



AppliFlex ST and GMP

Single-use bioreactors

Sustainable Life Science

Passion for all dimensions of Life

Together with our partners and customers, we do everything we can to improve on dimensions of life: Planetary Life, Human Life, Patient Life, Professional Life, Business Life and Societal Life.

To improve on Planetary Life for example, and to give us all a healthier and better future, we aim to do all we can to minimize our impact on the environment. We channel our efforts into a set of initiatives, carried out in collaboration with stakeholders across our value chain.

Getinge is committed to becoming a net-zero company by 2050 across the full value chain and our targets have been approved by the Science Based Targets initiative. Getinge has signed the UN Global Compact and we support its ten principles on human rights, labor, environment and anti-corruption. Our sustainability work is governed by our Code of Conduct and a number of policies such as human rights, anti-corruption and the environment.

Read more on www.getinge.com

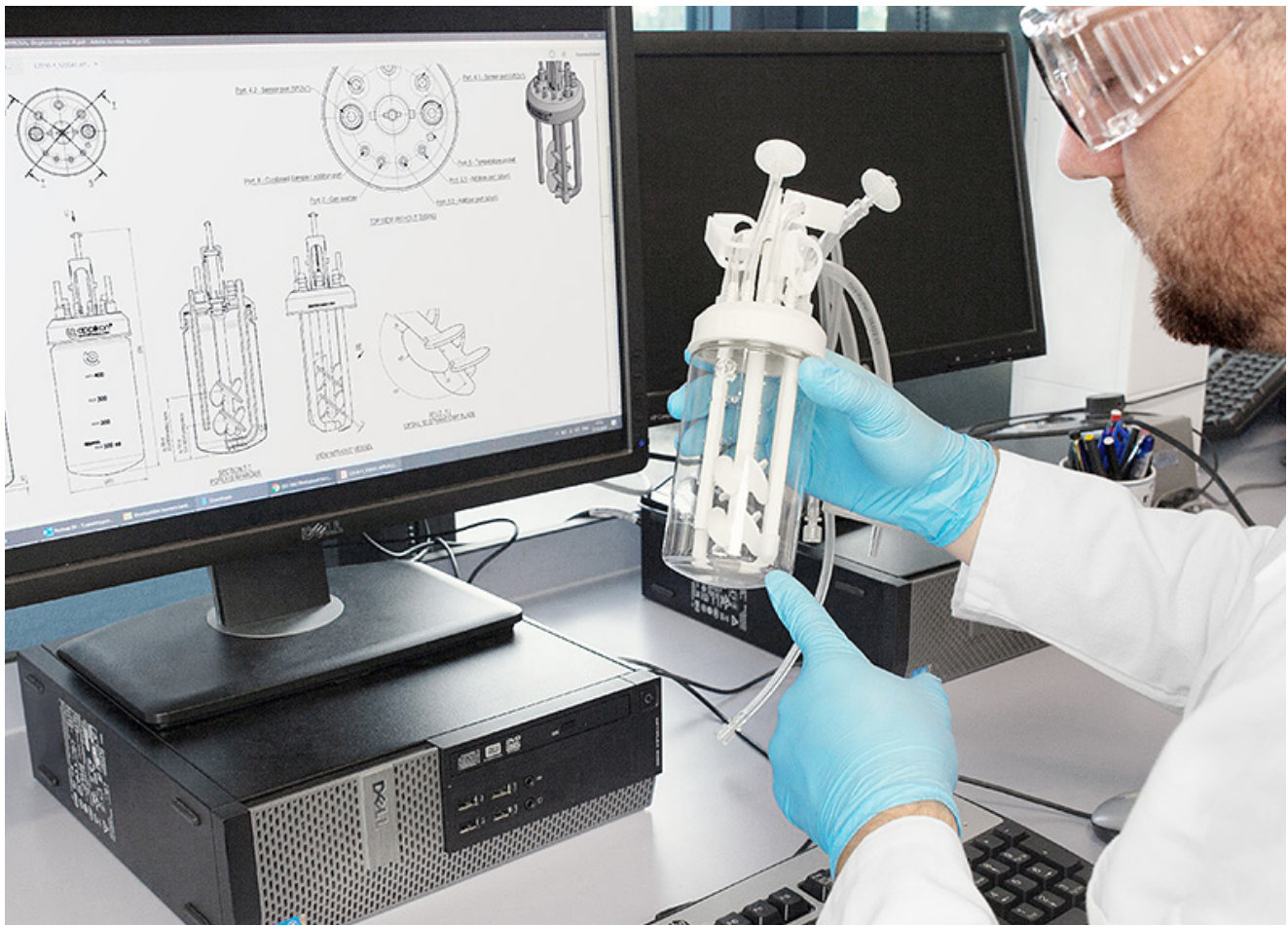


SUSTAINABLE
DEVELOPMENT GOALS



WE SUPPORT

ecovadis
Business Sustainability Ratings



Partner of Choice

For the life science industry

Our aim is to support scientists, (cell)biologists, lab managers and operators achieve their goals: Improving quality of life.

Our bioreactor system portfolio covers the whole upstream bioprocess, ranging from laboratory scale and

pilot plant scale to production scale. Whatever your application is, we have the right products for you to optimize the growth of cells and bacteria that is key to the production of life-saving products.



Vaccines



Bio-Pharmaceuticals



Regenerative Medicine



Food and Beverages



Bio-Chemicals



Bio-Fuels

AppliFlex ST

– Single-use Bioreactors for Lab-scale

The AppliFlex ST is a fully customizable stirred tank single-use bioreactor. By using 3D printing technology, we can create any head plate configuration and the optimal headplate design for your process. With this single-use system there is no risk of cross contamination between runs.

The pre-sterilized, ready-to-use bioreactor makes your life in the lab easier. No more assembly and sterilization before you can start your culture. No more cleaning after the culture is finished. Save time and costs, execute more runs, and reduce your time-to-market.

Benefits:

- Fully customizable to meet your bioprocessing needs
- No more cleaning, preparing and sterilizing bioreactors
- Perform more experiments in a shorter time
- Eliminate the risk of cross-contamination between runs
- Improve reproducibility and outcomes of your experiments



Applications:

- Microbial and cell culture
- Cell and gene therapy
- Cellular agriculture
- Screening studies
- Media optimization
- Process optimization
- Batch, Fed-Batch, Perfusion and Continuous cultivation

Features:

- Integrates with software automation and automated sampling tools
- Interchangeable with multi-use systems
- Removable topplate
- Shelf life 2 years
- Pre-sterilized and ready-to-go
- Fully closed bioreactor system
- Single-use sensor option available

Custom Design:

The AppliFlex ST differentiates from other single-use bioreactors by being a fully customizable stirred tank bioreactor. You can choose, or even design, the type and number of impellers, the number of liquid and gas additions and the type of sparger that are optimal for your process. No more unused ports or spargers with blind plugs, but an optimized bioreactor for your specific process development and R&D application.

The 3D printing production technology guarantees complete reproducibility between each bioreactor produced guaranteeing exact and identical conditions between runs. The AppliFlex ST offers the flexibility that you need for your specific bioprocess and is available for both cell culture and microbial applications.

The AppliFlex ST can be used as a single unit as well as a parallel processing system. The 500 mL AppliFlex ST is the scale down version of the 3 L bioreactor guaranteeing an easy scale-up of your process from 500 mL to larger volume cultivations. The 3 L and 15 L AppliFlex ST are designed to directly replace their autoclavable counterparts.

The single-use system can be exchanged with a multi-use system whenever your process or workflow needs a different approach.

The AppliFlex ST 500 mL and 3 L feature a fully removable topplate for operators to have easy access to the culture. Pouring into downstream processing vessels or other bioreactors has never been this easy. Optionally a closed lid is available which makes the vessel ready for transport, storage or freezing. A water supply is not required to operate the AppliFlex ST, cooling and heating are done using electric elements and the condenser is cooled electrically as well. This is only available on the 500 mL for now. No expensive laminar flowhood is needed to operate the system, except for operator handling.

The AppliFlex ST can easily be integrated into a DeltaV™ control installation using our V-Control software. This makes process transfer from the lab to production and from production to the lab very simple.



Related products:

- Livit Flex
- my-Control
- pH sensor
- DO₂ sensor/ LumiSens Optical DO₂ sensor
- V-Control software
- Lucillus® software
- Autosamplers

Specifications (Part 1/2):

Physical characteristics	500 mL	3 L	15 L
Dimensions (h x Ø)	236 x 75 mm	340 x 130 mm	500 x 223 mm
Weight	0.2 kg (1 bioreactor)	0.7 kg (1 bioreactor)	1,7 kg (1 bioreactor)
Bottom	Dished bottom	Dished bottom	Dished bottom
Total volume	575 mL	3 L	15 L
Working volume	100 – 400 mL	0.65 – 2.4 L	3 - 12 L
H/D ratio total volume	2.0	2.0	2.0
H/D ratio working volume	1.33	1.33	1.33
Impeller type	Marine / Rushton / Anchor / None / Hydrofoil / Helical and more...		Marine
Impeller diameter	Customizable	52 mm	74 / 88,8 mm - to be determined after testing
Sparger type	Pipe with Ø2mm hole / Open pipe / Sparger stone / Jet sparger / Porous sparger and more...		Porous sparger



Specifications (Part 2/2):

Operating conditions	500 mL	3 L	15 L
Working temperature	5 – 45 °C	5 – 45 °C	5 – 45 °C
Storage temperature	-80 – 45 °C	-80 – 45 °C	-80 – 45 °C
Design pressure	0 – 0.5 barg	0 – 0.1 barg	0 – 0.1 barg
Mixing time	~3 seconds	~3 seconds	~3 seconds
Connections	500 mL	3 L	15 L
Sterilization	>25 kGy Gamma irradiation		
Sensors options	500 mL	3 L	15 L
Measurement range	Single-use sensors or traditional multi-use sensors		

AppliFlex ST GMP

– Single-use Bioreactors for Clinical Applications

The AppliFlex ST GMP* is a customizable single-use bioreactor that is designed to meet all cGMP requirements for clinical CGT applications. It enables a seamless process transition from R&D to clinical production.

The AppliFlex ST GMP is available in 500 mL and 3 L and can be customized to your requirements.

Benefits:

- Seamless process transition from research to clinical production (both scale up and scale out)
- Designed to meet the requirements for clinical production, such as material requirements, traceability, particle requirements and much more
- Builds on the proven customization ability of the AppliFlex ST for research and development purposes



Applications:

- Cell therapy products
- Gene therapy products
- Viral vector components
- mRNA synthesis
- Biopharmaceutical cell culture

Features:

- Fully closed bioreactor system
- Pre-sterilized and ready-to-go
- Following the strictest cGMP standards
- Available as turnkey package
- Full customizable design

Specifications:

Physical characteristics	500 mL	3 L
Dimensions (h x Ø)	236 x 75 mm	340 x 130 mm
Weight	0.2 kg (1 bioreactor)	0.7 kg (1 bioreactor)
Bottom	Dished bottom	Dished bottom
Total volume	575 mL	3 L
Working volume	100 – 400 mL	0.65 – 2.4 L
H/D ratio total volume	2.0	2.0
H/D ratio working volume	1.33	1.33
Impeller type	Marine / Rushton / Anchor / None / Hydrofoil / Helical and more...	
Impeller diameter	Customizable	52 mm
Sparger type	Pipe with Ø2mm hole / Open pipe / Sparger stone / Jet sparger / Porous sparger and more...	
Operating conditions	500 mL	3 L
Working temperature	5 – 45 °C	5 – 45 °C
Storage temperature	-80 – 45 °C	-80 – 45 °C
Design pressure	0 – 0.5 barg	0 – 0.1 barg
Mixing time	~3 seconds	~3 seconds
Connections	500 mL	3 L
Sterilization	>25 kGy Gamma irradiation	
Sensors options	500 mL	3 L
Measurement range	Single-use sensors or traditional multi-use sensors	

Related products:

- Livit Flex
- my-Control
- pH sensor
- DO₂ sensor/ LumiSens Optical DO₂ sensor
- V-Control software
- Lucillus® software
- Autosamplers

* Disclaimer

Purpose/intended use: Getinge's GMP compliant systems are intended to be used in GMP compliant production and research environments. The system is not intended to be used as a medical device.





Getinge Service

– Total Process Control for You

With Getinge, service goes beyond replacing gaskets. Service is about in depth product knowledge to provide best in class preventive maintenance. Service is an investment in reliable equipment, a reliable process and about providing advice to the to help improve efficiency. In Getinge Service you will find our complete service offer to ease your daily challenges.

Getinge Service for bioreactor systems contains

- Workflow Optimization & Application Support
- Quality & Compliance
- Standard Service
- Extended Warranties
- Installation, Relocation and Retrofitting Services
- On-Demand Service



Quality & Compliance

All Getinge equipment is tested thoroughly throughout the manufacturing process. During our in house verification processes we perform comprehensive tests on all Getinge equipment. All quality documentation is supplied with our systems. The quality documentation is setup in such a way that it is ready to use for your validation and qualification process. Tailored to your requirements we can assist with Factory Acceptance Tests (FAT), commissioning, Site Acceptance Test (SAT) and IV/OV.

We bring over 40 years of experience with cGMP and EUDRALEX in verification, validation and qualification. Our projects department can assist you in defining your requirements right from the start. It will make your life easier knowing that our experts in the bioreactor field have defined your URS so that no detail is overlooked and all specifications are realistic and achievable.

Standard Warranty

All Getinge equipment is guaranteed for one year after delivery against defective materials and workmanship. All component parts of our products are covered by this warranty, except for normal consumable items such as glassware, sensors, O-rings and gaskets etc. Warranties are voided by unauthorized service of equipment.



Getinge Academy

– Be the Expert

Get trained and be ready! Well-trained scientists, operators, and engineers make sure that our systems are fully utilized in your operations. In our vision, training and instruction on how to operate our scientific equipment to make optimal use of its capabilities is not a one-time occurrence, but needs to be repeated on a regular basis.

That's why we created a curriculum to fit your needs. The courses range from educational hands-on and theoretical "Fermentation & Cultivation" sessions, to advanced SCADA/PIMS software training. Our team of bioprocess experts is ready to give you advice on basic or advanced process optimization questions, including process scale-up, aeration, mixing, temperature, pH, and dissolved oxygen control, plus other process controller settings.



Our in-house laboratory is equipped to run cultures and to mimic your process conditions so that recommendations can be drawn up for you based on hands-on experience. Through our Workflow Optimization Assessment we can even design training programs for your employees, as well as put together a curriculum for you. Training can also be held at your facility for a private training session or in a central location near you for general access. Customized training can be organized on demand, focusing on your specific process challenges. You can ask us to come to you to help improve your current workflow and bio-processes or even set-up completely new ones. Please contact us and we will be glad to act as your partner.

Available training courses

- Basic Cultivation course
- Advanced Cultivation course
- Basic Cell Culture course
- Basic Lucillus® PIMS training
- Advanced Lucillus® PIMS training
- On-Demand Service

Americas

Brasil

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Getinge is a global provider of innovative solutions for operating rooms, intensive care units, sterilization departments and for life science companies and institutions. Based on our firsthand experience and close partnerships with clinical experts, healthcare professionals and medtech specialists, we are improving everyday life for people – today and tomorrow.

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