SARSTEDT

Because Quality Management is More Than Just a Word to Us.

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SARSTEDT: Pioneering Quality, Defining Standards.

Ensuring quality, targeting solutions, reducing costs – these are our shared goals in the laboratory and medical technology sectors. For over 60 years, SARSTEDT's commitment to quality management has played a key role in achieving these aims. As a value-driven, family-owned company, we continuously question and refine our processes. For us, quality is not just a requirement but a steadfast promise.

At SARSTEDT, we see quality as a comprehensive process – from the initial contact to the end-use of our products. Sustainability is central to this approach: we pursue the most efficient paths, minimise resource consumption, and develop low-waste solutions to protect natural resources.

In this brochure, we provide an overview of the core aspects of our quality management:

- Continuous Improvement – we constantly optimise processes, products, and services.
- Preventative Focus – we aim to prevent errors from the outset.
- Patient Safety First – we prioritise patient safety in every decision.
- Regulatory Compliance – we meet all relevant standards and regulations.
- Transparent Operations – our processes and outcomes are fully traceable for your assurance.

Trust in our dedication to quality!

„The quality of our SARSTEDT products is built on carefully selected raw materials, precise manufacturing, and rigorous controls **– ensuring maximum reliability.**"

Tim Gelhausen
Product Manager Life Science

Jochen Hoffmann
Head of Quality Management

SARSTEDT – Consistent Quality Standards – Global Presence.

Our commitment to quality management goes beyond borders. With our global footprint, we ensure high product availability while maintaining consistent, high-quality standards across all regions. Through a network of 13 manufacturing sites and a centrally managed quality system, SARSTEDT guarantees that our customers can depend on proven SARSTEDT quality, wherever they are located.

North America

Our North American production facility enables us to serve customers across the USA and Canada with customised products and reliable delivery times.

South America

Our Brazilian site serves clients throughout the region, underscoring SARSTEDT's dedication to sustainable production practices and strict adherence to global quality standards, while meeting specific regional requirements.

SARSTEDT Headquarters, including production, is located in Nümbrecht, Germany.

Europe

With 10 manufacturing sites across Europe, SARSTEDT ensures localised production and rapid response times for our customers.

- Sales Units
- Production Sites

Australia

Our production facility in Australia enables us to provide tailored solutions and fast delivery across the Asia-Pacific region.

Quality Management at SARSTEDT

Supplier management and customer audits generate frequent questions about our quality management system and the processes that safeguard our product and service quality. The following pages provide a clear overview of SARSTEDT's quality management system by addressing some of the most common inquirie.

Material Properties

Our commitment to product quality starts with the raw materials. SARSTEDT's selected plastics are tailored for their intended applications, with materials certified for medical or food-related uses as appropriate. Plastics for medical and IVD products are also biocompatibility-tested according to ISO 10993ff. Naturally, we adhere to REACH and RoHS standards.

Certifications

Our quality and environmental management systems are certified according to the following standards and directives:

- EN ISO 13485:2016
- MDSAP
- (EU) 2017/745 Annex IX Chapter I+III (MDR)
- EN ISO 50001 – Energy Management
- EN ISO 14001 – Environmental Management

Customised Packaging Solutions

For industrial clients, we offer customised packaging options:

- Individual packaging
- Small packaging units
- Bagged packaging
- Double-bag packaging
- Triple-bag packaging
- Bulk packaging

Purity Levels

To optimise products for specific applications, SARSTEDT offers products in various purity grades:

- Non-Sterile
- Sterile
- Endotoxin-Free
- PCR Performance Tested
- Biosphere Plus
- TC Tested
- Cryo Performance Tested

Purity Level:
Sterile

- Sterilisation process validated according to ISO 11137ff.
- Methods used include: Electron Beam (Beta) Gamma Radiation Ethylene Oxide (Gas Sterilisation)

Purity Level:
PCR Performance Tested

- DNA-Free
- DNase-Free
- RNase-Free
- PCR Inhibitor-Free

Purity Level:
Biosphere Plus

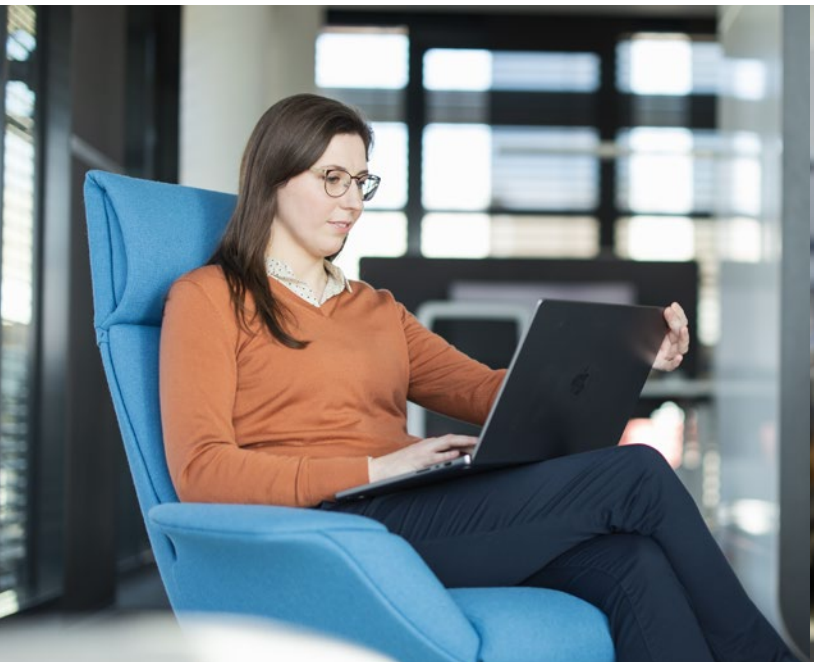
- Sterile
- DNA-Free
- DNase-Free
- RNase-Free
- PCR Inhibitor-Free
- ATP-Free
- Pyrogen-/Endotoxin-Free

Purity Level:
TC Tested

- Sterile
- Pyrogen-free/Endotoxin-free
- Non-cytotoxic
- DNA-free
- DNase-free
- RNase-free

Purity Level:
Cryo Performance Tested

- Sterile
- Pyrogen-/Endotoxin-Free
- Non-Cytotoxic
- Non-Mutagenic
- DNA-Free
- DNase-/RNase-Free



FAQ

General Information

Company	SARSTEDT AG & Co. KG
Head Office:	Sarstedtstraße 1, 51588 Nümbrecht
Founded:	1961
Founder:	Walter Sarstedt († 2013)
Website:	www.sarstedt.com
Email:	info@sarstedt.com
Phone:	+49 (0) 2293 305 0
Employees:	approx. 3,000
Number of shifts:	3
Production Sites:	Sites: 13 (Europe, North & South America, Australia)
Own Sales Organisations:	35
Commercial Register:	HRA 4094
VAT ID:	DE812294477
EUDAMED Actor ID/SRN:	DE-MF-000005649
EUDAMED Actor ID/SRN:	DE-IM-000011385

Quality Management System (QMS) / Certifications / Registration

Question	Yes	No	N/A
Does SARSTEDT operate a QMS?	☒	☐	☐
Is the QMS certified?	☒	☐	☐
Is SARSTEDT registered with regulatory authorities?	☒	☐	☐
Is SARSTEDT FDA registered?	☒	☐	☐
Is SARSTEDT BfArM registered?	☒	☐	☐
Is SARSTEDT EUDAMED registered?	☒	☐	☐
Is SARSTEDT registered as a pharmaceutical company?	☐	☐	☒
Does SARSTEDT have an environmental management system?	☒	☐	☐
Is SARSTEDT ISO 14001 certified?	☒	☐	☐
Does SARSTEDT have an energy management system?	☒	☐	☐
Is SARSTEDT ISO 50001 certified?	☒	☐	☐
Does SARSTEDT have an ESG management system?	☒	☐	☐
Is there a Code of Conduct?	☒	☐	☐
Has SARSTEDT signed the UN Global Compact?	☒	☐	☐
Does SARSTEDT use conflict minerals?	☐	☒	☐

Documents and Quality Records

Question	Yes	No	N/A
Does SARSTEDT provide a QM manual?	☒	☐	☐
Is the QM manual available to customers?	☐	☒	☐
Are procedure instructions issued?	☒	☐	☐
Are procedure instructions controlled?	☒	☐	☐
Are procedure instructions updated regularly?	☒	☐	☐
Are outdated versions of standard operating procedures (SOPs) withdrawn?	☒	☐	☐
Are documents revised?	☒	☐	☐
Are there defined retention periods for documents, records, and samples?	☒	☐	☐
Are records stored / kept in a secure manner?	☒	☐	☐
Are there inspection regulations?	☒	☐	☐
Are there quality records?	☒	☐	☐
Is there technical documentation?	☒	☐	☐

Supplier Management

Question	Yes	No	N/A
Does SARSTEDT only use approved suppliers?	☒	☐	☐
Are quality agreements established with suppliers?	☒	☐	☐
Are incoming inspections conducted?	☒	☐	☐
Are there inspection plans for incoming inspections?	☒	☐	☐
Are suppliers regularly evaluated?	☒	☐	☐
Is there an audit program for suppliers?	☒	☐	☐
Is there a process for supplier complaints?	☒	☐	☐
Are suppliers regularly evaluated?	☒	☐	☐

Customer Requirements

Question	Yes	No	N/A
Is there a process for reviewing customer requirements?	☒	☐	☐
Are customer requirements documented in writing?	☒	☐	☐
Can customer-specific products be manufactured?	☒	☐	☐
Is there the possibility to enter into quality agreements?	☒	☐	☐
Are change notifications possible?	☒	☐	☐
Are customer audits allowed?	☒	☐	☐
Is it possible to obtain batch certificates?	☒	☐	☐
Can customers receive copies of batch documentation?	☐	☒	☐
Can customer-specific information materials be provided?	☒	☐	☐
Are customer training sessions offered?	☒	☐	☐

Quality Assurance / Quality Control

Question	Yes	No	N/A
Is there quality assurance in production?	☒	☐	☐
Are incoming, in-process, and final inspections conducted?	☒	☐	☐
Are inspection plans and records available?	☒	☐	☐
Are measuring instruments used?	☒	☐	☐
Are measuring instruments regularly calibrated?	☒	☐	☐
Is tested and non-tested goods kept separate?	☒	☐	☐

Corrective and Preventive Actions (CAPA)

Question	Yes	No	N/A
Are non-conforming products segregated?	☒	☐	☐
Is there a quarantine area?	☒	☐	☐
Is the quarantine area locked?	☒	☐	☐
Is there a list of products in the quarantine area?	☒	☐	☐
Is there a CAPA system in place?	☒	☐	☐
Is there a system for rework?	☒	☐	☐
Is there a recall system in place?	☒	☐	☐
Is there a system for regulatory reporting?	☒	☐	☐

Product Development, Design Control, Design Changes

Question	Yes	No	N/A
Does SARSTEDT have a dedicated development department?	☒	☐	☐
Is there a defined process for product development?	☒	☐	☐
Is the development process carried out in defined stages?	☒	☐	☐
Does the development process utilise specifications and requirement documents?	☒	☐	☐
Are design reviews conducted?	☒	☐	☐
Are design validations performed?	☒	☐	☐
Is there an independent approval process for newly developed products?	☒	☐	☐
Are environmental considerations incorporated into the product development process?	☒	☐	☐
Is there a process for design changes?	☒	☐	☐
Are design changes reviewed across multiple disciplines?	☒	☐	☐
Are regulatory aspects considered when making design changes?	☒	☐	☐
Are customer agreements taken into account when implementing design changes?	☒	☐	☐

Management Review and Internal Audits

Question	Yes	No	N/A
Is an annual management review conducted?	☒	☐	☐
Are all mandatory aspects required by the standards considered during the review?	☒	☐	☐
Is there an internal audit programme in place?	☒	☐	☐
Are auditors assigned?	☒	☐	☐
Are audit reports generated?	☒	☐	☐
Are corrective actions from audits tracked?	☒	☐	☐

Personnel – Qualification and Training

Question	Yes	No	N/A
Is there an internal organisational chart?	☒	☐	☐
Is there an organisational chart for customers?	☐	☒	☐
Are there job descriptions in place?	☒	☐	☐
Is there a designated person according to Article 15 MDR (PRRC)?	☒	☐	☐
Is there a health and safety officer?	☒	☐	☐
Is there an environmental management representative?	☒	☐	☐
Is there an energy management representative?	☒	☐	☐
Is there an ESG manager?	☒	☐	☐
Is there a data protection officer?	☒	☐	☐
Is there a Chief Compliance Officer?	☒	☐	☐
Is there a representative for the Supply Chain Due Diligence Act?	☒	☐	☐
Are employees assigned roles according to their qualifications?	☒	☐	☐
Is there an internal vocational training programme?	☒	☐	☐
Is there an onboarding programme for new employees?	☒	☐	☐
Is there an internal training system?	☒	☐	☐
Is training needs analysis conducted?	☒	☐	☐
Are trainings documented?	☒	☐	☐
Is there an evaluation of training effectiveness?	☒	☐	☐

Product Complaints / Complaint

Question	Yes	No	N/A
Is there a procedure for product complaints?	☒	☐	☐
Is there a department for complaint management?	☒	☐	☐
Are product complaints systematically investigated?	☒	☐	☐
Are corrective and preventive actions taken based on complaints?	☒	☐	☐
Does the customer receive a written report regarding their complaint?	☒	☐	☐

Premises and Production Environment

Question	Yes	No	N/A
Are the production conditions specifically adapted to purity requirements?	☒	☐	☐
Are the production rooms monitored?	☒	☐	☐
Are records of monitoring results maintained?	☒	☐	☐
Is there air quality monitoring?	☒	☐	☐
Is there machine monitoring?	☒	☐	☐
Is there product monitoring?	☒	☐	☐
Is there staff monitoring?	☒	☐	☐
Is access to the production rooms regulated?	☒	☐	☐
Is there specialised workwear?	☒	☐	☐
Is hair protection and, where necessary, gloves worn?	☒	☐	☐
Is disinfectant used?	☒	☐	☐
Are cleaning plans in place?	☒	☐	☐
Are records kept of cleaning activities?	☒	☐	☐

Preventive Maintenance

Question	Yes	No	N/A
Is there a maintenance department?	☒	☐	☐
Is preventive maintenance implemented?	☒	☐	☐
Is maintenance carried out according to defined plans?	☒	☐	☐
Does preventive maintenance cover buildings, infrastructure, as well as machines, equipment, and tools?	☒	☐	☐
Are records of maintenance activities maintained?	☒	☐	☐

Process Validation and Qualification

Question	Yes	No	N/A
Is there a validation programme in place?	☒	☐	☐
Does the validation programme include the following?			
- Production processes?	☒	☐	☐
- Packaging processes?	☒	☐	☐
- Sterilisation processes?	☒	☐	☐
- Transportation processes?	☒	☐	☐
- Shelf-life studies?	☒	☐	☐
- Computer systems?	☒	☐	☐

Do you require further information?

Department / Contact	
Head of Quality Management:	jochen.hoffmann@sarstedt.com
Person responsible according to Article 15 MDR (PRRC):	kerstin.weuste@sarstedt.com
Complaints:	complaint@sarstedt.com
General Inquiries:	info@sarstedt.com
Customer Service:	export@sarstedt.com
Hotline:	0800 0833050
Certificates and Information:	www.sarstedt.com/download/qualitaetsmanagement

All information as of 30.09.2024.

Notes

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

Visit our website: www.sarstedt.com

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