

Quality certificate



SARSTEDT quality

Particular care is required in the production of consumables for diagnostics, science and research. High-quality materials, high-tech production facilities, rigorous controls from raw material through to the finished product and ongoing improvements form the basis for the high quality of all SARSTEDT products.

Transparent quality management

SARSTEDT's quality management system is certified according to the international standard EN ISO 13485 by an independent body, which is accredited by DakkS (Deutsche Akkreditierungsstelle GmbH). This system is integrated into all processes, guaranteeing that SARSTEDT's products are of outstanding quality, and forms the basis for consistent progress and transparency.

All production and testing processes are closely monitored, ensuring precise and reliable products for medical and scientific applications.

High-quality raw materials

Only materials of the highest purity and quality are used to manufacture SARSTEDT products. They are specifically selected and validated for the individual application in question.

The materials' compliance with international guidelines and standards is checked and documented on an ongoing basis. The addition of additives like bisphenols, biocides, latex and heavy metals is avoided during the production of all products made from polypropylene, polyethylene and polystyrene.

Controlled production

SARSTEDT products are manufactured under strict guidelines. Automated processes and regulated conditions in controlled production areas minimise the risk of contamination and reduce sources of error. The modern production facilities are regularly maintained and cleaned, guaranteeing compliance with the strict hygiene and purity guidelines.

Tight monitoring and ongoing measurement of particle contamination based on ISO 14644-1 at production locations with controlled areas is pursued to validate that the necessary purity is achieved and maintained during production.

Compliance of the materials and end products with the stipulated specifications is guaranteed by incoming, interim and outgoing checks. Validated and consistent production processes are complemented by functional tests that are carried out and assessed by qualified specialists, guaranteeing consistent high quality and reliability in all areas of application.

SARSTEDT QUALITY



Guaranteed purity

The purity of SARSTEDT's sterile products is achieved thanks to controlled production areas and validated sterilisation processes as per ISO 11137-1 and 11137-2. SARSTEDT's purity standards, Biosphere® plus, PCR Performance Tested, TC Tested and Cryo Performance Tested, also provide maximum safety for highly sensitive applications. Regular analyses guarantee that certified limit values are complied with.

Reliable quality

For the procurement of materials, only manufacturers and suppliers aiming at maximum quality are selected. Suppliers must provide evidence that their processes are regulated and documented. This procedure is verified on an ongoing basis.

Materials must be kept available in the long term and be unalterable. These are fundamental elements that are contractually agreed with the suppliers in order to ensure that SARSTEDT's products remain of the highest quality in the long term.

Since SARSTEDT products are used directly on patients and in the most modern research and development laboratories, they conform to the highest safety, precision and hygiene standards. As a global company, we ensure that our products meet the statutory and official regulations of the various countries and markets.

CERTIFIED