

PRODUCT CERTIFICATE

Product: Contec Sterile Denatured Ethanol
Product Code: SBT0570DEW
Product Description: Sterile 70% Denatured Ethanol in water for injection 0.5L Trigger Spray
Batch Number: 181100960
Manufacture Date: NOV / 2018
Expiry Date: NOV / 2021

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:	0.865 to 0.895	0.882

Manufactured product via a Quality System certified to ISO 9001:2008, tested in accordance with documented quality procedures and approved when required specifications are met.

IRRADIATION

Irradiation certificate number: 2173-1108A

Irradiation Dose (kGy): > 25 kGy > 35.4

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 9001:2008 Quality Management System
ISO 13485:2012 Quality Management System – Medical Devices
ISO 11137:2006 Sterilisation of Healthcare Products – Requirements for Validation & Routine Control – Radio-sterilisation

STERILITY

Sterility test number: (19375)-3198/MFEP

Sterility test result: No evidence of microbial growth

Test method as described in the current edition of the European Pharmacopoeia.

Name: 1: Rob Cox

2: John Gray

Position: 1: European Operations Manager

2: Quality Manager

Date: 1: 11 Feb 19

2: 11 Feb 19

Authorised Signature: 1:

For and on behalf of Contec Inc

2:

COA30 Rev 1

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: 2173-1108A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
0.5L Alcohol DV4738	181100960	601	Case

Validation Reference Number: 4738

PO Number: 96916

Processing Run Start Date: 07-Jan-19 08:20 AM

Processing Run End Date: 08-Jan-19 08:45 AM

Specified Dose Range (kGy):	25.0 - 95.0	Calculated Min Dose (kGy):	35.4
Reference Dose Range (kGy):	28.0- 85.4	Calculated Max Dose (kGy):	49.2

Other Information

181100960, 10 PLTS

Signature Manifest

Reviewed and E-Signed By: **Mark Morse (QA Officer)**

Date/Time E-Signed: 2019-01-10 10:07 AM

Document Content Revision: 1

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
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