# HIGH QUALITY READY-TO-USE MOLDED GLASS VIALS POWERED BY SG EZ-FILL®



#### OFFICIAL REPRESENTATIVE:

## PLASTRADE

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### WHY DO PHARMACEUTICAL COMPANIES CHOOSE STERINITY VIALS ?



#### Trust

SGD Pharma and Stevenato Group are recognized industry leaders in primary packaging for injectable drugs. Each vial follows strict validated steps from manufacturing to final delivery to protect the **physical and microbiological integrity while minimizing the risk of contamination of the aseptic area**. The SG EZ-fill® platform is a proven solution used for a variety of primary packaging components.



#### Increased quality and safety

Molded glass is a proven solution for vial sizes from 10ml and above. The Type I molded glass from SGD Pharma offers a **higher mechanical resistance** that reduces the risk of particles contamination due to breakage during the fill/finish and Lyophilization steps. The **improved chemical performance** minimizes the risk of extractables to meet United States Pharmacopoeia (USP) <660> and USP <1660> guidelines.



#### Flexibility and agility

By choosing Sterinity vials, Pharmaceutical companies **can focus on their core business** of developing and offering new products to market faster. They can also extend their product portfolio to new primary packaging options. SG EZ-fill® provides access to a broad range of Ready-To-Use primary packaging components, all with the same validation standards and packaging process.



#### Reduced Total Cost of Ownership (TCO)

Sterinity allows pharmaceutical companies to outsource their non-core activities. By doing this the investment in facilities and equipment is avoided as well as all the associated operational costs.

SGD Pharma has partnered with SG EZ-fill® to offer washed, depyrogenated and sterilized «Ready-to-Use» Type I molded glass vials.









### Vial manufacturing

Molded glass vials for injectable drugs are produced in an SGD Pharma state-of-the-art facility in France. All glass is 100% inspected in an ISO 8 room. The vials undergo an additional inspection prior to entering SG EZ-fill® process located in Italy.

### Washing

SGD Pharma vials are washed with WFI (Water For Injection) and dried in an ISO 8 class area.

### Depyrogenation

Vials are depyrogenated in a tunnel accordingly to Pharmacopoeia requirements.

### Loading into the secondary packaging

Vials are placed into final packaging: either in a Nest & Tub or in a tray. Both options are handled in ISO 5 and ISO 7 environments.

## Tyvek® sealing & steribag bagging

The secondary packaging is sealed with a Tyvek $^{\odot}$  lid under ISO 5 classification, packed in steribags and then placed into a box in an ISO 7 / ISO 8 environment. Final configuration includes packaging in pallets.

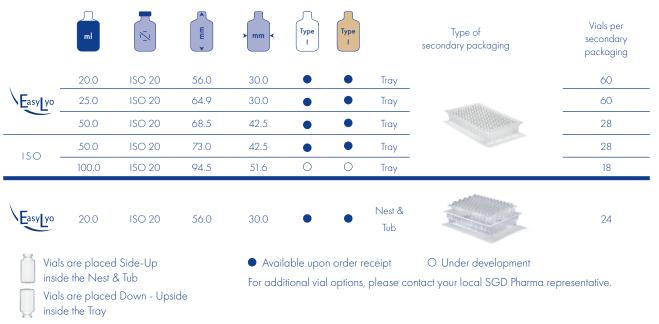
## Sterilization

All the components are sterilized by EtO using a validated process meeting ISO 11135 requirements. This final step grants the highest cleanliness of all the packaging components and reduces the risk of microbiological contamination of the aseptic area.

## Storage & delivery

Vials are stored at SGD Pharma with a shelf life of 5 years for human use. SGD Pharma manages the delivery and releases the certificate of conformity.

# SGD PHARMA HIGH QUALITY READY-TO-USE MOLDED TYPE I GLASS VIALS



www.sgd-pharma.com

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