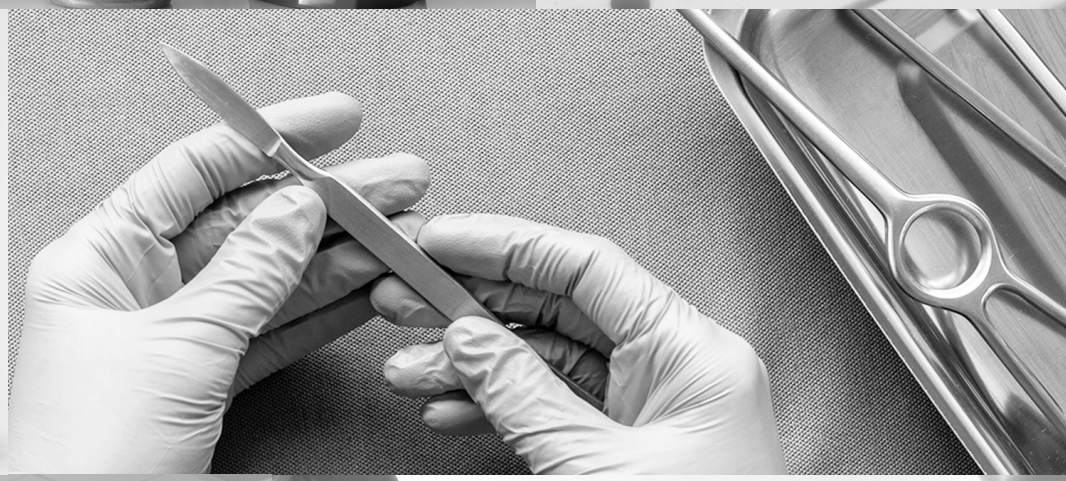
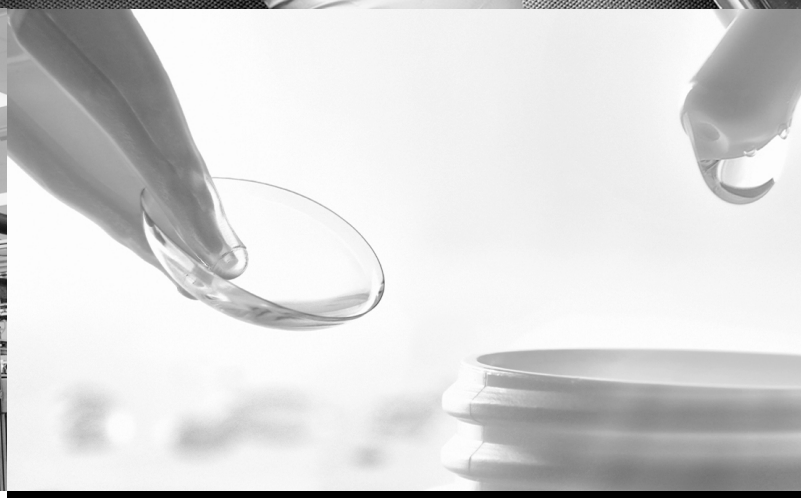




Best-Fit Solutions for Medical Device Quality Control

Simplifying Progress

SARTORIUS

Solutions for Medical Device Manufacturers

Pave Your Way to Market by Controlling Quality with Smart and Robust Solutions

Best-fit solutions assist you through the entire development and production process to fulfill biocompatibility, cleanliness, safety and packaging standards. Benefit from precision weighing solutions, ultra-pure water systems and our expertise in filtration, topped with Data Analytics software for straightforward and reliable quality control.

With over 150 years of trusted service and proven innovation, quality and reliability, Sartorius can help you bring your life-enhancing medical devices safely and efficiently to market.

Drug Delivery Systems

Safeguard superior quality of your high-tech devices for administering active ingredients safely and effectively.

Surgical Instruments

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

Diagnostic Kits

Reach the full potential of your quality control and bring your diagnostics safely, efficiently and compliantly to market.

Wearables and Disposables

Rely on robust, simple and reliable quality control solutions from raw materials to finished products.

Implants

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

Contract Manufacturing

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

For more information, please visit
www.sartorius.com/md

Explore the Process Steps for Ensuring Reliable Quality Controls

R&D and Process Development

Quality control starts in the design phase and continues through the whole product life cycle. It is vital activity for successful commercialization, assuring the consistent and compliant manufacturing of life enhancing products.

Solutions for your applications:

- Density Check of Solid Material & Liquids
- Nanoparticle Concentration
- Gravimetric Dose Accuracy Assessment
- Analytical Characterization - Biocompatibility
- Cytotoxicity - Biocompatibility
- Data Analytics

Raw Material Testing

The quality of the final product hinges on the quality of the raw materials. To prevent device defects and impairment of patient safety, your raw materials must be stable and safe for use.

Solutions for your applications:

- Density Check of Solid Material & Liquids
- Moisture Determination of Raw Material
- Particulate Matter Analysis
- Analytical Characterization – Biocompatibility
- Microbial Water Testing & Bioburden

In-Process Control

In-process quality control tests are performed at regular intervals to establish that product quality and specifications are met at all stages of production.

Solutions for your applications:

- 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
- Counting with Reference Weight

Final Release Testing

Every lot requires tests to ensure active ingredients are free of contaminants. Error-free assembly, conform to controlled tolerances, is necessary for accurate dose-delivery.

Solutions for your applications:

- Check Coatings – Application of Correct Amounts
- 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

Check Coatings – Applications of Correct Amounts

Weighing by difference solutions from Sartorius are your best fit to verify that coating systems have applied the exact amount. 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 Annex 11

Density Check of Solid Material & Liquids

Coatings, 3D inks, plastics, metals - guaranteeing the specified density of raw materials is crucial for stability and safety of devices. Deviations may have profound effects on the final product's performance.

Our solutions are tailored to the needs of density applications. Durable, high-performance Cubis® III balances and pycnometers,and precise calculation:

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

Gravimetric Dose Accuracy Assessment

The accuracy of drug delivery devices is critical to patient safety. To avoid failures or variations resulting in over- or under-dosing, you must check if the drug is released 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
- Fast stabilization, even in unstable environments

Counting with Reference Weight

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 Cubis® III 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

Error-Proof Packaging

Sartorius Checkweighing Solutions ensure that complex, but small medical device systems have been assembled completely 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.

Cubis® III 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

Moisture Determination of Medical-Grade Plastics

Raw and packaging materials can vary in their characteristics and hygroscopic properties. However, they need a specific moisture content for optimal processing and to assure the appearance and functionality of the final product.

Even the smallest deviations can be captured by MA-160 or MA-35 Moisture Analyzers:

- Measure minimum moisture content down to 0.005 %
- Process up to 4 samples simultaneously
- Achieve highest precision, even for very dry samples
- Comply with EN868 for sterile barrier systems

Analytical Characterization - Biocompatibility

The biological risk of a medical device 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.

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

- Minisart® Syringe Filters with low retention volumes
- Minimum leachables or extractables

Particulate Matter Analysis

GMP Annex 1 requests that medical devices be scrupulously clean. From raw material or environment, clothing, machining and lubricants, particle sources are abundant. They affect biocompatibility and safety as they build an additional surface for microbial growth, or can be lodged in a patient's vascular capillary system.

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

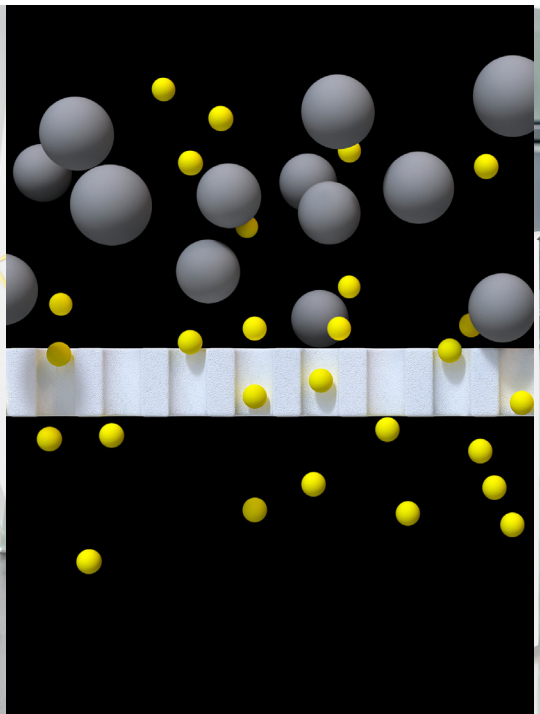
- Arium® Pro VF delivers ultrapure, particle-free rinsing
- Cellulose Nitrate membranes filters with excellent retention rates
- Accurate filter Cubis® III Ultra-Micro balances, protected against drafts and electrostatic charges

Rinsing & Sterile Preparation

The production of medical device 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 Arium® Comfort II Water Systems provide ultrapure water for impurity-free and safe operation adapted to your needs:

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



Microbial Water Testing & Bioburden

Microbial contamination must be evaluated in water, raw materials and prior to sterilization of medical devices. Membrane Filtration is the method of choice for the evaluation of microbial contamination of liquids such as purified water or rinsing fluids used during the manufacturing process.

Using the right products helps you reduce risks that could impact patient health, lead to unnecessary delays or product recalls.

Our Microsart® microbial enumeration solutions 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
- Comply with regulations

Microbial Air Monitoring

Microbial air monitoring is a must to evaluate the microbiological flora at your manufacturing facility for deviations from norm or undesirable organisms.

The MD8 Airscan® air sampler and gelatin filters enable accurate and reliable analysis – without the risk of cross-contamination:

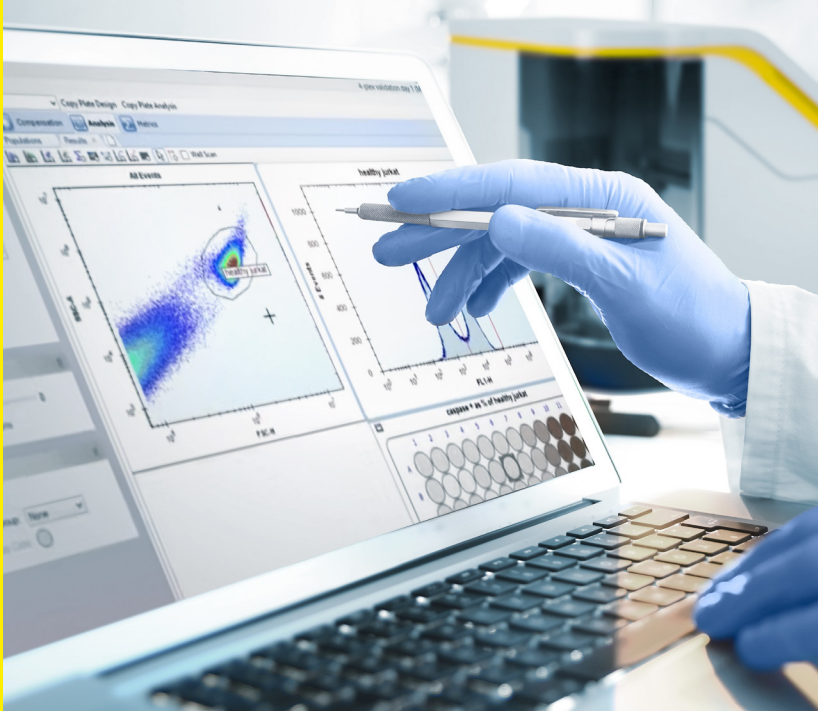
- Continuous sample collection with just one filter
- Less intervention/risk of secondary contamination l
- Water-soluble filters assure the best recovery of trapped microorganisms

Nanoparticle Concentration - Separation

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

Sartorius Lab UltrafiltrationVivaspin® Turbo 15 RC move you one step ahead:

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



Cytotoxicity – Biocompatibility in R&D

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.

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:

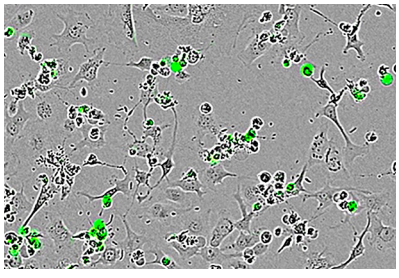
- Visualize and quantify cell behavior around the clock
- Time-lapsed, kinetic measurements in long-term

While not CFR 21 compliant, the Incucyte® Live-Cell Analysis System is ideal for research and development studies across multiple medical devices applications such as oncology, immune-oncology, immunology or neuroscience.

Data Analytics

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



Learn More:

Contract Manufacturing & Integration

Learn More:

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

Process 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:

- Integrated Weigh Cells
- Robotic Dispensing Head
- Single-Use Buffer Tank for Filling Lines
- Small Scale Sterile Air/Gas Filtration

Ready-to-Use Filtration Devices & Membranes

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
- Ultrafiltration devices
- Membranes for In Vitro Diagnostics, Microarrays & OEM

Customized Components

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 or specifically branded and packaged products, or components to be integrated into your equipment:

- CE-approved final devices (some restrictions apply)
- Custom syringe filters (non CE-marked) as components
- Custom ultrafiltration devices
- Custom manifolds
- Custom mechanical and electronic pipettes
- Custom membranes
- Integrated weigh cells & pipettes

Additional Medical Device Solutions

Achieve Optimal Weighing Performance with Cubis® III High-Resolution Balances

Medical Device manufacturers need the most reliable weighing results. The Cubis® III platform provides a completely configurable, high-performance portfolio of both lab weighing hardware and software to meet your expectation on the highest level.

External environmental influences or improper handling can lead to inaccurate results or poor weighing performance, which are not caused by the balance. To ensure high accuracy during weight measurements and excellent repeatability of the results you need to heed certain basic rules and requirements. Following the instructions and recommendations, your balance will always provide the best weighing performance and highly reliable results.

Claristep® Filtration System & Minisart® Syringe Filters

Clarification by filtration removes particles from samples, improving the reliability of your results and extending the service life of HPLC columns.

Free Handbook:

Learn More:

Perform Reliable Testing of Endotoxin Levels on Medical Devices with Smart Pipetting Solutions

Tacta® Mechanical Pipettes
- Effortless pipetting thanks to ergonomic design
- Volume lock for reliable pipetting results
- Easy calibration and adjustment

Picus® 2 Electronic Pipettes
- Accurate and precise pipetting results
- Fully electronic operation and easy to use
- Light weight pipette for superior pipetting ergonomics

Low Retention Tips
- Optimal sample recovery
- Purity certified - Sartorius pipette tips are tested for endotoxin content with a limit of 100 times lower than the regulatory requirement

Octet® in Nanoparticle Research

The Octet® platform serves as an invaluable tool in nanoparticle (NP) development. The label-free BLI technology allows the monitoring of several critical quality attributes (CQAs), including binding affinity, kinetics and stability.

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

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

For more information, please visit
www.sartorius.com/md

Specifications subject to change without notice.
Copyright Sartorius Lab Instruments GmbH & Co. KG.
Version 06 | 2026