
Certificate of Sterility

Product:	Sterile SatPax 670
Catalog No.:	SSP670.001.24
Lot #:	0804721
Irradiation Run #:	973009
Date of Manufacture:	October 22, 2012
Expiration Date:	October 2015
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: 25.0 kGy
Maximum Specified Dose: 45.0 kGy

Minimum Delivered Dose: 27.0 kGy
Maximum Delivered Dose: 39.9 kGy

Reviewed and approved by:



Steve Shoffner
Quality Assurance Admin
Approval Date: November 1, 2012

Berkshire



Berkshire

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