

PRODUCT CERTIFICATE

Product: Contec Sterile IPA
Product Code: SBC570I
Product Description: Sterile 70% Isopropanol in purified water (EP) 5L Capped
Batch Number: 241202959
Manufacture Date: DEC / 2024
Expiry Date: DEC / 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: 2173-53195A
Irradiation Dose (kGy): > 25 kGy > 51.5



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: 0000933375
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: 03 JUN 25 2: 03 JUN 25
Authorised Signature: 1:  2: 
For and on behalf of Contec Inc

COA14 Rev 4

Manufactured by:
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STERIS: Gamma Certificate Of Processing

Prepared For CONTEC CLEANROOM UK LTD (8250)
Gamma Process Run ID 2173-53195A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
70% 5L Sterile Alcohol DV5524	241202959	192	Case

Validation Reference Number: 5524

Processing Run Start Date 19-Jan-2025 4:38 AM

Processing Run End Date 19-Jan-2025 9:43 PM

Specified Dose Range (kGy)	25.0 - 95.0	Calculated Min Dose (kGy)	51.5
Reference Dose Range (kGy)	35.1 - 90.2	Calculated Max Dose (kGy)	78.1

PO Number: 146638

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

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 20-Jan-2025 5:20 AM

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


27 Feb 25

Document ID: 197:

N/A

Last Revised in Rel 2.0.0.0

Rel Date: 13-Aug-2018

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