

# Flex-Line™ Robotic Filler

## Key Features

- Ability to Handle Vials, Syringes, Cartridges
- Smaller Footprint, Faster Changeover Between Formats, Faster Build Time
- One FAT, SAT, and Validation, Maximize Revenue
- Conformance to GMP guidelines for Annex 1, 21 CFR Part 11
- Robotic handling, No-Touch Transfer (NTT), Automated de-bagging

## Filler Specifications

Dimensions (mm)	W: 2580, L: 3430, H: 3030
Working Surface Height	950 mm +/- 20 mm
Vial Range	2R - 50R
Syringe Range	1ml - 5ml
Cartridge Range <sup>1</sup>	1ml - 3ml
Weigh <sup>1</sup>	7,000Kg Approx.
In-feed System	Semi-automatic Debagging
Dosing System	Piston pumps
Weigh Check	Statistical weigh check (1 load cell)
Mechanical Plungering	Mechanical plungering and stoppering
Outfeed System	Machine outfeed via rolling conveyor
De-lidding & Filling Enclosure	Comecer Isolator
Debagging Enclosure	Restricted Access Barrier (RABS)
Contact Parts	Electropolished AISI-316L
Surface Bench Material	AISI316 (fine-brushed) stainless steel
Exterior Panels	Exterior Panels AISI-304 stainless steel
Electrical Cabinet	IP 54; cabinet located remotely
HMI	HMI Beckhoff 18.5"
Main Drive and Critical Movements	Servo Motor
Utility Requirement (other options available)	"400 Volt 3 Phase + Neutral + Ground 50/60 Hz 7kW approx."
Air Consumption	800 NI/min (Max) – 6 bars (87 psi)
Regulations	"CE Mark, GMP, Annex 11/ 21CFR part 11, UL 508A"
Documentation	Documentation Included



Container	Capacity (ml)	Filling Speed UPM (max)	Nest Quantity	Filling Accuracy (+/-)
<b>VIAL</b>				
2R	4.0	140	100	1%
4R	6.0	140	100	1%
10R	13.5	70	48	1%
20R	32.5	50	24	1%
30R	32.5	30	24	1%
50R	37.5	30	16	1%
<b>SYRINGE</b>				
1 ml long	1.0	200	100	1%
1 ml short	1.0	200	100	1%
3 ml	3.0	150	100	1%
5 ml	5.0	70	48	1%
<b>CARTRIDGE</b>				
1.5 ml	1.0	150	100	1%
1.8 ml	1.8	150	100	1%
3 ml	3.0	140	100	1%

\*Mechanical speed of machine with water

## Isolator Specifications

Isolator Unidirection Air Speed	0.45m/s 150 to 300 mm below LAF Filter Face
Operating Pressure	+15Pa to +30Pa with Respect to Installation Area
Operating Temperature	Ambient
Operating Humidity	Ambient
EMS	Viable & Non-Viable Probes

## All Grade A Chambers Will Consist of the Following:

- AISI 316L stainless steel chambers with Mirror Bright internal surface finish Ra<0.5µm
- Enclosure air tight class 3 ISO 10648-2
- The particle content in the air of the LAF chambers in operational conditions complies with the ISO 14644-1 and EEC-cGMP requisites
- Grade A "At rest" (EEC-cGMP)
- Class ISO 5 (ISO 14644-1) <= 3520 particles/m3 for particles Ø >= 0.5µm
- Access Doors made with hinged safe tempered glass panels
- Chambers tightness ensured by inflatable gasket system and electromechanical interlocks
- The chamber is designed to take air from a Class C or Class D room
- Ventilation System: Inlet/Outlet Frequency controlled fans, ON/OFF Pneumatic valves for the air interception

## Included in Scope:

- Customer sheathings made of AISI 304 Scotch Brite RA<0.8µm
- Inlet H14 laminar filters
- Glove Ports and extenders (final quantity determined during Mock-up)
- Glove flanges and internal barriers for glove detection
- Anemometer sensor (for chamber equipped with laminar airflow only)
- Pressure transmitters for filter obstruction and chamber's pressure regulation
- AISI 316L flange for automatic machine integration
- Hinged front view panels with inflatable seals made of FDA approved Silicon rubber, each panel is supplied with handles and integrated safety switches
- All internal angles have a minimum radius of curvature of 20mm to facilitate the cleaning and sterilization operations
- Ventilation System: Inlet/Outlet Frequency controlled fans, ON/OFF Pneumatic valves for the air interception
- All welds are ground, smoothed, and polished
- All welds are passivated and pickled
- All stainless steel is welded using TIG method (in argon atmosphere)

## Additional Flex-Line™ Options

Debagging Extension UDAF
Manual Debagging
N2 During Filling
Product Tank (5 or 8 L)
Tank Mixer
Disposable Surge/Product Bag
Product recirculation
Peristaltic pumps
Vacuum Plungering
UDAF
O-Rabs
NVPC-VPC supports
PMS Complete system
Exit conveyor
Outfeed UDAF extension
Siemens or Allen Bradley I/O & Communications
Additional change Parts
Stainless Steel Remote Cabinet
Documentation Included