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## Certificate of Sterility

<b>Product:</b>	Sterile SatPax 670
<b>Catalog No.:</b>	SSP670.001.24
<b>Lot #:</b>	0807348
<b>Irradiation Run #:</b>	1166916
<b>Date of Manufacture:</b>	September 25, 2013
<b>Expiration Date:</b>	September 2016
<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 11137:2006: Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose, to a Sterility Assurance Level of  $10^{-6}$  and AAMI TIR33:2005: Sterilization of health care products - Radiation – Substantiation of a selected sterilization dose – Method VD<sub>max</sub>.

Minimum Specified Dose: 25.0 kGy  
Maximum Specified Dose: 45.0 kGy

Minimum Delivered Dose: 27.5 kGy  
Maximum Delivered Dose: 41.5 kGy

Reviewed and approved by:



Steve Shoffner  
Quality Assurance Admin  
Approval Date: October 2, 2013

# Berkshire



### Berkshire

USA: 800-242-7000/413-528-2602  
London: 44-870-757-2877  
Singapore: 65-252-4313  
Tokyo: 81-3-5827-2380