

## PRODUCT CERTIFICATE

Product: Contec Sterile IPA  
Product Code: SBT170IW  
Product Description: Sterile 70% Isopropanol in water for injection 1L Trigger Spray  
Batch Number: 250203009  
Manufacture Date: Feb / 2025  
Expiry Date: Feb / 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	0.877
% IPA v/v at 20°C (calculated)	73.5% to 69.6%	70.1

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: 2173-54685A  
Irradiation Dose (kGy): > 25 kGy > 53.1



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

### STERILITY

Sterility test number: 0000935194  
Sterility test result: No evidence of microbial growth  
Test method as described in the current edition of the European Pharmacopoeia.

Name: 1: Nicola Hunter 2: Kobey Robson  
Position: 1: Quality Assurance Officer 2: Quality Assurance Officer  
Date: 1: 10 Jun 25 2: 11 JUN 25  
Authorised Signature: 1:  2:   
For and on behalf of Contec Inc

COA13 Rev 5

**Manufactured by:**  
Contec Cleanroom (UK) Ltd  
Unit 6A Wansbeck Business Park  
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# STERIS: Gamma Certificate Of Processing

Prepared For CONTEC CLEANROOM UK LTD (8250)

Gamma Process Run ID 2173-54685A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
Sterile 70% Alcohol DV5508	250203009	1120	Case
Validation Reference Number: 5508			

Processing Run Start Date 12-Mar-2025 8:46 AM

Processing Run End Date 13-Mar-2025 8:08 AM

Specified Dose Range (kGy)	25.0 - 95.0	Calculated Min Dose (kGy)	53.1
Reference Dose Range (kGy)	31.1 - 83.0	Calculated Max Dose (kGy)	76.9

PO Number: 148124

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

**Gamma Process Run Approval authorized by STERIS**

DateTime Esigned 13-Mar-2025 2:59 PM

Operating facilities are in compliance with applicable regulations providing services under a certified ISO 13485 quality system and processing in accordance with STERIS practices and procedures.

## Processing Location

Synergy Health Sterilisation UK  
Limited, a STERIS Company  
Brunel Close  
Drayton Fields Industrial Estate  
Daventry  
Northants  
NN11 8RB  
Phone: + 44(0) 1327 706 111

  
21 Mar 25

Document ID: 202

N/A

Last Revised in Rel 2.0.0.0

Rel Date: 13-Aug-2018

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