
Certificate of Sterility

Product:	Sterile SatPax 670
Item#:	SSP670.001.24
Lot #:	0814883
Irradiation Run #:	1751011
Date of Manufacture:	June 15, 2016
Expiration Date:	06/2019
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>28.9 kGy</u>
Maximum Specified Dose: <u>45.0 kGy</u>	Maximum Delivered Dose: <u>39.6 kGy</u>

Reviewed and approved by:

DeWayne Steele

DeWayne Steele
Quality Assurance Specialist
Approval Date: June 22, 2016

Berkshire



Berkshire
USA: 800.242.7000/413.528.2602
London: 44. (0).870.757.2877
Singapore: 65.6252.4313
Tokyo: 81.3.5827.2380