
Certificate of Sterility

Product:	Sterile SatPax 670
Catalog No.:	SSP670.001.24
Lot #:	0813310
Irradiation Run #:	1627569
Date of Manufacture:	November 17, 2015
Expiration Date:	11/2018
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 Minimum Delivered Dose: 28.9 kGy
Maximum Specified Dose: 45.0 kGy Maximum Delivered Dose: 40.1 kGy

Reviewed and approved by:

DeWayne Steele

DeWayne Steele

Quality Assurance Specialist

Approval Date: November 24, 2015

Berkshire



Berkshire

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

www.berkshire.com
