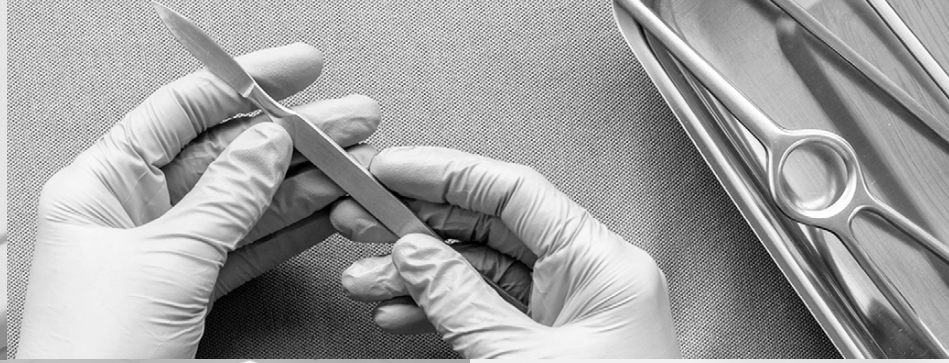

2022 Guide to Medical Devices Quality Control and Testing

Simplifying Progress

SARTORIUS

Introduction

To remain competitive in the medical device market, you need to be able to reduce costs while improving quality.

Sartorius offers a variety of solutions for your medical device manufacturing and quality control processes—options that can improve your productivity and help you meet rigorous compliance standards.

Some of our solutions include:

- Moisture Content in Plastic Resins
- GxP Pipetting Compliance
- Air Monitoring in Cleanroom Environment
- Weighing Compliance to US FDA - Data Integrity Principles
- Accurate Weighing Results for Medical Stents
- Ultrapure Water for HPLC Analysis

Partner with Sartorius to streamline your time-consuming, labor-intensive, and potentially error-prone manufacturing processes and ensure product quality.

Discover More

Moisture Content in Plastic Resins

How to Accurately Measure the Moisture Content of Plastic Resin?

Moisture content is an important variable that must be monitored for and controlled during the production of plastic medical device parts. ASTM standard D6869 is the benchmark for measuring the moisture content of plastic resin, and stipulates the use of Karl Fischer titration as the applicable standard method. Herein, we show that the Sartorius Mark 3 High Performance Moisture Analyzer correlates well with Karl Fischer titration standards for a number of plastic resins commonly used in medical device manufacture.

Download the App Note

GxP Pipetting Compliance

Are You GLP/GMP Compliant When It Comes to Pipetting?

Are you following methods for current Good Laboratory Practice (cGLP) or current Good Manufacturing Practice (cGMP)?

Our new application note introduces tools and principles that can help you with these demanding requirements, especially when it comes to your pipetting practices. A pipette is a precision measuring apparatus that has a significant influence on your lab results, but it can also be your companion in ensuring compliance.

Download the App Note

Air Monitoring in Cleanroom Environments

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

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 Annex E chapter of EN 17141 details guidance on culture-based microbiological monitoring methods and sampler verification.

This Application Note focuses on viable microbial monitoring and demonstrates that microbial air monitoring by Gelatin Membrane Filtration meets the requirements of the EN 17141 and the ISO 14698.

Download the App Note

US FDA Weighing Compliance

Advanced Weighing Compliance for Use in Regulated Medical Devices Industry

Sartorius's Cubis® II balance is designed to follow US FDA data integrity principles for accurate, legible, contemporaneous, original, and attributable (ALCOA) data. The Cubis® II balance, with pharma package, contains all the technical controls to support compliance with common regulations.

Achieve full compliance with additional procedural controls and systems for long-term data storage.

Download White Paper

Accurate Weighing for Medical Stents

How to Achieve Accurate Weighing Results for Medical Stents

Download our handbook to discover four steps to highly accurate and reproducible weighing results with the Cubis®II balance -the perfect choice for stent manufacturers in the Medical Devices industry.

Ensure high-throughput and boost your productivity via fast stabilization times, regardless of the stent size or weighing conditions in your facility.

Download the Booklet

Ultrapure Water for HPLC

Ultrapure Laboratory Water for HPLC Analysis in Medical Devices

The presence of trace contaminants in your solvent during gradient elution can result in "ghost or phantom peaks," so the quality of your solvent is often decisive in the reliability of your HPLC analytical run. However, deionized or distilled water still contains quantities of organic substances, which can cause ghost peaks. Water of the quality required for HPLC can be either purchased from a manufacturer or produced on site with a water purification system. Our application note evaluates a water purification system as an alternative to commercially sold ultrapure water for the preparation of high-purity eluents for HPLC analysis.

Download the App Note

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Visit Our Website For More Information

Additional Resources

Discover More

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