

# Qualification

## Configurable Single-use Systems

### Benefits

- Compliance with regulatory requirements (GLP | GMP)
- Strict Sartorius test standards
- Comprehensive documentation; easy to integrate into your existing quality management system



#### **Product Information**

Sartorius SAT (Site Acceptance Testing) is your guarantee for GLP- | GMP-compliant operation of your system. Our trained specialists are perfectly prepared to perform all necessary tests to ensure successful on-site equipment qualification. Our comprehensive and customer-specific documentation can be easily integrated into your existing quality management systems.

#### **Specifications**

- On-site qualification (SAT) will be performed by one of our qualified service technicians and, if required, qualification tests will be documented:
  - Verification of product and test specifications
  - Test plan and report
  - Inspection of re-piping
  - Testing re-I | 0

The qualification is available for the following single-use systems:

- FlexAct<sup>®</sup> Systems for the following:
  - Preparation of buffers and media
  - Cell harvest | Depth filtration | DBF (clarification by body feed filtration)
  - Virus inactivation (pH reduction)
  - Virus filtration
  - Ultrafiltration | Diafiltration

### **Customer Prerequisites**

- All equipment is already at the site where SAT will be performed
- Sufficient space for access to the equipment is available
- Power supply and supply (feed) lines are available at the place of installation
- A helper must be available to assist with lifting and carrying the equipment. The customer provides lifting devices (eg.: fork lift)
- The customer must designate the person responsible at the customer's site when placing an order

Interested? Just get in touch with us for a free service consultation. You will find all important information on our website at www.sartorius.com/service.



Sartorius Stedim Biotech GmbH August-Spindler-Strasse 11 37079 Goettingen, Germany Phone +49.551.308.0 Fax +49.551.308.3289 www.sartorius-stedim.com

USA Toll-Free +1.800.368.7178 Argentina +54.11.4721.0505 Brazil +55.11.4451.6226 Mexico +52.5555.62.1102 UK +44.1372.737159 France +33.442.845600 Italy +39.055.63.40.41 Spain +34.913.586.098 Russian Federation +7.812.327.5.327 Japan +81.3.4331.4300

Japan +81.3.4331.4300 China +86.21.68782300

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