

# ProSpore Ampoule

## Mesa Biological Indicators

Self-contained glass ampoules for steam sterilization

ProSpore Ampoule is a self-contained biological indicator for steam sterilization ideal for validating the sterilization of liquid loads, while also suitable for loads containing dry goods. No activation is required. Simply expose the unit to the sterilization process and incubate afterwards. ProSpore Ampoule is validated for **48-hour reduced incubation**.



### ProSpore 4ml

- 510(k) received for use at 121°C for healthcare facilities
- May be used between 118 - 135°C\*
- Vivid purple to yellow color change

### ProSpore 1ml

- Intended for use with industrial steam sterilization processes between 118 - 135°C
- Negative controls (NC) available
- Vivid purple to yellow color change



## Negative Controls

The negative control is a media ampoule made from the same lot of media used to make the corresponding spore ampoules.

## Certification

Each lot of ProSpore is certified for population, species, D-value, z-value, purity and expiry. Shelf life is 18 months from date of manufacture. ProSpore (log 5 and higher) comply with AAMI/ISO 11138-1 and AAMI/ISO 11138-3.

\*Industrial Use Only

# ProSpore Ampoule

## Specifications

ProSpore Ampoule is a hermetically sealed, type I borosilicate glass ampoule. The ampoule is filled with a modified Soybean Casein Digest Broth containing bromocresol purple acid indicator. Each ampoule also contains a population of *G. stearothermophilus* spores. ProSpore Ampoule (4 ml) has received 510(k) notification for sale to healthcare facilities with a 48-hour incubation period. Growth is evident by either turbidity and/or a color change from purple to or toward yellow. Expiration is 18 months from the date of manufacture.

## Ordering Information

*ProSpore Ampoule is a refrigerated item and requires overnight shipping. For pricing information, please see current price list.*

### ProSpore 4ml Ampoule

Outer Diameter: 14.75mm +/- 0.15mm			
Height: 52.0 - 55.0mm			
Species	Catalog #	Min. Population	Qty/Box
<i>G. stearothermophilus</i>	PS-4-10	1.0 x 10 <sup>4</sup>	10
<i>G. stearothermophilus</i>	PS-4-50	1.0 x 10 <sup>4</sup>	50
<i>G. stearothermophilus</i>	PS-5-10	1.0 x 10 <sup>5</sup>	10
<i>G. stearothermophilus</i>	PS-5-50	1.0 x 10 <sup>5</sup>	50
<i>G. stearothermophilus</i>	PS-6-50	1.0 x 10 <sup>6</sup>	50

### ProSpore 1ml Ampoule

Outer Diameter: 10.75mm +/- 0.15mm			
Height: 48.5 - 53.0mm			
Species	Catalog #	Min. Population	Qty/Box
<i>G. stearothermophilus</i>	PS1-4-15	1.0 x 10 <sup>4</sup>	15
<i>G. stearothermophilus</i>	PS1-4-100	1.0 x 10 <sup>4</sup>	100
<i>G. stearothermophilus</i>	PS1-5-15	1.0 x 10 <sup>5</sup>	15
<i>G. stearothermophilus</i>	PS1-5-100	1.0 x 10 <sup>5</sup>	100
<i>G. stearothermophilus</i>	PS1-6-15	1.0 x 10 <sup>6</sup>	15
<i>G. stearothermophilus</i>	PS1-6-100	1.0 x 10 <sup>6</sup>	100
<i>G. stearothermophilus</i>	PS1-5-60NC*	1.0 x 10 <sup>5</sup>	50 +10NC
<i>G. stearothermophilus</i>	PS1-6-60NC*	1.0 x 10 <sup>6</sup>	50 +10NC