Simplifying Progress

Medical Device Solutions eBook

version 1

SARTORIUS

Best-Fit Solutions for Your Quality Control

Pave your way to market by controlling quality with smart and robust Sartorius solutions.

Drug Delivery Systems

Safeguard superior quality of your hightech devices for administering active ingredients safely and effectively.

Implants

Manufacture implants with long-term quality, safety and efficacy supported by straightforward QC solutions.

Diagnostic Kits

Reach the full potential of your QC and bring your diagnostics safely, efficiently and compliant to market.

Wearables & Disposables

Rely on robust, simple and reliable QC solutions from raw material to finished products.

Surgical Instruments

Ensure constant quality down to the smallest detail for safe, effective and compliant precision tools.

Contract Manufacturing & Integration

Build on a reliable partnership with customized solutions tailored to your individual requirements.

Drug Delivery Systems	Implants	Diagnostic Kits	Wearables & Disposables	Surgical Instruments	Contract Manufacturing & Integration

R&D – Process Development	Raw Material Testing	In- Process Control	Final Release Testing
▪ Density Check of Solid Material & Liquids ▪ Nanoparticle Concentration ▪ Gravimetric Dose Accuracy Assessment ▪ Analytical Characterization - Biocompatibility ▪ Cytotoxicity - Biocompatibility ▪ Data Analytics - DOE	▪ Density Check of Solid Material & Liquids ▪ Moisture Determination of Raw Material ▪ Particulate Matter Analysis ▪ Analytical Characterization -Biocompatibility ▪ Microbial Water Testing & Bioburden	▪ Check Coatings – Application of Correct Amounts ▪ Moisture Determination ▪ Nanoparticle Filtration of Liquids - Concentration – Detection ▪ Particulate Matter Analysis ▪ Dose Accuracy Assessment ▪ Continuous Microbial Air Monitoring ▪ Rinsing & Sterile Preparation ▪ Data Analytics - MVDA ▪ Counting with Reference Weight	▪ Check Coatings Application ▪ Error-Proof Packaging ▪ Density Check of Solid Material & Liquids ▪ Moisture Determination of Packaging Material ▪ Microbial Testing: Bioburden & Sterility ▪ Gravimetric Dose Accuracy Assessment ▪ Analytical Characterization - Biocompatibility




R&D – Process Development	Raw Material Testing	In- Process Control	Final Release Testing
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Ready-to-Use Filtration Devices and Membranes	Process Automation	Aseptic Connection & Disconnection	Customized Components	Transfer – Transport - Storage	Data Analytics
▪ Syringe filters ▪ Ultrafiltration devices ▪ Membranes for *In Vitro* Diagnostics, Microarrays & OEM	▪ Integrated weighing cells ▪ Robotic dispensing head ▪ Single-use buffer tank for filling lines ▪ Air venting filters	▪ Quickseal ▪ Sterile connection ▪ Aseptic disconnection	▪ Custom membranes & devices ▪ Custom pipettes ▪ Integrated weigh cells	▪ Tubing ▪ 2D bags ▪ Bottle closure ▪ Biosafe bags	▪ Umetrics solutions

Density Check of Solids & Liquids

Measure Liquids, Pastes and Solids – Precisely, Accurately and With Full Regulatory Compliance

Coatings, 3D inks, plastics, metals - guaranteeing the specified density of materials is crucial for stability and safety of drug delivery systems. Deviations due to impurities or poor quality may have profound effects on the final product's performance.

Our solutions are tailored to the needs of density applications. Durable, high-performance balances and pycnometers integrate with user management systems to generate traceable results, for precise and reproducible density calculation.

- Check density of solids, liquids and pastes with one balance, even highly viscous or solid materials with densities in excess of 3 g/cm3
- Increase measurement precision and process safety
- Document results compliant to 21 CFR Part 11 & EU GMP Annex 11, USP Chapter 41

- **Cubis® II analytical balances** are designed for high-performance weighing and offer completely digital workflow management following the US FDA data integrity principles (ALCOA). On-board QApps contribute to correct usage by guiding through weighing processes, increasing measurement accuracy, precision and process safety.
- The **Pharma Software Application Package** supports compliance with 21 CFR Part 11 and EU GMP Annex 11, USP Chapter 41 and includes features like user management, digital signatures, audit trail and USP minimum weigh.
- Simply combine the **Density Kit YDK03MS** and you can determine additional key physical property characteristics like specific gravity or density on solids, liquids and even pastes.

Density Check

eBook - Connectivity & Compliance

Flyer - Cubis® II Density QApp

Manual - Density kit

Brochure - Cubis® II

Nanoparticle Filtration of Liquids – Concentration - Detection

Maximum Recovery in Minimum Time

ISO 10993-1 requests a safety evaluation and risk assessment to exclude potential harmful effects of nanomaterials. Prior to evaluating reference values like conjugation or encapsulation efficiency, zeta potential and size distribution, a successful purification and concentration of the suspension or dispersion is essential. However, typical separation methods like size-exclusion chromatography and diafiltration require extensive, costly and time-consuming manual handling and subsequent concentration steps.

Sartorius' Ultrafiltration Solution moves you one step ahead:

- Perform purification and concentration steps simultaneously and reduce manual handling time
- Highest recovery in the fastest possible time
- Save consumable costs

- Vivaspin® Turbo 15 RC (Regenerated Cellulose) is the fastest RC centrifugal concentrator on the market, providing the best possible recoveries in combination with the Turbo PES. Choose between RC and PES (Polyethersulfone) membranes, whichever is best suited to your molecular target. Ensure highest recoveries in the fastest possible time!

Vivaflow

Catalog - Ultrafiltration

Poster - Ultrafiltration selection guide

Application Note - Nanoparticles

Gravimetric Dose Accuracy Assessment

Evaluate Uniform Dose Delivery Over Time

The accuracy of drug delivery devices is critical to patient safety. Guaranteeing the correct delivery dosage is obligatory for drug delivery systems like insulin-pumps, drug-eluting stents or intrauterine devices (IUD). To avoid failures or variations resulting in over- or underdosing, you must check whether the drug is applied at constant rates over time.

Our weighing solutions are best in class for medical device measurement accuracy for the critical parameters of flow, mass or volume over time:

- Determine weight of smallest sample amounts with highest precision
- Ensure and check exact drug uptake on device
- Fastest stabilization means higher throughput, even in unstable environments

- Weigh small sample amounts precisely, and even in unstable environments, with the Cubis® II Micro Balance. The software solution Interval Print enables accurate measurement of a sample flow by calculating the average weight values over a defined period. Your results are saved to a CSV file and can be easily exported.

MPS Balance

eBook - Connectivity & Compliance

Brochure - Cubis® II

Brochure - Cubis® II Sample Holders

Manual - Cubis® MPS

Manual - ME36S

Analytical Characterization - Biocompatibility

Save Time and Improve Reproducibility

The biological risk of a drug delivery system is often directly linked to its surface properties. Assessing the composition of materials and their ability to release extractables and leachables is standard in evaluating biocompatibility. FTIR, MS, ICP-MS and GC require robust, reliable sample preparation and streamlined workflows to ensure clean, reproducible, interference-free results.

Sartorius provides user-friendly sample prep tools for Chemical Characterization per ISO 10993-18. Use time-saving solutions for preparing samples for content and purity analysis for robust and reliable sample processing procedures.

- Fast, simple and economical
- Fully automated preparation of standards
- 21 CFR Part 11 and EU GMP Annex 11, USP Chapter 41 compliant records
- Filtration solutions with low retention volumes and maximal recoveries
- Minimum leachables or extractables

- Ultrapure Lab Water Systems Arium® Mini plus UV with Unique Bagtank Technology & Arium® Pro UV produce ASTM Type 1 ultrapure water for preparation of buffers and sample dilutions. Minimize chemical ion interference and move TOC levels down to a minimum to ensure consistent baselines, reduce ghost peaks and avoid background noises in chromatograms.
- Benefit from automated preparation and documentation of 100% comparable standards with the Cubis® MSA Dosing System with Q-App Software. Documentation your test procedures compliant to 21 CFR Part 11.

Flyer - Sample Preparation

App Note - UP Water for ICP-MS

Brochure - Cubis® MSA Dosing

Poster - Minisart® Selection Guide

Flyer - Cubis® II Metrohm

Catalog - Pipetting & Dispensing

HPLC Sample Preparation

Cytotoxicity - Biocompatibility

Insight into Active Biological Processes in Real-Time

Cytotoxicity testing is a standard biocompatibility test to evaluate toxicity levels or irritancy potential of the drug delivery system or material. According to ISO 10993-5, the quantitative MTT Assay involves the incubation of cultured mammalian cells in contact with a device and/or extracts to determine biological response.

Sartorius' Incucyte® Live-Cell Analysis Systems are ideally suited to perform non-invasive monitoring under stable culture conditions and quantitative live-cell imaging and analysis in real-time:

- Visualize and quantify cell behavior around the clock
- Time-lapsed, kinetic measurements in long-term
- Incucyte® Cytotox Dyes, in combination with the Incucyte® Live-Cell Analysis System, kinetically measure dynamic changes in cell membrane integrity to quantify cytotoxicity over multiple days. The Incucyte® Cytotoxicity Assay provides real-time measurements of cell death in response to treatments, pharmacological agents or environmental factors and can be used to determine biocompatibility.
- While not CFR 21 compliant, the Incucyte® Live-Cell Analysis System is ideal for research and development studies across multiple drug delivery applications such as oncology, immune-oncology, immunology or neuroscience.

App Note - Cytotoxicity Assay

Incucyte® Cytotox Dyes

Contact your local Incucyte Specialist

Data Analytics

Optimize Production Processes

Every production process follows a strict set of rules. If those rules are broken, you need to know –the earlier, the better. SIMCA®-online monitors your processes in real-time for a continuous snapshot of operations. Identify when set parameters change, fix them before they affect production and keep quality consistent. With this level of control, you can maximize efficiency and minimize costs. Enjoy the confidence of high quality in your product and a real boost to your business growth.

- SIMCA®-online monitors your production processes in real-time for a continuous snapshot of operations. Our proprietary multivariate prediction technology gives you early warning of process anomalies that will affect the product. With this real-time process intelligence, your production team can proactively drive the best possible outcomes. And that means you can ensure consistent product quality, maximize productivity and prevent costly re-work or scrapping.

Product - leaflet

Contact an Application Specialist

Data Analytics

Develop Complex Formulations

When it comes to evaluating the chemical properties of a formulation, data analytics streamlines the process. MODDE® Design of Experiments (DOE) software lets you select the most influential ingredients for a new formulation and focus on these in product development.

Predict the properties of untested formulations based on the properties tested and reduce the number of experiments you need to do to find the most promising product for your purposes, saving time and money.

- Significantly reduce experimental costs
- De-risk projects and increase success rates
- Make the most of valuable samples, raw materials and human resources
- Accelerate progress and time-to-market while keeping within budget
- Achieve quality goals and satisfy Quality by Design (QbD) requirements .

- MODDE® does a lot more than ordinary Design of Experiments (DOE) software. Its built-in guidance and quality measures ensure users make the best experimental choices, so you get the most relevant and effective outcomes. MODDE® is designed to help experimentalists get DOE right from the start.
- MODDE® provides optimization by a guided workflow wizard that helps scientists and engineers intensify processes, reduce waste and optimize process output using a top-notch approach to mitigate risks.

Product - leaflet

Contact an Application Specialist

Moisture Determination

Economic and Reliable Moisture Content Analysis

Every material processed during production needs a specific and constant moisture content for optimal processing and functionality of the final product. Even the smallest deviations can be captured by moisture analyzers.

Sartorius offers robust and reliable solutions so you can accurately detect and document lowest moisture contents quickly and easily within your routine applications:

- Measure minimum moisture content down to 0.005 %
- Process up to 4 samples simultaneously
- Achieve highest precision, even for very dry samples
- Compliant to ASTM Standard D6980, ISO 868-7 Annex

- Mark 3 HP Moisture Analyzer is the genuine alternative to Karl-Fisher titration because it is easy to use and operates without using harmful chemicals. A high-resolution weighing system and special design make the Mark3 HP the perfect solution for precisely analyzing the moisture content of even very dry samples.

Playbook - Moisture Analyzer

Application Note - Plastics

Datasheet - Mark3

Particulate Matter

Capture and Quantify Smallest Particles

GMP Annex 1 requests that medical devices be scrupulously clean and free of interfering residues. From raw material or environment, clothing, machining and lubricants, particle sources are manifold. Glass, elastomer, hair and other particles can affect biocompatibility and safety as they build an additional surface for microbial growth, or worst case can be released and lodged in a patient's vascular capillary system.

Sartorius' solutions are designed for capturing particulate matter, reliable optical analysis and accurate quantification:

- Ready-to-use ultrapure, particle-free rinsing water
- Membrane filters with excellent retention rates
- Accurate filter weighing balances, protected against drafts and electrostatic charges

- Arium® Pro VF delivers ultrapure water for reliable particle analyzes. The implemented UV lamp ensures excellent breakdown of organics and the integrated ultrafiltration filter provides optimal reduction of particles for reliable optical measurement. Dispense water in the exact quality and quantity required for your analyses, when and where you need it with the New Arium® Smart Station.
- Choose Cellulose Nitrate Membranes for precise surface capture and high sample visibility. Surfactants and colloids pass through the membrane filter during filtration, thereby not affecting results. Facilitate accurate weighing of filters with the Cubis® II Ultra-Micro and Micro Balance filter models with the respective QApp. The stainless steel draft shield F protects against drafts and electrostatic charges.

Filter Weighing

Brochure - Cleanliness Analysis

Brochure - Filter Balances

Brochure - Cubis® II

Brochure - Cubis® II Sample Holder

Datasheet - Arium® Pro

Brochure - Arium® Smart Station

Microbial Water Testing & Bioburden

Simplify Your Microbial Limits Testing Workflows

Microbial contamination can be present in raw materials or can be introduced during production. To prevent biofilms, corrosion and hardness deposits, cooling water for machines, autoclaves or instruments for production like lasers, welders, cutters or drills must be hardness-reduced, deionized and free from bacterial contamination.

Continuous microbiological testing during manufacturing as per ISO 11737-1 is crucial to ensure consistent, reliable product quality and patient safety. Using the right products helps you reduce risks that could impact patient health, lead to unnecessary delays or product recalls.
Our membrane filtration solutions for standard microbial enumeration protocols per USP <61> facilitate an efficient, accurate detection of potentially pathogenic or spoilage microorganisms:

- Save time with ready-to-use sterile filtration devices
- Minimize the risk of secondary contamination and false positives
- Reliable results

- Single and multi-branch Microsart® Manifolds are easy to clean and rinse, provide reliable and reproducible results and are adaptable to various filter device formats to suit your individual needs.
- To reduce the risk of secondary contamination, the Microsart® @filter combined with the Microsart® @media system with its integrated adhesive ring in the lid. This effortlessly affixes the membrane and positions it correctly on the agar plate for a touch-free membrane transfer. No liquid remains after filtration.

eBook – Pharma QC

Brochure - Microbiological QC

Datasheet - Microsart @filter

Datasheet - Microsart @media

Datasheet - Microsart Manifold

Datasheet - Microsart ejet

Check coating – Application of Correct Amount

Your Solution to Check Coatings, Protection Layers & Foils

Extended wear, delivery of drugs, biocompatibility or corrosion resistance - coatings on medical device provide numerous benefits. To fulfill their function reliably, coatings, protection layers and foils must be picked up uniformly.

Weighing by difference solutions from Sartorius are your best fit to verify coating systems have applied the exact amount of medical grade polymer or API to an implantable device, such as a DES (Drug Eluting Stent). For reliable, reproducible and straightforward weighing workflows:

- Highest precision for smallest quantities, protected against drafts and electrostatic charges

Sample holders accommodate differently shaped products

- Full data traceability and integrity
- Compliant to 21 CFR part 11 and EU GMP Annex 11

- Cubis® II Microbalances offer complete digital workflow management while supporting all requirements to achieve 21 CFR part 11 and EU Annex 11 compliance. A stand-alone solution for advanced user management, audit trail, electronic signature and safe data transfer prevent data manipulation. Benefit from easy set-up, simple maintenance and weigh differently shaped products conveniently by choosing the best fitting draft-shield and customized holders. The stainless steel draft shield F protects against drafts and electrostatic charges.
- Let the Backweighing QApp guide you through weighing workflows for simple, differential weighing with alphanumeric lot tracking.

Cubis® II Microbalance

eBook - Connectivity & Compliance

Brochure - Cubis® II

Flyer - Cubis® II backweighing QApp

Brochure - Cubis® II Sample Holders

Brochure - Quintix® & Secura®

Continuous Monitoring for Airborne Microorganisms

Keep Your Microbiological Limits Under Control

Airborne microbes pose a risk of contamination for products and raw materials. Continuous monitoring is a must to evaluate the microbial flora at your manufacturing facility for deviations from norm or undesirable organisms. For clarifying investigations, the verifiable avoidance of product contamination and reliable microbial identification are crucial.

Sartorius' secure and flexible technology for air sampling by filtration enables accurate and reliable analysis – without the risk of cross-contamination by changing agar plates:

- Be prepared for GMP Annex 1 regulations
- Continuous sample collection with just one filter
- Less intervention/risk of secondary contamination
- Save time (no more frequent changing of agar plates)
- Retain smallest airborne micro-organisms at the most accurate level
- Water-soluble filters assure the best recovery of trapped microorganisms
- Pair traditional growth-based methods with rapid detection methods

- Opt for total safety and convenience using Sartorius MD8 Airscan® technology. Collect samples using a single gelatine membrane filter without compromising the integrity of the clean room. Avoid false positives, especially in Grade A environments where the action limit is set at "zero CFU." Our proprietary, water-soluble filters retain even the smallest airborne microorganisms with an efficiency of 99.999%, practically ruling out potential false negative results. Focus on other tasks as your air sampler eliminates the need for routine intervention required by other conventional impaction-based samplers.

App Note - Air Monitoring

Datasheet - MD8 Airscan®

Datasheet - Gelatine Filter

App Note - Continuous Air Monitoring

Rinsing & Sterile Preparation

Your Water Supply, When and Where you Need It

The production of drug delivery systems requires a supply of highly purified water (DI, RO, EDI Ultrapure), which is deionized and free from impurities like bacteria or particles. It feeds lab equipment like washing machines, automatic endoscope re-processors (AERs), steam sterilizers or autoclaves enabling sterile preparation of instruments, parts and assemblies.

Sartorius Water Systems provide ultrapure water for impurity-free and safe operation adapted to your needs:

- Essential quality parameters at a glance
- Touchscreen display and intuitive menu navigation
- Favorites function with direct access for recurring volumes
- Excellent retention rates of impurities
- Bag Tank Technology avoids secondary contamination

- Arium® Comfort II delivers ASTM Type 1 ultrapure and Type 2 pure water of the highest quality in one system. The system combines reverse osmosis with EDI and resin technology for optimized impurity-free water quality.
- Optimize your endotoxin removal by adding an Arium® CellPlus Ultrafilter to your Arium® Comfort II system.
- Dispense ultrapure water, in the exact quality and quantities required for your daily analyses, when and where you need it. To further increase your flexibility, combine the Arium® Comfort II with the Arium® Smart Station dispensing unit.

Arium Smart Station

Brochure - Arium® Systems

Datasheet - Arium® Comfort 2

Brochure - Arium® Smart Station

Datasheet - Arium CellPlus Ultrafilter

Microbial Testing –Bioburden & Sterility Testing

Reliable Microbial Enumeration

Finished products must be free from microbial contamination to ensure consistent, reliable product quality and safety as per ISO 11737-1. Any undetected presence of microorganisms may cause unnecessary delays or product recalls. Prior to final sterilization and packaging, bioburden testing is carried out to determine the population of viable microorganisms on or in the product. Post sterilization, it can demonstrate the integrity of the sterilization process and sterility assurance during shelf life.

Our membrane filtration solutions for standard microbial enumeration protocols per USP <61> facilitate an efficient, accurate detection of potentially pathogenic or spoilage microorganisms:

- Save time with ready-to-use sterile filtration devices
- Minimize the risk of secondary contamination and false positives
- Touch-free membrane transfer

- Single and multi-branch Microsart® Manifolds are easy to clean and rinse, provide reliable and reproducible results and are adaptable to various filter device formats to suit your individual needs.
- To reduce the risk of secondary contamination, the Microsart® @filter combined with the Microsart® @media system with its integrated adhesive ring in the lid. This effortlessly affixes the membrane and positions it correctly on the agar plate for a touch-free membrane transfer. No liquid remains after filtration.

eBook - Pharma QC

Brochure - Microbiological QC

Datasheet - Microsart @media

Datasheet - Microsart ejet

Datasheet - Microsart @filter

Datasheet - Microsart Manifold

Counting with Reference Weight

Count Big Quantities of Small Parts

Counting individual pieces is time-consuming. Counting on a balance is a fast and automated way to accurately check large numbers of components based on individual weight.

Sartorius balances provide you the weighing capacities you need by ensuring full traceability of data, time-saving workflows and accurate results.

- Ease counting in warehouses, incoming-goods or in production
- Count big quantities of small parts in bulk
- Connect to your ERP

- The large weighing pans of Cubis® II Analytical and Precision Balances provide you the weighing capacities you need. Use the Essential Package Application Counting to calculate the quantity and precise weight of each piece.
- The Pharma Software Application Package supports compliance to 21 CFR Part 11 and EU GMP Annex 11, USP Chapter 41 and includes features like user management, digital signatures, audit trail and USP minimum weight.

eBook - Connectivity & Compliance

eBook - Cubis® II QApps

Brochure - Cubis® II

Brochure - Quintix® & Secura®

Error-proof in Packaging

Check Correct Assembly

Sartorius Checkweighing Solutions ensure that complex, but delivery systems have been assembled completely in QC and that no part is missing - before and after packaging. The readability of balances will be determined by the weight of the smallest component in the finished product assembly. The fully-modular device can be customized to your specific needs.

- High resolution
- Accommodates differently shaped products
- Full data traceability and integrity
- Document results in compliance with FDA 21 CFR Part 11 & EU GMP Annex 11, USP Chapter 41

- Benefit from easy setup and simple maintenance and weigh products with conveniently customized sample holders. On-board QApps guide you through weighing processes, increase measurement accuracy, precision and process safety. The Average Weight control QApp checks if a sample weight is within a specified tolerance.

eBook - Connectivity & Compliance

eBook - Cubis® II QApps

Brochure - Cubis® II

Brochure - Quintix® & Secura®

Ready-to-Use Filtration Devices & Membranes

Eliminate the need for developing new solutions. Count on our proven and validated solutions to keep you agile, facilitate your quality management, accelerate your time-to-market and ease the scalability of your production processes.
Sartorius supplies customers with a wide variety of microporous flat membrane filters in multiple pore sizes/diameters or formats to meet customer application needs. Benefit from 90 years of filter membrane expertise and select your membrane of choice.

Syringe Filters - Sartorius Premium Filters for Sterile filtration, Clarification and Particle Removal from Liquid Gases

Fastest Ultrafiltration on the Market

Membranes for In Vitro Diagnostics, Microarrays & OEM

Contact an Application Specialist

Ready-to-Use Filt

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Contact an Application Specialist

Syringe Filters - Sartorius Premium Filters for Sterile filtration, Clarification and Particle Removal from Liquid Gases

Sartorius syringe filters made of Polypropylene housing and a membrane filter feature maximum chemical compatibility and minimum extractables to ensure excellent results.

Sartorius filters made of acrylic housing provide high flow rates and low adsorption characteristics. This housing type is color-coded, e.g. for easy pore size identification.

- Ready-to-use, pre-sterilized and single-packed units
- Wide selection of pore sizes, membrane material and diameter
- Individually integrity tested
- Biocompatible according to ISO 10993-1 for CE-Minisart

Fastest Ultrafiltration on the Market

Sartorius offers the most comprehensive range of ultrafiltration process methods for the purification and concentration of your biological and inorganic samples, e.g. proteins, viruses and nanoparticles.

Centrifugal Concentration
- Highest target recoveries in the fastest possible time
- Unique choice of membranes for samples from 0.1 to 90 mL

Pressurized Concentration
- Compressed gas or air provides the vector for ultrafiltration
- Process single or sensitive samples with volumes from 5 to 98 mL

Crossflow (Tangential Flow)
- Progressive concentration as sample is re-circulated over membrane surface
- Eliminates membrane fouling for sample volumes from 0.1 to 5 L

Static Absorption
- Absorbent cellulose pad draws solvents through the membrane
- No additional equipment for starting volumes from 1 to 20 mL

Ready-to-Use Fil

Eliminate the need for developing new s ur quality management, accelerate your time-to-market and ease the scalability o Sartorius supplies customers with a wide hats to meet customer application needs. Benefit from 90 years of filter mer

Syringe Filters - Sartorius Premium Filters for Ste r In Vitro Diagnostics, Microarrays & OEM Clarification and Particle Removal from Liquid G

Membranes for In Vitro Diagnostics, Microarrays & OEM

Being the first industrial manufacturer of membranes, Sartorius has developed an unmatched expertise in the production of microporous membranes. Our exceptional variety of OEM membranes allows you to select the best-performing items for your device.

- Nitrocellulose membranes are ideally suited for protein assays
- Polyethersulfone (PES) membranes set new standards for liquid and gas filtration applications
- Utilized in medical device applications

Contact an Application Specialist

Error-Proof Automation

Let our solutions provide support where practical, repetitive processes such as check weighing, dispensing or filling are best handled by automated systems. Automation in production enables high-throughput, fast turnaround times, reduced errors and increased reproducibility. By combining our technology leadership and manufacturing excellence with your unique requirements, we can help you find the best performance for your production systems..

Integrated Weighing Cells

Robotic Dispensing Head

Single-Use Buffer Tank for Filling Lines

Small Scale Sterile Air/Gas Filtration

Contact an Application Specialist

Error-Proof Autor

Let our solutions provide support where p
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Integrated Weighing Cells

Small Scale Sterile Air/Gas Filtration

Contact an Application Specialist

Integrated Weighing Cells

For lab and process applications, Sartorius will engineer Original Equipment Manufacturer (OEM) weigh cells and load cells for integration of a force or weighing sensor into your plant equipment or machine. We offer weigh cells featuring electromagnetic force compensation and electronic modules that can be installed in or connected to other equipment requiring a weighing function.

- Automated checking of volumes by weighing
- High throughput, small footprint
- Secured filling, assembling, dosing, closing and counting
- Zero defect expectation

Error-Proof Auton

Let our solutions provide support where p
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Integrated Weighing Cells

Small Scale Sterile Air/Gas Filtration

Contact an Application Specialist

Robotic Dispensing Head

Select customizable components and
products for accurate, precise and reliable liquid handling, tailored to your application.

The rLINE® Robotic Dispenser Module scores with an outstanding accuracy and reliability with the enhanced DC-motor concept, electronic brake system and optical sensor. Combination of the Liquid Level Sensor with conductive robotic tips enables detection of liquid surface in the target vessel. This prevents erroneous attempts to aspirate liquid before the liquid surface has been reached.

- Outstanding accuracy and reliability
- Off-the-shelf modules or tailored to fit specific applications

Error-Proof Autor

Let our solutions provide support where p
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Integrated Weighing Cells

Small Scale Sterile Air/Gas Filtration

Contact an Application Specialist

Single-Use Buffer Tank for Filling Lines

OctoPlus FF® can be configured with a large variety of components and connectors for a wide range of applications.

- Single-use alternative to traditional stain less steel “break tank “or “buffer tank” systems

Error-Proof Autor

Let our solutions provide support where
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manufacturing excellence with your uniq

handled by automated systems. Auto-
bining our technology leadership and
stems..

Integrated Weighing Cells

Small Scale Sterile Air/Gas Filtration

Small Scale Sterile Air/Gas Filtration

Midisart® and Minisart® filter families are the clear choice for small scale sterile air/gas filtration applications. Trust in our products for critical applications like filling and transfer vessels.

- Hydrophobic PTFE membrane
- Autoclaving (max. 60 cycles)
- 100% integrity tested

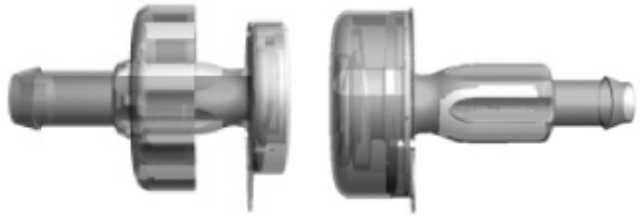
Contact an Application Specialist

Aseptic Connection & Disconnection

Sartorius provides simple solutions for ruling out contamination. This allows for the aseptic connection and disconnection of tubes, bags, bottles and sampling manifolds with validated closure.
We help you implement effective solutions for your specific process requirements. Sterility assurance is given by adherence to our stringent validation regimes.
Our consistent technology performance relies on robust designs, product validation, ease of use, qualification, maintenance and operator training services.

Quickseal®

Opta® SFT Sterile Connector



Clipster® Aseptic Disconnector

Datasheet - Clipster®

Datasheet - Quickseal®

Contact an Application Specialist

Aseptic Connection & Disconnection

Sartorius provides simple solutions for ru tubes, bags, bottles and sampling manifolds with validated closure.
We help you implement effective solutio to our stringent validation regimes.
Our consistent technology performance and operator training services.

Quickseal®

Aseptic Disconnector

Datasheet - Clipster®

Datasheet - Quickseal®

Contact an Application Specialist

Quickseal®

Quickseal® is installed on an array of tube materials including platinum-cured silicone, C-Flex® and other thermoplastic elastomers. It is extensively tested, proven aseptic and exceptionally strong.

- Smart component on single-use tube, bag or bottle assembly
- Sampling manifold, or on single-use bioreactors and more

Aseptic Connection & Disconnection

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Our consistent technology performance and operator training services.

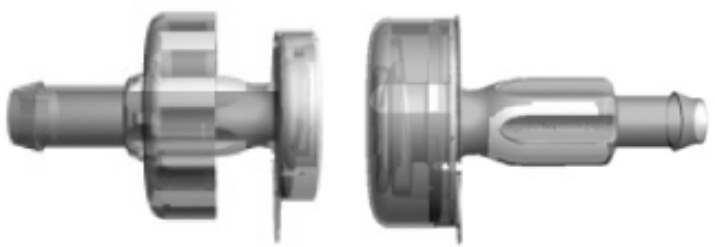
Quickseal®

Aseptic Disconnector

Opta® SFT Sterile Connector

Opta® SFT Sterile Connector is a single-use device that connects two separate, pre-sterilized components in manufacturing processes.

- Easy-to-use and backed by extensive validation
- 100% in-house integrity tested



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Quickseal®

Aseptic Disconnector

Datasheet - Clipster®

Datasheet - Quickseal®

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Clipster® Aseptic Disconnector

Clipster® Aseptic Disconnector is a single-use device that aseptically disconnects tubing while maintaining product sterility.

- Aseptic disconnection in non-classified and classified environments
- Can be applied to multiple tubing types and size

Customized Components

Customized Solutions for Your Handling, Sampling, Preparation Requirements

When off-the shelf doesn't work for you, Sartorius can offer a wide range of OEM or Private Label products tailored to your needs, whether customized stand-alone branded and packaged products, or components to be integrated into your equipment.
We offer an extensive portfolio of user-friendly filtration devices, membranes, weigh cells and dispensing solutions, as well as connecting and disconnecting technologies

Custom Membranes in a Variety of Formats

Custom Pipettes

Integrated Weighing Cells

Contact an Application Specialist

Customized Com

Customized Solutions for Your Handling,

When off-the shelf doesn't work for you, S eds, whether customized stand-alone branded and packaged products, or com We offer an extensive portfolio of user-frie nnecting and disconnecting technologies

Custom Membranes in a Variety of Formats

ated Weighing Cells

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Custom Membranes in a Variety of Formats

As the first industrial manufacturer of membranes, Sartorius has developed an unmatched expertise in the production of microporous membranes. Our exceptional variety of OEM membranes allows you to select the best-performing membrane for your device.

- Nitrocellulose membranes are ideally suited for protein assays
- Polyethersulfone (PES) membranes set new standards for liquid and gas filtration applications
- Utilized in medical device applications

Customized Com

Customized Solutions for Your Handling

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nnecting and disconnecting technologies

Custom Membranes in a Variety of Formats

rated Weighing Cells

Contact an Application Specialist

Custom Pipettes

IVD kit manufacturers often integrate pipettes into sample prep routines to ensure uniformity of results.

Sartorius handheld pipettes will elevate your users' pipetting experience with the state-of-the-art and ergonomic pipetting benefits they want most.

- Eliminates user-based variance
- Allows for pre-programmed workflows
- Continuous technical support for easy integration
- Disposable tips available for complete systems
- Global service, calibration and support network

Customized Com

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Custom Membranes in a Variety of Formats

ated Weighing Cells

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Integrated Weighing Cells

Sartorius manufactures a wide range of weighing cells for integration into any machinery or instrumentation where it is important to capture accurate and reproduceable weighing data.

- Featuring the latest electromagnetic force compensation technology
- Weight capacities up to 8.2kg
- Readability from 0.01g to 1 µg
- Sartorius weighing cells are exceptionally fast, robust and reliable and come in different configurations for easy installation into almost any application.

Transfer – Transport - Storage

Ready-to-use transfer sets and safe storage bags offer flexibility and facilitate the transfer of critical fluids or drugs.

Tuflux® TPE & SIL

Flexsafe® 2D Bags in Shell for Liquid Handling & Shipping

MyCap® Bottle Closure - Designed for You

Biosafe Bags & Rapid Transfer Port

Datasheet - Tuflux® SIL

Datasheet - Tuflux® TPE

Brochure - Biosafe® Transfer Systems

MyCap

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Transfer – Transpo

Ready-to-use transfer sets and safe stora

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Biosafe Bags & Rapid Transfer Port

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Datasheet - Tuflux® TPE

Brochure - Biosafe® Transfer Systems

MyCap

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Tuflux® TPE & SIL

For transfers between single-use, multi-use or hybrid systems, Tuflux® is the right solution. With Tuflux® Tubing, you benefit from the purest Silicone and TPE for the transfer of critical fluids, with excellent extractable/leachable profiles and the highest cleanliness and safety.

- Broad range of standards Tuflux® SIL & TPE
- 7 internal dimensions from ⅛" (3.2 mm) to ¾" (19.1 mm)
- Wall thickness from 1.6 to 4.8 mm

Transfer – Transport - Storage

Ready-to-use transfer sets and safe stor

Tuflux® TPE & SIL

Biosafe Bags & Rapid Transfer Port

Datasheet - Tuflux® SIL

Datasheet - Tuflux® TPE

Brochure - Biosafe Transfer Systems

MyCap

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Flexsafe® 2D Bags in Shell for Liquid Handling & Shipping

Proven Flexsafe® 2D Pre-Designed Solutions (PDS) have been designed for all pharmaceutical fluid storage or sampling such as media, buffer, drug substance and drug product. You can rely on Flexsafe® to provide safe and convenient storage for your most critical drug substances.

- Versatile range from 20mL to 50L
- For sterile filtration, storage, and transfer of all pharmaceutical fluids

Transfer – Transport - Storage

Ready-to-use transfer sets and safe stora

Tuflux® TPE & SIL

Biosafe Bags & Rapid Transfer Port

Datasheet - Tuflux® SIL

Datasheet - Tuflux® TPE

Transfer Systems

Contact an Application Specialist

MyCap® Bottle Closure - Designed for You

Mycap® bottle closure systems make customized, affordable molded bottle closures available to everyone. Mycap® bottle closures are one-piece, ready-to-use and single-use aseptic fluid transfer systems for bottles.

- Platinum-cured silicone seal
- Diverse range of capabilities and configurations
- Fit almost any bottle, flask, tube or rigid container with a screw cap
- Can be designed to meet individual requirements
- Mycap® expands capabilities, removes uncertainty and eases validation.

Transfer – Transport - Storage

Ready-to-use transfer sets and safe storag

Tuflux® TPE & SIL

Flex
& Sh

Biosafe Bags & Rapid Transfer Port

Datasheet - Tuflux® SIL

Datasheet - Tuflux® TPE

Brochure - Biosafe® Transfer Systems

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Biosafe Bags & Rapid Transfer Port

Biosafe® simplifies transfer of closure components, ensuring an aseptic transfer. With the robust design and proven performance of the Biosafe® RTP (Rapid Transfer Port) system, you can secure and simplify the transfer of your components, monitoring tools and liquids into your isolated line. Biosafe® bags are available in RTU (Ready to Use) and RTS (Ready to Sterilize) options that already contain stoppers from your supplier - and in RTF (ready to fill) options for processing stoppers at your facility.

Data Analytics

Optimize Your Manufacturing Processes with Actionable Insights

Umetrics® Suite helps you drive digital transformation and Pharma 4.0. The data analytics solutions help harness the wealth of data within your organization, identifying vital elements to improve the results of your research, development and manufacturing processes. With improved process understanding and more consistent product quality, you will be able to reduce risk, be faster to market and grow your business.

- Develop robust products and processes
- Minimize amount of experiments
- Find substitute raw materials
- Optimize batch processes
- Ensure faster troubleshooting
- Reduce risk of costly downtime
- Address process deviations in real-time
- Maintain regulatory compliance
- Full backwards traceability of predictions
- SIMCA® can be used to evaluate Post Market Surveillance data

Product - leaflet

Contact an Application Specialist

Sales and Service Contacts

For further information, visit sartorius/medical devices.com

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

USA
Sartorius Corporation
565 Johnson Avenue
Bohemia, NY 11716
Phone +1 631 254 4249
Toll-free +1 800 635 2906

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