
Certificate of Sterility

Product:	Sterile SatPax 670
Catalog No.:	SSP670.001.24
Lot #:	0812114
Irradiation Run #:	1539116
Date of Manufacture:	June 23, 2015
Expiration Date:	06/2018
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
Maximum Specified Dose: 45.0 kGy

Minimum Delivered Dose: 25.4 kGy
Maximum Delivered Dose: 43.1 kGy

Reviewed and approved by:

DeWayne Steele

DeWayne Steele

Quality Assurance Specialist

Approval Date: June 29, 2015

Berkshire



Berkshire

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