

# Quality & Purity Why Settle for Less?

From Raw Material to Certification: Precision, Reliability & Purity



# Why Settle for Less?

Maximum precision, sophisticated design and the highest purity are the demands we place on our products. Our commitment to quality means the tips have a high level of purity and accuracy.

For over 50 years, we have been manufacturing tailor-made pipette tips. Based on this experience as well as our technical competence and using ultra-modern production methods we provide you with pipette tips of the highest quality and purity.

To ensure the highest possible level of quality for SARSTEDT pipette tips, we pursue various different strategies at all levels. We always use **medical grade** raw materials at state-of-the-art production facilities in **Germany**.

We guarantee a consistently high level of quality by using standardised processes and constantly monitoring and analysing these.

We have developed our own standards of quality. For example, the label "Biosphere® plus" is a purity standard for laboratory products which guarantees the highest purity and quality. Further to this our pipette tips are **IVD compliant** and adhere to **ISO 8655-2**.

This brochure explores four essential pillars that distinguish our pipette tips: Medical Grade Materials, Stringent Production, Certified Reliability, and Sustainability. The next page will provide an overview of these key topics, with each section diving deeper into how we ensure excellence in every aspect of our process.

Development and production from a single source in Germany.



# How we ensure high quality & purity.



#### Medical Grade Materials:

High quality starts at the source. That's why we rely exclusively on medical-grade raw materials when manufacturing our pipette tips. From the very beginning, this ensures the high level of purity and precision required for laboratory environments. Our focus lies not only on compliance, but on setting a reliable foundation for consistently dependable results.



#### **Stringent Production:**

Our production takes place under controlled cleanroom conditions in Germany. Every step of the process is monitored, automated where possible, and executed by trained professionals in protective clothing. This strict framework allows us to maintain a consistently high level of quality and purity. For sterile tips, we use Ethylene Oxide gas sterilisation in accordance with ISO 11135.



#### Certified Reliability:

Independent laboratories test every single batch to verify that our pipette tips meet our own high internal standards, as well as international requirements such as ISO 8655 and the In Vitro Diagnostic (IVD). This commitment to third-party validation underlines our promise: reproducible results you can rely on – every time.



#### Sustainability:

We view sustainability as part of product quality. That's why our packaging is designed to be recyclable and reusable. Our refill system offers a smart and resource-saving alternative: used boxes are returned, processed, and transformed into new products – for example our block racks. In this way, we combine ecological responsibility with practical innovation.

## Medical Grade Materials



### Uncompromising Quality from the Start

Your samples deserve only the best for analytical accuracy right from the start. We need to ensure our tips have a high level of purity so they can be used in medical and forensic laboratories. To meet this high level of quality and purity we only use **medical grade polypropylene** for the manufacture of our pipette tips.

#### Virgin Medical Grade:

This is a virgin plastic, but with additional specific requirements for use in medical or biotech applications.

Medical Grade plastics are used in the production of medical devices, laboratory materials or packaging for medicines.

The virgin plastic for our pipette tips has the following additional requirements:

- The use of Medical Grade ensures compliance with biocompatibility requirements, e.g. in accordance with ISO10993.
- Is sterile or sterilisable without losing its properties.
- The use of additives such as lubricants, plasticisers or biocides is avoided.

The Polypropylene we use also meets the standards of numerous international guidelines and norms. Medical Grades are tested in accordance with ISO 10993, for example. Naturally, we adhere to REACH and RoHS standards.

We only choose suppliers who endorse our philosophy of maximum quality.

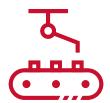


For more information on our Quality Management system: https://www.sarstedt.com/qualitymanagement



To make the highest quality tips we use the highest quality material, this allows you to avoid undesirable effects through material contamination. Therefore our tips provide stable, and reliable results which ensures the integrity of your samples and data.

## Stringent Production



### For Consistent Quality

For maximum reproducibility in your day-to-day work - trust our experience of over 50 years of precision manufacturing

The Medical Grade Material we use is put through a stringent production process to ensure consistency in quality. This means the tips you receive from us are always of the highest quality.

Through automated processes and under regulated conditions in controlled production areas, we minimise the risk of contamination and reduce sources of error. Regular maintenance and cleaning of our modern manufacturing facilities and measuring particle contamination in accordance with ISO 14644-1, allows us to meet applicable hygiene and purity regulations. Our stringent production ensures the consistent fit of our tip to the cone of your pipettor time and time again.

During initial, intermediate, and final inspections, we check whether materials and end products comply with specified specifications. Functional testing by qualified personnel, along with validated and consistent manufacturing processes, ensures the consistent high quality and reliability of our products in various application areas.

The Sterile Pipette Tips are sterilised with Ethylene Oxide (EtO) in accordance with ISO 11135. Furthermore according to ISO 18385, Ethylene Oxide Gas is the preferred method of decontamination in forensics.

In addition to production under laminar flow and tests conducted by independent laboratories our production process adheres to the following stringent ISO certification to ensure you receive the highest quality tip. ISO 14644-1 (Partial Contamination). This Validates the necessary purity is achieved and maintained.

We also have the following ISO standards in production for sustainability.

- ISO 50001 Energy Management
- ISO 14001 Environmental Management System (EMS)

We are focused on sustainability right from concept to design of our box systems. We have reduced the use of plastic materials in our pipette tip production by as much as 64%.



## **Certified Reliability**

### Proven Quality You Can Count On



Reliable results begin with verified quality. When your workflows depend on precision, you need assurance that every single tip performs exactly as expected. At SARSTEDT, we make that promise measurable batch by batch.

Independent laboratories confirm that all relevant limit values are met—especially those required for sensitive applications.

Our pipette tips are certified according to ISO 8655-2 and IVD. In addition, our Biosphere® plus quality label sets strict criteria for purity, validated through external testing.

These certifications aren't just claims—they're printed directly on the product label and supported by test documentation available on request.

With SARSTEDT, you receive more than a product. You receive the confidence of certified reliability—so you can focus on your work, not on repeat testing.



## PCR Performance Tested quality • The SARSTEDT quality and purity standard

'PCR Performance Tested' was specifically tailored on the basis of the requirements and the needs of working with nucleic acids (e.g. qPCR, PCR, purification and storage). With this quality classification you get assurance that SARSTEDT consumables can be used directly in nucleic acid analysis.

We guarantee that the following limit values will be adhered to:

Human DNA <0.5 pg/μl · Bacterial DNA <0.02 pg/μl · DNase <1x10<sup>-5</sup> U/μl · RNase <1x10<sup>-9</sup> Kunitz units/μl

Subject to technical modifications.



#### Biosphere® plus quality • Added assurance

Scientific analysis methods have become increasingly more refined in recent years, so that even individual molecules can be detected. Due to the heightened sensitivity, the user places significantly greater demands on the consumable material compared to just a few years ago, in order to be able to rule out even the slightest contamination.

With the Biosphere® plus quality, a purity standard was developed which offers the user the highest possible protection against any contamination.

All Biosphere® plus certified products undergo a validated decontamination procedure, in addition to the ultrapure production conditions. In this way, the limit values can be significantly lower compared to the PCR Performance Tested quality. In addition, Biosphere® plus items are free from ATP and are pyrogen-free/endotoxin-free and sterile in accordance with ISO 11135.

Biosphere® plus - items fulfil the following purity criteria, which are certified by an independent laboratory:

- > Sterile > DNA-free > ATP-free
- > Free from DNase and RNase > pyrogen-free/endotoxin-free

We guarantee that the following limit values will be adhered to:

Human DNA <0.5 fg/ $\mu$ l · Bacterial DNA <0.2 fg/ $\mu$ l · DNase <5x10<sup>-7</sup> U/ $\mu$ l

RNase <5x10<sup>-11</sup> Kunitz units/µl · ATP <1x10<sup>-12</sup> mmol/µl · Pyrogens <0.002 EU/ml · Sterility validated according to ISO 11135

Subject to technical modifications.

#### ISO 8655-2 ensures conformity of our Pipette Tips

To ensure maximum precision and reliability, even when handling the smallest volumes, SARSTEDT pipette tips undergo rigorous conformity checks. These checks are conducted in combination with pipettes from leading manufacturers and adhere to the international ISO 8655-2 standard. Pipette tips that meet these stringent requirements are easily identifiable by their conformity certificate and the relevant markings on labels and brochures.

In certified, accredited, or GMP laboratories, it is essential to use pipette tips that comply with ISO 8655-2 to maintain the highest standards of accuracy and performance.

Adherence to this standard ensures the consistent fit of our tip to the cone of your pipettor time and time again. Which means you have consistent reliable results and data.

Our certificates of conformity attest to the regular verification of this accuracy.

#### IVD-certified quality – for safe and precise solutions

Whether for routine testing or more specialised diagnostics, SARSTEDT tips are designed to support accurate results and help maintain the safety of both your samples and your laboratory processes. SARSTEDT tips are CE-marked and approved as an in vitro diagnostic. The IVD certification ensures that our tips meet the rigorous standards required for in vitro diagnostic devices, guaranteeing high quality, reliability, and precision.







#### SARSTEDT – A solution for everything. The advantages of compatibility for you:

Does your laboratory use different pipette types? Thanks to SARSTEDT, you only need one supplier for pipette tips! Pipette tips from SARSTEDT are compatible with various pipette suppliers. The risk of contamination is minimised thanks to precise manufacturing and an optimum fit, and the tips provide maximum precision when collecting and dispensing liquids. With SARSTEDT, everything comes from a single source – and thanks to the bundled delivery, our tips will also help make your laboratory more sustainable.

- > Are the pipette tips also compatible with my pipettes?
- > Do the tips meet the compliance requirements according to ISO 8655-2?

## FIND OUT MORE!



sarstedt.com/ compatibilityoverview-pipette-tips

# Certified reliability at a glance



Certification	Name	Description
ISO 8655-2	Piston-operated volumetric apparatus; Part 2: Pipettes	The International Standard for Pipettes
ISO10993 FF	Biological evaluation of medical devices	A series of standards for evaluating the biocompatibility of medical devices to manage biological risk.
ISO 14644-1	Cleanrooms and associated controlled environments	Specifies the classification of air cleanliness in terms of concentration of airborne particles in cleanrooms and clean zones
ISO 18385	Minimising the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes	Specifies requirements for the production of products used in the collection, storage, and analysis of biological material for forensic DNA purposes,
ISO 50001	Energy management systems – Requirements with guidance for use	Specifies requirements for establishing, implementing, maintaining and improving an energy management system
ISO 14001	Environmental management systems – Requirements with guidance for use	The internationally recognized standard for environmental management systems
ISO 11135	Sterilisation of healthcare products – Ethylene Oxide	Requirements for the development, validation and routine control of a sterilization process for medical devices
IVD	In Vitro Diagnostic Directive	Ensures a medical device meets the EU's safety and quality standards

# Responsibility leads to sustainability.

For over 60 years, our family-run company has combined a profound understanding of long-term thinking with expertise along the entire value chain. Our approach to sustainability is based on the United Nations' 17 Sustainable Development Goals, with a particular focus on the areas of health, education, climate protection and sustainable production. Since 2023, we have been transparent in aligning our company with the standards of the UN Global Compact to ensure that our strategy follows globally recognised principles.

Our commitment is evident in efficient processes, minimised resource consumption and innovative, resource-saving solutions. We attach great importance to sensible recycling to ensure that natural resources are used responsibly.







# One system – three options



## The revolutionary refill scheme for pipette tips

SARSTEDT's Refill Revolution marks a significant step towards increasing sustainability in laboratory environments worldwide. With this innovative scheme, SARSTEDT offers an environmentally friendly solution for the use of pipette tips by reducing the amount of plastic waste generated without compromising on precision and reliability.

By introducing a clever refill system, the Refill Revolution enables laboratories to replenish their used pipette tip boxes easily and efficiently. This not only helps to reduce plastic consumption, but also optimises logistics and storage in everyday laboratory work. It also saves a considerable amount of time in daily laboratory routines. Join the SARSTEDT Refill Revolution and find out for yourself how sustainability and high scientific standards can go hand in hand.



Discover the 360° solution for your pipettes from SARSTEDT: refillrevolution.sarstedt.com/en/





#### The box

- Easy to refill thanks to its unique design
- Space-saving stacking system
- Universal and robust
- Secure lid
- Autoclavable box
- Recyclable box and tray
  - Easy to stack inside one another, takes up little space when collected
- Optional rubber feet available for slip resistance



#### The SingleRefill

- Easy to refill thanks to its unique design
- Up to 41% less plastic material than the box
- Saves energy and resources during production
- Simple, fast refilling, available at the highest purity level
- Maximum hygiene and safety
- Combining sustainability and efficiency in the laboratory



#### The StackPack

- Efficient and sustainable
  - Low material consumption with a high throughput
- Time-saving thanks to the stacking system with 480 tips per StackPack
- Saves up to an incredible 70% in storage space compared with the box
- Economical stacking system
- Effective protection against contamination
- Easy removal of individual trays
- Suitable for refilling or for direct use from the stack



# If you have any questions, we'll be happy to help!

Visit our website: https://www.sarstedt.com/en/

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