
Certificate of Sterility

Product:	Sterile SatPax HA
Catalog No.:	SSPHA.001.12
Lot #:	0805594
Irradiation Run #:	1048788
Date of Manufacture:	March 1, 2013
Expiration Date:	March 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 11137:2006: 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_{max}.

Minimum Specified Dose: <u>25.0 kGy</u>	Minimum Delivered Dose: <u>25.9 kGy</u>
Maximum Specified Dose: <u>45.0 kGy</u>	Maximum Delivered Dose: <u>39.5 kGy</u>

Reviewed and approved by:



Steve Shoffner
Quality Assurance Administrator
Approval Date: March 12, 2013

Berkshire



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