

# CERTIFICATE OF QUALITY

## VersaCap®

<b>Catalog Number:</b>
<b>Lot Number:</b>
<b>Description:</b>

### Materials of Construction:

All materials are USP Class VI Compliant:  
Polypropylene Cap with platinum-cured silicone gasket  
Polypropylene adapter with platinum-cured silicone gasket  
Polycarbonate adapter with platinum-cured silicone gasket

### Sterilization Method:

Autoclave at 15 PSI (121°C/250°F) for 20 minutes

### Good Manufacturing Practice:

This product was manufactured in a Class 100,000 cleanroom facility that is registered to ISO 13485 for medical device manufacturing.

### Component Material Toxicity:

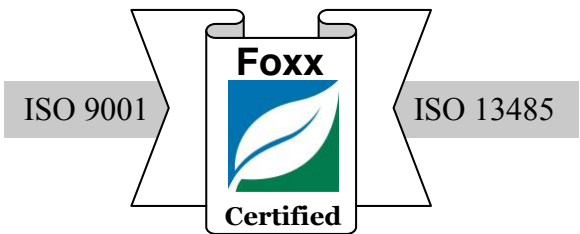
All component materials have been tested against the requirements for United States Pharmacopoeia (USP) class VI Biological Test for Plastics, current edition. The plastics meet the requirements of the United States Food and Drug Administration (FDA) for food and beverage contact in Class II devices.

### ISO 9001 Quality Standard:

This product was manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Systems Standard.

### Audit Criteria:

Audit criteria tests are conducted to determine viable microbial bioburden of the product.



*Brian J. Abbott*  
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Manager, Regulatory Affairs and QA

Reference Document: 10000001  
ECN 177 Revisi Date: 3/3/2015

SAMPLE

