

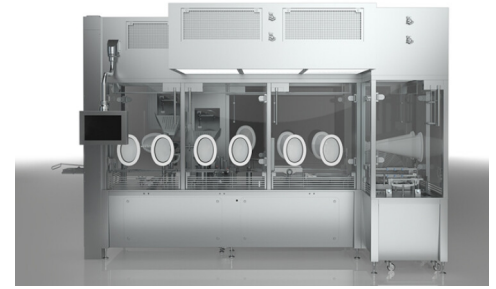
Cellefill oRAB

Vial filling machine and containment solution to fast track your cell, gene and biological therapies.

Flexicon
Liquid Filling

Features and benefits

- Fast track your cell and gene and biological therapies and futureproof for GMP compliance
- Maximise production efficiency with recipe driven, remote set-up and no format parts for the entire vial range
- Highly accurate, precision filling from micro volumes to 50 ml with better than $\pm 1\%$ achievable at most volumes
- Fully integrated environmental monitoring system in strategically risk-assessed locations
- Reduced risk of batch loss with flexible in-process controls including 100% weight check with zero waste start-up
- Integrated aseptic vial filling and containment solution reduces risk and cost
- Expert guidance and support throughout your project, from initial enquiry through to installation, to after sales support and validation package expertise, we are your project partner every step of the way.

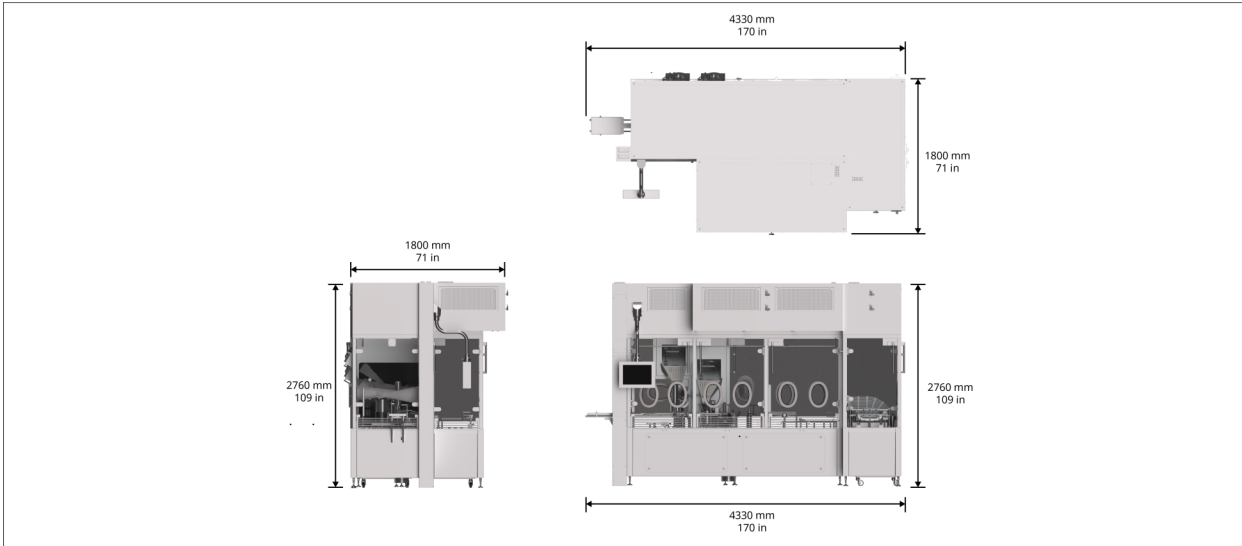


Technical specifications

| | Cellefill oRAB |
|--------------------------|--|
| Filling volume range | Limited only by RTU vial size, filling volume range is from micro-volumes to 50 ml |
| Accuracy | achievable at most volumes $\pm 1.0\%$ |
| Capacity | 1500 units/hour |
| Batch Size | 10 - 10,000 vials per batch |
| Power supply | 230/400V 3ph, 50Hz |
| Weight | 2900 kg |
| Load per square meter | 605 Kg |
| Barrier Technology | Open Restricted Access Barrier |
| Filling Line Type | Aseptic process filling line with manual disinfection |
| Application | Sterile product protection of sensitive biologics, antibodies, cell protein or nucleic acid-based products |
| Cleanroom Class | Grade B / ISO 7 cleanroom |
| Vial Size | ISO 2R - 50R |
| Weigh Check | 20-100 % |
| Stoppers | ISO standard or Lyo, 13 mm and 20 mm |
| Cap diameter range | ISO standard or flip-top, 13 mm or 20 mm |
| Infeed and outfeed trays | Vial RTU compatible with SG EZ-Fill® and SCHOTT adaptiQ® trays |
| Port type | Castus® alpha RTP 190 iCON, Sartorius Biosafe® 110 Monolever |
| Validation | Turnkey Validation FAT, SAT IQOQ |

Throughput capacity up to 1500 vials/hour (based on batch size of 1000 vials/hour and dependent on customer configuration).
NTT process for de-bagging inner bag (oRAB model) or both inner/out bags (iASP/iBIO versions)
Environmental monitoring: Integrated viable and non-viable, active and passive
Glove testers: optional accessory for all models
Automated hygrometer control system: Optional on iASP and iBIO models

Cellefill oRAB dimensions



| Description | oRAB |
|------------------------------------|---------|
| Minimum required operational space | 2000 mm |
| Footprint LOA | 4330 mm |
| Footprint WOA | 1800 mm |
| Height Overall | 2760 mm |

Disclaimer: The information in this document is believed to be correct, but Watson-Marlow Flexicon A/S accepts no liability for any errors it contains, and reserves the right to alter specifications without notice. WARNING: These products are not designed for use in, and should not be used for, patient-connected applications. Cellefill is a registered trademark of Watson-Marlow Limited. SG EZ-Fill is a registered trademark of Stevanato Group. adaptiQ is a registered trademark of SCHOTT Pharma.

wmfts.com/global



Wednesday, April 5, 2023