

PRODUCT CERTIFICATE

Product: Contec Sterile IPA
Product Code: SBT170IW
Product Description: Sterile 70% Isopropanol in water for injection 1L Trigger Spray
Batch Number: 250303013
Manufacture Date: MAR / 2025
Expiry Date: MAR / 2028

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	0.873
% IPA v/v at 20°C (calculated)	73.5% to 69.6%	71.6

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: 3726935
Irradiation Dose (kGy): > 25 kGy > 28.7



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: 0000930942
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: 23 MAY 25 2: 23 May 25
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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 TEL (0)1246 561230 FAX www.sterigenics.com

R55480102

03/24/2025 9:39:59 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3726935
P.O.#	410253			Sales Order #	3763620
25 - 95 kGy		Gamma Irradiation		Irradiation Date/Time:	03/22/2025 07:37:34 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	250303013	61150/STR002090
			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	28.7 KGY	Pass	EMORRIS	03/23/2025 14:31:12 GMT
		Reason Code Test				EDWARD MORRIS	
450.00	Maximum Dose	25.0 kGy	95.0 kGy	41.0 KGY	Pass	EMORRIS	03/23/2025 14:31:27 GMT
		Reason Code Test				EDWARD MORRIS	

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: 03/24/2025 09:38:00 GMT