

**PRODUCT CERTIFICATE**

Product: Contec Sterile IPA  
Product Code: SBT170IW  
Product Description: Sterile 70% Isopropanol in water for injection 1L Trigger Spray  
Batch Number: 250202986  
Manufacture Date: FEB / 2025  
Expiry Date: FEB / 2028

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**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).

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**IRRADIATION**

Irradiation certificate number: 3718640  
Irradiation Dose (kGy): > 25 kGy > 28.6

We certify that the notified goods have undergone irradiation by exposure to  $\gamma$  (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

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**STERILITY**

Sterility test number: 0000930582  
Sterility test result: No evidence of microbial growth  
Test method as described in the current edition of the European Pharmacopoeia.

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Name:	1: Heath Aitchison	2: Kobey Robson
Position:	1: Quality Administrator	2: Quality Assurance Officer
Date:	1: 23 MAY 25	2: 23 MAY 25
Authorised Signature:	1: 	2: 

For and on behalf of Contec Inc

## Certificate of Processing

STERIGENICS Seymour Link Road Woodthorpe Mastin Moor  
TEL (0)1246 561230 FAX www.sterigenics.com

R55480102

03/10/2025 11:12:41 GMT  
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<b>Customer Name:</b>	<b>FLEXIBLE MED. GBP UK LANCASTER</b>	<b>Processing Facility:</b>	<b>Markham Vale</b>	<b>Work Order #</b>	<b>3718640</b>
<b>P.O.#</b>	<b>410172</b>			<b>Sales Order #</b>	<b>3753988</b>
<b>25 - 95 kGy</b>		<b>Gamma Irradiation</b>		<b>Irradiation Date/Time:</b>	<b>03/07/2025 16:23:22 GMT</b>

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	250202986	61149/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	OCUPIT	03/08/2025 13:49:22 GMT
	Reason Code Test					OLIVER CUPIT	
450.00	Maximum Dose	25.0 kGy	95.0 kGy	40.8 KGY	Pass	OCUPIT	03/08/2025 13:49:40 GMT
	Reason Code Test					OLIVER CUPIT	

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: 03/10/2025 11:11:49 GMT