
Certificate of Sterility

Product:	Sterile SatPax 670
Item#:	SSP670.001.24
Lot #:	0808000
Irradiation Run #:	1227847
Date of Manufacture:	December 19, 2013
Expiration Date:	12/2016
Manufacturing Site:	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>27.3 kGy</u>
Maximum Specified Dose: <u>45.0 kGy</u>	Maximum Delivered Dose: <u>43.7 kGy</u>

Reviewed and approved by:



Steve Shoffner
Quality Assurance Administrator
Approval Date: January 21, 2014

Berkshire



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