

# Equipment Qualification (IQ | OQ)

## Sterisart® Universal Pumps



### Benefits

- Compliance with regulatory requirements (GLP | GMP)
- Risk-based verification of device performance
- Proof of suitability for your devices
- Extensive documentation and certificates
- Documentation available paper-based or digital
- Audit security

### Product Information

You must demonstrate proof of suitability for the equipment in your GLP | GMP regulated laboratory. The Sartorius equipment qualification is documented proof that your Sterisart® pump has been installed correctly, works reliably and is suitable for use. Our IQ | OQ qualification follows the “risk-based approach”, as recommended for equipment inspections in regulated industries. Specially trained Sartorius service engineers perform all the necessary tests directly on-site at your premises. The comprehensive and customer-specific documentation is available paper-based or digital and can easily be integrated into existing quality management systems.

## Specification

- On-site qualification (IQ | OQ) by a specially trained service technician
- Performance of device-specific tests for the Installation Qualification (IQ). This includes, among others:
  - Checking the equipment delivery for completeness and any transport damage
  - Documentation of installation conditions
  - Verification of correct installation of equipment components
- Performance of device-specific tests for the Operational Qualification (OQ). This includes, among others:
  - Function tests
  - Initial metrological equipment check
  - Training of the operating personnel
- Complete documentation in special IQ | OQ templates

## Customer Prerequisites

- Device is at the installation site and has been sufficiently acclimatized
- The device is freely accessible

### Digital vs. Paper-Based IQ|OQ Documentation

Documentation can be provided paper-based in a folder or as a digital document. Digital documents are handled in a 21 CFR Part 11-compliant process without any software downloads required.

## Are You Interested?

We would be pleased to hear from you! We are happy to provide you with a non-binding service quote. For more information about our service portfolio, please visit: [www.sartorius.com/en/services/instrument-service](http://www.sartorius.com/en/services/instrument-service)

Learn More:



### Germany

Sartorius Lab Instruments GmbH & Co. KG  
Otto-Brenner-Straße 20  
37079 Göttingen  
Phone +49 551 308 0

### USA

Sartorius Corporation  
3874 Research Park Dr.  
Ann Arbor, MI 48108  
Phone +1 734 769 1600

 For further contacts, visit  
[www.sartorius.com](http://www.sartorius.com)