

PRODUCT CERTIFICATE

Product: Contec Sterile IPA
Product Code: SBT170IW
Product Description: Sterile 70% Isopropanol in water for injection 1L Trigger Spray
Batch Number: 190401085
Manufacture Date: APR / 2019
Expiry Date: APR / 2022

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

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: 2461748
Irradiation Dose (kGy): > 25 kGy > 29.7kGy



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: 0000472074
Sterility test result: No evidence of microbial growth
Test method as described in the current edition of the European Pharmacopoeia.

Name: 1: Lee Rodgers 2: John Gray
Position: 1: Snr. Quality Technician 2: Quality Manager
Date: 1: 06 Aug 19 2: 06 Aug 19
Authorised Signature: 1:  2: 
For and on behalf of Contec Inc

COA13 Rev 4

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



Certificate of Processing

STERIGENICS Seymour Link Road Woodthorpe Mastin Moor
TEL FAX www.sterigenics.com

R55480102

06/26/2019 8:45:04 GMT
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Customer Name: CONTEC CLEANROOM GBP UK
ASHINGTON
P.O.# 101143 101145
25 - 95 kGy

Processing Facility: Markham Vale
Gamma Irradiation
Irradiation Date/Time: 06/24/2019 01:30:48 GMT

Work Order # 2461748
Sales Order # 2261152

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	600	BX	SBT170IW	IPA 70% with WFI	190401085	NA
	Dose Map		302_0018	HI: TA5 LO: 1.1C6		
102.000	320	BX	SBT170DEW	DE 70% with WFI	190601149	NA
	Dose Map		302_0018	HI: TA5 LO: 1.1C6		
	920	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	29.7 KGY	Pass	MFORD MARTYN FORD	06/25/2019 12:39:51 GMT
450.00	Maximum Dose	25.0 kGy	95.0 kGy	47.6 KGY	Pass	MFORD MARTYN FORD	06/25/2019 12:40:05 GMT

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: EMMA BROWN
Reason: Work Order Completions

Date: 06/26/2019 08:43:50 GMT

Goodman