

Bulk Drug Substance Filling

Fast and Precise Filling Performance

- Fully automated
- Up to 200 liters in less than 60 minutes
- In various sizes of 2D Allegro™ biocontainer bags
- With highest possible filling accuracy
- Perfectly prepared for any following process, like freezing and storing

RoSS.FILL is a flexible platform for dispensing operations into Allegro single-use biocontainer bags and bulk filtration that are supported by RoSS systems. The fluid path is designed to be fully disposable and is able to accommodate a variety of sterile connection and disconnection options.

Size, shell number and detailed specifications will be designed according to your individual needs.



Table 1

Technical specifications (hardware)

Feature	Benefit
Modular	Multiple fill racks can be connected to the control unit at point of use
Flexible	Flexible solution for single-use biocontainer bags (see RoSS.FILL) and bottles (with bottle fill Flex Rack) All manifold systems customizable Different pump and sampling tubings available Flexible for all available bulk filtration filters Biocontainer manifold if required designed and supplied by request
Filling	High filling range from 40 mL – 500 L
Losses	Less product losses. Sterility is maintained

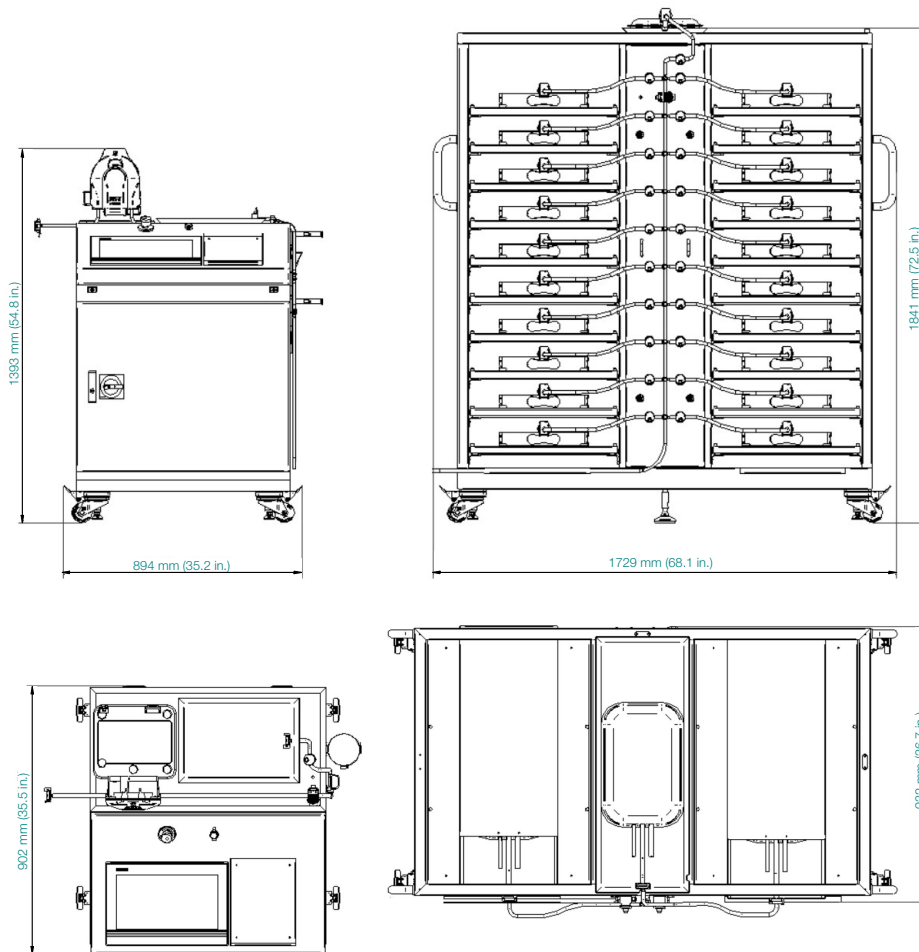
**Table 2**

Technical specifications for control unit and fill rack

Attribute	Specification
Part number	LGRSUSFILL
Capacity	Designed to accommodate any RoSS shell size available and up to 20 single-use biocontainer bags, customizable to any scale/size
Filling	Up to 20 biocontainer bags/run, any number of runs can be handled by one recipe using manifold change
Power	EU 230 VAC $\pm$ 10% / USA 115 VAC $\pm$ 10%
Ambient temperature range	15 to 25 °C
Maximum relative humidity	75%
Dimensions for control unit (W x D x H)	894 x 902 x 1393 mm (35.2 x 35.5 x 54.8 in.)
Dimensions fill rack (W x D x H)	1729 x 932 x 1841 mm (68.1 x 36.7 x 72.5 in.)
Net weight control unit	175 kg
Net weight fill rack	675 kg
Materials of construction	Type 304 (1.4301) stainless-steel with a surface finish of $\leq$ 2.4 $\mu$ m Ra.
Automation	Automated system control local programmable logic controller (PLC). Control system manufacturer Siemens S7 – Allen Bradley or DeltaVu upon request
Filling specification	OIML R60 class C3
Movability	Mobile, lockable wheels
Measurement	Volume measurement – individual weight cell per shell location – The accuracy of each scale is 0.2 to 5 kg: $\pm$ 20 g (per biocontainer bag in RoSS shell) and from 5 to 20 kg: $\pm$ 25 g (per biocontainer bag in RoSS shell) except sample scale. Label printer – included Air sensors – included Pressure sensors/transmitters - included
Accessories	Manifold and connection can be designed Standard modular system available Aseptic disconnection type – aseptic/crimp Valve types – pinch valve Valve actuation type – electric Valve quantity – 22 Up to 3 samples, customizable on request Feed pump type – Watson-Marlowu 600 series pump Provision for filter on feed to manifold – included
Human machine interface (HMI)	Shows the current state of the system including alarms, valve positions, tared values and fill weight
IP rating	IP54 except pressure sensor, pump and label printer (IP20)
Data integrity	Accessed via a password Back-up electronic records must be restorable to the system Data cannot be modified or deleted without approval and justification
Data	Ability to store recipes and a time-stamped audit trail of the system
Software integration	Optional manufacturing execution system (MES) integration
Goods manufacturing practices	GMP, CFR Part 11 compliant software control unit can be used with the bottle rack or the biocontainer bag/shell rack
Control system	Siemens Simatic; Delta V or Allen Bradley optional

## Flexibility for Bottles and Bags

One control unit – several options for bottles and biocontainer bags



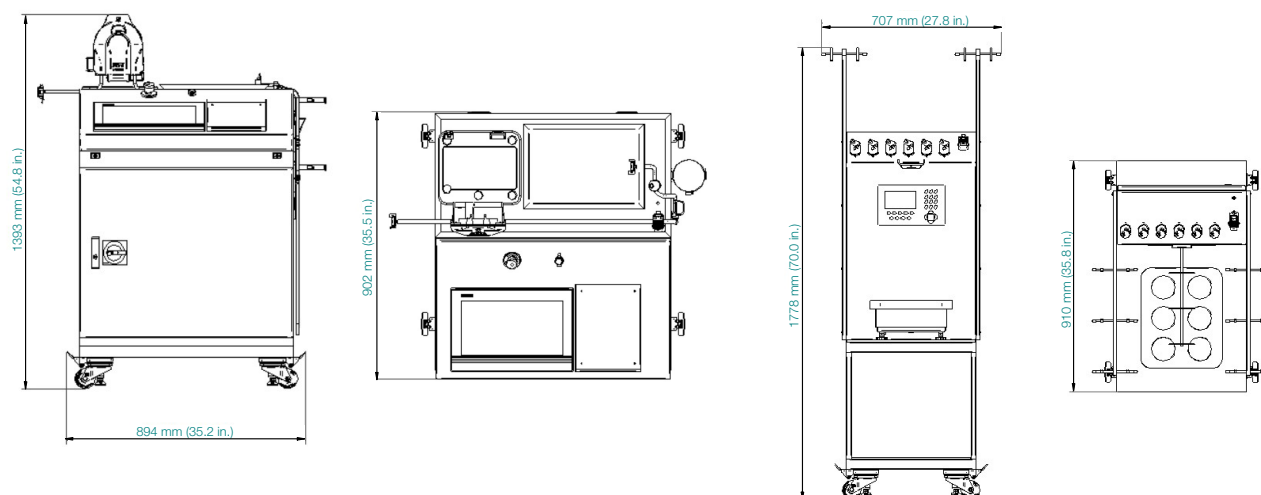
## Benefits

- Fully automated filling, filtration and draining system for Allegro single-use biocontainer bags
- Filling of up to 200 liters of substance in less than 1 hour
- Highest accuracy on lowest footprint
- Ease of use in operation/recipe driven processing
- Flexible design to fill biocontainer bags and bottles
- Modular system with separate control unit and pumping station as well as storage rack made up of RoSS trays filled with Allegro single-use biocontainer bags
- Integration of bulk filtration and differential pressure measurement to manifold possible
- Option to take samples
- Optional MES integration



## Control Unit and Bottle Filling Rack

The RoSS.FILL Flex Rack enables you to now also fill bottles with your RoSS.FILL, making the transition from bottles to single-use biocontainer bags easy.



## Benefits

- Multiple bottles get connected to control unit at point of use
- Optimized backbone manifolds for highest possible recovery and filling accuracy
- High recovery (total hold-up volume below 200 mL)
- 1 automatic valve/bottle, or one valve/weight cell
- 1 weight cell per modular rack
- Filling of up to 100 bottles/run
- GMP, CFR Part 11 compliant software control unit can be used with the bottle rack or the biocontainer bag/shell rack
- Flexible solution for Allegro single-use biocontainer bags (see RoSS.FILL) and bottles (with Flex Rack)
- Same control unit (just switching rack)
- Standard Siemens system
- DeltaV connection optional



**Corporate Headquarters**

Port Washington, NY, USA  
+1-800-717-7255 toll free (USA)  
+1-516-484-5400 phone

**European Headquarters**

Fribourg, Switzerland  
+41 (0)26 350 53 00 phone

**Asia-Pacific Headquarters**

Singapore  
+65 6389 6500 phone

Visit us on the Web at [www.pall.com/biotech](http://www.pall.com/biotech)  
Contact us at [www.pall.com/contact](http://www.pall.com/contact)

Pall Corporation has offices and plants throughout the world. To locate the Pall office or distributor nearest you, visit [www.pall.com/contact](http://www.pall.com/contact).

The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

*IF APPLICABLE* Please contact Pall Corporation to verify that the product conforms to your national legislation and/or regional regulatory requirements for water and food contact use.

© Copyright 2021, Pall Corporation. Pall, , and Allegro are trademarks of Pall Corporation.  
® Indicates a trademark registered in the USA. ♦DeltaV is a trademark of Emerson Electric Co, RoSS is a trademark of Single Use Support, Siemens is a trademark of Siemens AG, and Watson-Marlow is a trademark of Watson Marlow Limited.

USD3436/CN21.07741

3/21