

PRODUCT CERTIFICATE

Product: Contec Sterile IPA
Product Code: SBC570I
Product Description: Sterile 70% Isopropanol in purified water (EP) 5L Capped
Batch Number: 250303033
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	0.874
% 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: 2173-55810A
Irradiation Dose (kGy): > 25 kGy > 53.4



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: 0000938067
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: 19 JUN 25 2: 19 JUN 25
Authorised Signature: 1:  2: 
For and on behalf of Contec Inc

COA14 Rev 4

Manufactured by:
Contec Cleanroom (UK) Ltd
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STERIS: Gamma Certificate Of Processing

Prepared For CONTEC CLEANROOM UK LTD (8250)
Gamma Process Run ID 2173-55810A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
70% 5L Sterile Alcohol DV5524	250303033	256	Case
Customer Item ID:	SBC570I		
Validation Reference Number:	5524		

Processing Run Start Date 21-Apr-2025 2:15 PM

Processing Run End Date 22-Apr-2025 6:50 AM

Specified Dose Range (kGy)	25.0 - 95.0	Calculated Min Dose (kGy)	53.4
Reference Dose Range (kGy)	35.1 - 90.2	Calculated Max Dose (kGy)	83.4

PO Number: 148981

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

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 22-Apr-2025 7:18 AM

Operating facilities are in compliance with applicable state and federal regulations providing services under a certified quality system which meets the following requirements (if applicable): FDA QSR (will be updated to QMSR), ISO 9001, EN/ISO 13485 current certified version, national pharmaceutical GMP and is in alignment with EN ISO 11137 current certified version. STERIS AST certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

Processing Location

Synergy Health Sterilisation UK
Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
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