

PRODUCT CERTIFICATE

Product: Contec Sterile IPA
Product Code: SBT170IW
Product Description: Sterile 70% Isopropanol in water for injection 1L Trigger Spray
Batch Number: 250202989
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	0.875
% IPA v/v at 20°C (calculated)	73.5% to 69.6%	70.8

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: 2173-54951A
Irradiation Dose (kGy): > 25 kGy > 51.3



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: 0000930583
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: 22 MAY 25	2: 22 May 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
Ashington
UK

America
Contec Inc
P.O.Box 530
Spartanburg SC
USA

Europe
Contec Inc
ZI du Prat RP 3707
56037 VANNES
France

China
Contec Cleanroom Technology (Suzhou) Co. Ltd
No. 17 Longyun Road
Suzhou 215024
China

www.contecinc.com
infoeu@contecinc.com

STERIS: Gamma Certificate Of Processing

Prepared For CONTEC CLEANROOM UK LTD (8250)
Gamma Process Run ID 2173-54951A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
Sterile 70% Alcohol DV5508	250202989	1120	Case
Customer Item ID:	SBT170IW		
Validation Reference Number:	5508		

Processing Run Start Date 19-Mar-2025 6:36 PM

Processing Run End Date 20-Mar-2025 2:11 PM

Specified Dose Range (kGy)	25.0 - 95.0	Calculated Min Dose (kGy)	51.3
Reference Dose Range (kGy)	31.1 - 83.0	Calculated Max Dose (kGy)	76.8

PO Number: 148317

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


Gamma Process Run Approval authorized by STERIS

DateTime Esigned 21-Mar-2025 2:11 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

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