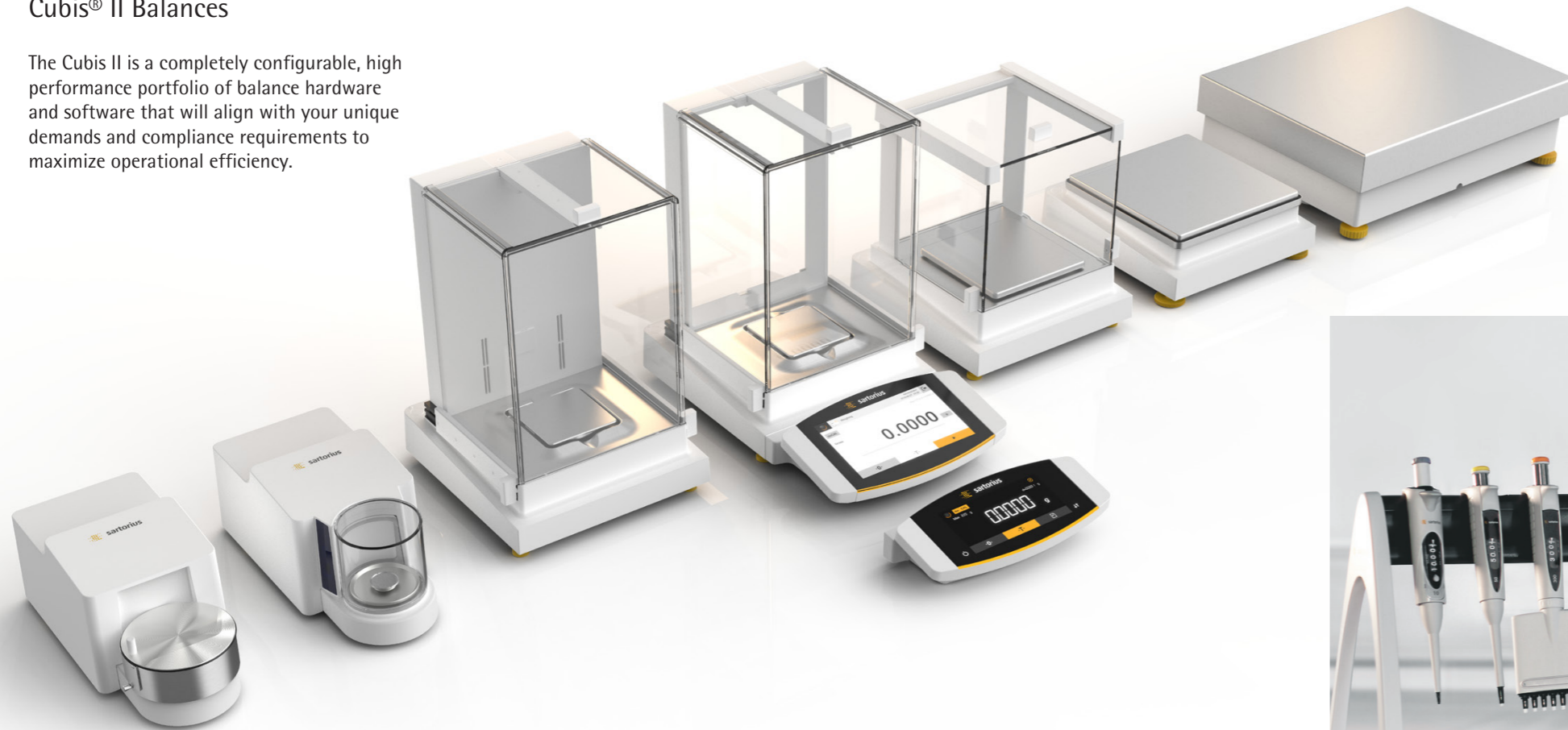
Picus® NxT Electronic Pipettes

Picus® NxT is Sartorius's leading and most sophisticated electronic pipette. The smallest and lightest electronic pipette on the market increases productivity and provides protection from Work Related Upper Limb Disorders (WRULD) or Repetitive Strain Injuries (RSI). Its new generation technology, electronic brake, and piston control system guarantee accurate and user-independent pipetting results.

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.

Minisart® Syringe Filters

Minisart® syringe filters are optimized for sample preparation, with components featuring maximum chemical compatibility and minimum extractables, ensuring excellent results. Minisart® syringe filters with glass fiber prefilter are optimized for particle-laden liquids. The version with polypropylene housing contains a quartz prefilter without any binders and is the perfect choice for ultrapure sample preparation.

Contact

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.

Discover More:

www.sartorius.com/microbio-qc