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## Certificate of Sterility

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| <b>Product:</b>             | Sterile SatPax ValuSeal-HA |
| <b>Item#:</b>               | SSPHA.001.12               |
| <b>Lot #:</b>               | 0808247                    |
| <b>Irradiation Run #:</b>   | 1242299                    |
| <b>Date of Manufacture:</b> | February 4, 2014           |
| <b>Expiration Date:</b>     | 02/2017                    |
| <b>Manufacturing Site:</b>  | Whitsett, North Carolina   |

This certifies that the above product has been sterilized with Cobalt 60 gamma radiation and has been dosimetrically released as sterile. The specified minimum dose has been delivered to the product. This is in accordance with procedures outlined in ANSI/AAMI/ISO 11137-2:2013: Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose, to a Sterility Assurance Level of  $10^{-6}$ .

|   |   |
|---|---|
| Minimum Specified Dose: <u>25.0 kGy</u> | Minimum Delivered Dose: <u>28.9 kGy</u> |
| Maximum Specified Dose: <u>45.0 kGy</u> | Maximum Delivered Dose: <u>39.2 kGy</u> |

Reviewed and approved by:



Steve Shoffner  
Quality Assurance Administrator  
Approval Date: February 12, 2014

# Berkshire



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