

## Livit ACE

A breakthrough in Adherent Cell Expansion



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## **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 anticorruption. 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











# **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.



Bio-Pharmaceuticals



Regenerative Medicine



Food and **Beverages** 



Bio-Chemicals

Bio-Fuels

# Creating innovations that improve people's quality of life and save lives

With a firm belief that every person should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions aiming to improve clinical results and optimize workflows.

Getinge is a global provider of innovative products and solutions for healthcare, research and pharmaceutical production. With a focus on bringing the most innovative technologies to market.

Getinge identified CellRev and its pioneering processing technology, as a promising partner for development and commercialisation of an industry first continuous adherent cell processing platform. CellRev is an innovative supplier of processing solutions to improve the efficiency of cell manufacturing. The company works with cell-based vaccine and therapy developers to reduce cost, increase productivity, and unlock process bottlenecks to ensure more patients have access to life-saving treatments.



# Continuase™

### Enabling continuous processing

CellRev's proprietary Continuase<sup>™</sup> reagent facilitates a controlled rate of cell detachment in adherent cell culture processes.

Continuase<sup>™</sup> is a mixture of natural enzymes which facilitates the controlled detachment rate of adherent cells. When added to cell culture media as part of CellRev's patented continuous bioprocess technology, Continuase<sup>™</sup> keeps the detachment rate equal to growth rate to allow steady state operation. Continuase<sup>™</sup> is for research use only.

#### Features:

- Bacterially derived, free from human and animal components
- Rigorous screening to ensure consistency in enzymatic activity for every batch



#### Benefits:

- Compatible with microcarriers as well as flat systems as part of the Livit ACE platform
- Enables steady state operation for extended period (tested for continuous running up tp 60 days)

#### FAQs:

Q. Will this detach all the cells? Not if used as per the defined protocol.

Q. Can this be used as Trypsin, TrypLE or Accutase? No. Continuase<sup>™</sup> is not a bulk detachment product. It has been formulated for controlled detachment in continuous processing

Q. Does Continuase<sup>™</sup> work the same for all cell types? No. Each cell type has its own unique extracellular matrix thus some basic dose dependent studies need to be performed

Q. Does residual Continuase<sup>™</sup> remain in the process? Depending on the process, centrifugation, size exclusion chromatography, and other suitable filtration methods could be used to separate Continuase

Q. Is this available in different grades? Food grade and GMP grade products are in our pipeline

# Continuous bioprocessing

### Efficient adherent cell expension

The solution to limitations and inefficiencies that are commonly associated with existing cell culture processes within the cell-based vaccine, cell therapy, or cellular agriculture market is continuous bioprocessing!

#### **Benefits:**

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Continuous cell processing, as highlighted by the FDA, poses a significant opportunity for cellular product developers to improve cost, process stability, and consistency of products.

Continuous processing can;

- Eliminate manual handling and human error
- Increase quality assurance through online monitoring and control
- Reduce manufacturing time and increase efficiency
- Reduce capital costs by using smaller equipment and less manufacturing space
- Respond efficiently in the event of a supply shortage



### **Cell Growth**

Cells are seeded and grown in the bioreactor as per any other cell culture process. The target confluence is established during customer trial work.

#### **Cell Detachment**

CellRev's proprietary reagent Continuase<sup>™</sup> is added to the culture at a predefined concentration to trigger the release of cells to facilititate further expansion. This patented method enables the controlled detachment of adherent cells from a variety of surfaces. The rate of cell detachment is maintained equal to growth rate to allow steady state operation at high cell densities.

#### **Cell Collection**

Cells are collected continuously for cell banking or downstream processing. This reduces the need for large scale batch harvesting and facilitates optimal downstream design.

## **Livit ACE**

## A breakthrough in Adherent Cell Expansion



Livit ACE combines the best of CellRev's proprietary processing technologies with Getinge's bioprocessing expertise and equipment into one cell manufacturing solution.

Livit ACE is a complete package providing a novel bioprocessing solution. It is a cost-effective alternative to expensive process development and complex technology selection.

The main equipment in the Livit ACE platform are a Getinge Livit Flex controller and software, an Applikon bioreactor (either single-use or multi-use), and a Carr Biosystems UFMini<sup>®</sup>. The platform can be designed to work with microcarriers as well as flat systems.

#### **Benefits:**

- Significantly reduced COGS
- Reduced development timelines and costs
- Reduced capital cost and footprint requirement through improved productivity
- Scalable with improved product reproducibility
- Elimination of the need to adapt naturally adherent cells
- Cost-effective integration of a transferable upstream process
- Substantial reduction in material waste as well as labour cost

### **Applications:**

- Cell-based vaccines
- Cell therapies
- Cellular agriculture
- Continuous cultivation
- Process intensification

#### **Related products:**

- Livit Flex
- Carr Biosystems UFMini®
- Continuase<sup>™</sup>
- Applikon autoclavable bioreactors
- AppliFlex ST single-use bioreactors
- Applisens sensors
- SCADA software

#### Livit ACE workflow:

### Features:

- Complete process solution including standard application development\*, equipment, technology transfer, commissioning and training support
- Royalty free use of patented process technology for use in an R&D setting\*\*
- Flexible design through use of either microcarriers or flat plate systems based on customer needs

The workflow below provides a summary of the different stages of application development through to commissioning and technology transfer.



\* Custom protocol development outside of standard workflow available separately \*\* Subject to contract

# **Livit Flex**

### - The next generation in bioprocess control



Livit Flex brings nearly half a century of Applikon expertise together with the latest technologies to deliver an intuitive and easily configurable bioprocess controller that fits any R&D application.

Livit Flex can be configured as a single or dual control system for single-use or multi-use bioreactors to optimize bench space in the laboratory. The Livit Links enable plug-and-play connection of sensors and auxiliaries with the controller automatically recognizing new devices.

Both experienced and new users will be up and running in no time thanks to the new, intuitive Livit software platform with built-in data acquisition. Livit software is fully configurable and easy to use. Every sensor or actuator has its own widget so users can easily access and modify all settings, and even connect multiple Livit Flex controllers in a network. By accessing and controlling multiple controllers from one PC in a lab, users can easily set-up parallel experiments and monitor all experiments from one central location.

Combining the flexibility of the Livit Flex controller, the intuitive Livit software, and Getinge bioreactors enables you to accelerate your R&D processes and bring your pharmaceutical and biotech products to market faster.

### **Benefits:**

- Optimized system configuration and investment that match your dedicated needs
- Faster development thanks to system flexibility and advanced software functionalities
- Reduced risk of operator error and training time through intuitive and user-friendly interface

### **Applications:**

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

#### **Related products:**

- Applikon autoclavable bioreactors
- AppliFlex ST single-use bioreactors
- AppliSens sensors
- Lucullus<sup>®</sup> software (a registered trademark of Securecell)
- V-Control software

### **Specifications:**

#### **Features:**

- Single or dual bioprocess control system
- Up to 8 variable speed pumps
- Up to 12 mass flow controllers or up to 8 mass flow meters
- Electronic gas selection block
- Plug-and-play sensor and actuators through Livit Links
- Built-in data acquisition, alarm and user management
- OPC-UA compliant
- Compatible with V-Control and Lucullus® software
- Compatible with Applikon multi-use and AppliFlex ST single-use bioreactors

| Sensors                                |  |
|--|--|
| pH Sensor                              | Traditional electrochemical or Single-use  |
| DO sensor                              | Traditional Polarographic, LumiSens or Single-use  |
| Redox                                  | Traditional electrochemical  |
| Temperature                            | Pt-100, measurement Range: 0-150 °C accuracy 0,1°C   |
| Foam/level                             | Resistive based measurement  |
| Weight                                 | Input for external balances through flexible Livit Links   |
| Optional                               | Wide variety of 3rd party sensor technology supported through flexible Livit Links such as biomass, pCO2, etc.   |
| Additional I/O                         | Up to max. 48 analog inputs and outputs through flexible Livit Links (max. amount depending of system configuration)   |
|  |  |
| Actuators (optional)                   |  |
| Gas                                    | Up to 12 MFC's up to 1.5 L/min or up to 8 MFC's or MFM's for flows up to 40 L/min<br>with accuracy up to 0.5% RD + 0.1% FS.<br>Option for electronic gas selection block |
| Liquids                                | Up to 8 internal variable speed pumps, option for multiple external pumps through<br>Livit Links   |
| Stirring                               | 0-2000 rpm   |
| Temperature                            | Heating blanket, cooling with cold water valve and thermocirculator option available   |
| Control                                |  |
| Control Hardware and Software platform | Getinge proprietary and Getinge Firmware   |
| Certifications                         | CE certified, GAMP compliant   |
| 21 CFR part 11 compatible              | Yes, if combined with Lucullus GMP or V-Control  |
| Communication & SCADA                  | Lucullus® PIMS, V-Control (DeltaV™)<br>Getinge OPC-UA server available   |

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GETINGE 🛠

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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