

PRODUCT CERTIFICATE

Product: Contec Sterile IPA
Product Code: SBT170IW
Product Description: Sterile 70% Isopropanol in water for injection 1L Trigger Spray
Batch Number: 241002899
Manufacture Date: OCT / 2024
Expiry Date: OCT / 2027

ANALYSIS

Test	Specification	Results
Colour:	Colourless	Complies
Clarity:	Clear	Complies
Filtration:	Filtered to 0.2 microns	Complies
Endotoxins:	<0.25 EU/ml	Complies
SG at 20°C:	0.868 to 0.878	0.874
% IPA v/v at 20°C (calculated)	73.5% to 69.6%	71.2

Manufactured product via a quality system certified to ISO 9001:2015 or ISO 13485*, tested in accordance with documented quality procedures and approved when required specifications are met. (*as required by site of manufacture).

IRRADIATION

Irradiation certificate number: 3647605
Irradiation Dose (kGy): > 25 kGy > 28.6



We certify that the notified goods have undergone irradiation by exposure to γ (Gamma) irradiation with an exposure of not less than 25 kGy to conform to the European Pharmacopoeia.

Irradiation treatment applied was accordance with:

ISO 13485:2016 Quality Management System – Medical Devices
ISO 11137:2015 Sterilisation of Healthcare Products – Requirements for Validation & Routine Control – Radio-sterilisation

STERILITY

Sterility test number: 0000882039
Sterility test result: No evidence of microbial growth
Test method as described in the current edition of the European Pharmacopoeia.

Name: 1: Kobey Robson 2: Nicola Hunter
Position: 1: Quality Assurance Officer 2: Quality Assurance Officer
Date: 1: 09 DEC 24 2: 10 DEC 24
Authorised Signature: 1:  2: 
For and on behalf of Contec Inc

COA13 Rev 5

Manufactured by:
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Certificate of Processing

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11/04/2024 11:39:22 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3647605
P.O.# 409287 Sales Order # 3667878
25 - 95 kGy Gamma Irradiation Irradiation Date/Time: 11/03/2024 02:00:16 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	1120	BX	SBT170IW	IPA 70% with WFI	241002899	60522/STR002090
	Dose Map		302_0114	RF: 15.6A1, AF Min: 0.718		
	1120	BX	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	-----Signed By----- User	Date /Time
450.00	Minimum Dose	25.0 kGy	95.0 kGy	28.6 KGY	Pass	PSAXTON	11/03/2024 18:10:50 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	95.0 kGy	43.0 KGY	Pass	PSAXTON	11/03/2024 18:11:17 GMT
		Reason Code Test				PAUL SAXTON	

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: CLAIRE CICALA-MAESTRE
Reason: Work Order Completions

Date: 11/04/2024 11:38:01 GMT