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## Certificate of Sterility

<b>Product:</b>	Sterile SatPax 670
<b>Item#:</b>	SSP670.001.24
<b>Lot #:</b>	0810507
<b>Irradiation Run #:</b>	1419855
<b>Date of Manufacture:</b>	November 24, 2014
<b>Expiration Date:</b>	11/2017
<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>27.6 kGy</u>
Maximum Specified Dose: <u>45.0 kGy</u>	Maximum Delivered Dose: <u>40.0 kGy</u>

Reviewed and approved by:

*DeWayne Steele*

DeWayne Steele

Quality Assurance Specialist

Approval Date: December 9, 2014

# Berkshire



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