

# Zebragard™

## 0.2 µm VTZ-grade Small Filter Cartridge (L Model)

### Description

The Zebragard™ PVDF membrane barrier filter cartridge is a convenient, ready-to-use filter designed to facilitate in-line pre-use, post sterilization integrity testing (PUPSIT) of single or redundant sterile process filter systems. The filter features a uniquely patterned sterilizing grade PVDF membrane having dual hydrophilic and hydrophobic characteristics that enable effective passage of both liquids and gases. This unique feature, coupled with pleated membrane technology, affords high flow rates and faster air flow recovery at low pressures, broad chemical compatibility, and minimal extractables.

The Zebragard™ filter is 100% integrity tested during manufacture and has the added benefit of quality certification that meets the critical demands of the pharmaceutical, biotechnology and related industries.

### Materials of Construction

All components of the filter are either animal component free or in compliance with EMEA/410/01 Rev. 3 (EDQM 5.2.8 07/2011:50208), and US Code of Federal Regulations 9 CFR 94.18 and 21 CFR 189.5 These materials are listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

|                     |                                |                        |
|---------------------|--------------------------------|------------------------|
| Membrane:           | Polyvinylidene fluoride (PVDF) | CFR Title 21, 177.2510 |
| Upstream support:   | Polypropylene                  | CFR Title 21, 177.1520 |
| Downstream support: | Polypropylene                  | CFR Title 21, 177.1520 |
| Outer guard:        | Polypropylene                  | CFR Title 21, 177.1520 |
| Core:               | Polypropylene                  | CFR Title 21, 177.1520 |
| End caps:           | Polypropylene                  | CFR Title 21, 177.1520 |
| O-rings:            | Typically silicone             | CFR Title 21, 177.2600 |
| Sealing method:     | Thermal bonding                |                        |

**Pore Size** 0.2 µm (sterilizing grade)

**Effective Filtration Area** 5.0" (13 cm): 3.3 ft<sup>2</sup> (0.31 m<sup>2</sup>)

**Minimum Bubble Point** 18 psi (1.24 bar) in 60% IPA/40% water, with air or nitrogen  
17 psi (1.17 bar) in 70% IPA/30% water, with air or nitrogen

**Bacterial Retention** >10<sup>7</sup> per cm<sup>2</sup> removal of *Brevundimonas diminuta* per ASTM F838

### Operating Characteristics

|                              |                                    |
|------------------------------|------------------------------------|
| Operating temperature range: | 32 °F to 100 °F (0 °C to 38 °C)    |
| Maximum temperature rating:  | 180 °F @ 30 psid (82 °C @ 2.1 bar) |
| Maximum operating pressure:  | 80 psig @ 100 °F (5.5 bar @ 38 °C) |
| Maximum reverse pressure:    | 15 psig @ 100 °F (1.0 bar @ 38 °C) |

### Sterilization

Autoclave: 250 °F to 275 °F @ 15 to 30 psi (121 °C to 135 °C @ 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles.

Steam-in-place (SIP): 250 °F to 275 °F @ 15 to 30 psi (121 °C to 135 °C @ 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles.

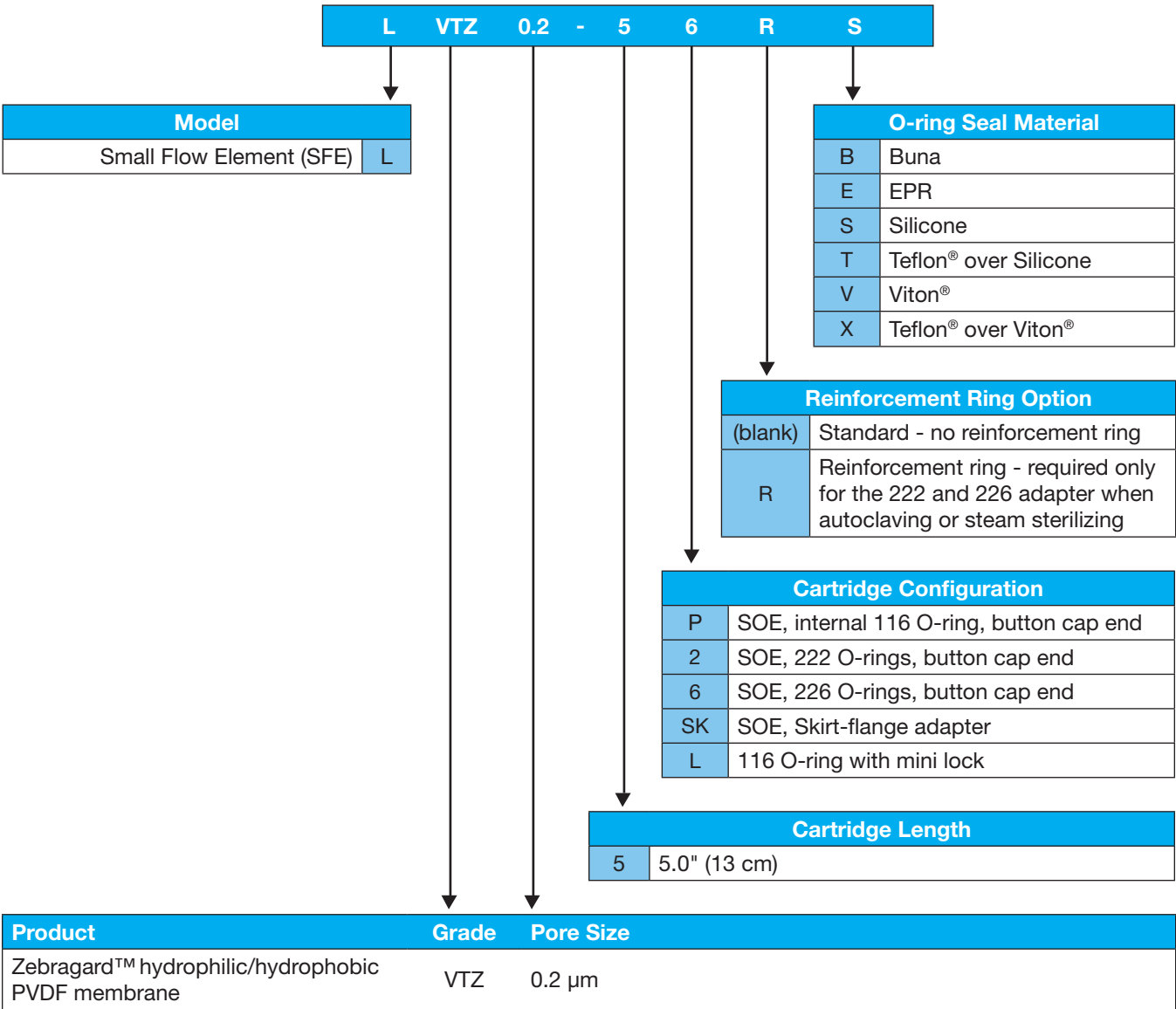
### Biological Safety

Zebragard™ filters meet the requirements as specified in USP 43 <88> Class VI plastics, <87> cytotoxicity and physicochemical tests; after flush, filters comply with USP 43 oxidizable substances test. Bacterial endotoxin levels in aqueous extracts of Zebragard™ filters are less than 0.5 EU/mL, as determined using the current <USP 85> *Limulus amoebocyte lysate* (LAL) test. No binders, adhesives, or surfactants are used in the construction of Zebragard™ filters. Filters comply with Commission Regulation (EU) No. 10/2011.

### Quality Assurance

A Certificate of Quality is supplied for Zebragard™ filters verifying the high standards and superior performance of the product. Zebragard™ filters comply with the Food and Drug Administration Code of Federal Regulations, Title 21, Parts 210 and 211. Product is manufactured and packaged in a cleanroom facility that, through voluntary compliance, meets or exceeds FDA Good Manufacturing Practice Standards. To ensure product reliability, Meissner's Quality Assurance staff continually audits the manufacturing process for conformance to its Quality Management System. Each Zebragard™ filter is integrity tested during manufacture and clearly marked with filter type, lot number, and unique serial number. The serial number for all cartridge filters can be found on the product packaging.

Ordering Guide



Additional information about this filter product is available in the Zebragard™ Green Docs at [www.meissner.com/green-docs](http://www.meissner.com/green-docs).

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