Certificate of Sterility

Product:	Gamma Wipe CapSure VP
Catalog No.:	GWCPSVP.ST.25
Lot #:	0807162
Irradiation Run #:	1159060
Date of Manufacture:	September 1, 2013
Expiration Date:	September 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: 25.0 kGy Minimum Delivered Dose: 32.0 kGy Maximum Specified Dose: 50.0 kGy Maximum Delivered Dose: 43.3 kGy

Reviewed and approved by:

Sherry Phillips Quality Manager

Approval Date: September 18, 2013





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