

PRODUCT CERTIFICATE

Product: Contec Sterile IPA
Product Code: SBT170IW
Product Description: Sterile 70% Isopropanol in water for injection 1L Trigger Spray
Batch Number: 241002909
Manufacture Date: OCT / 2024
Expiry Date: OCT / 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 | 0.875 |
| % 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: 2173-51578A
Irradiation Dose (kGy): > 25 kGy > 53.1



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: 0000882038
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: 09 DEC 24 2: 09 DEC 24
Authorised Signature: 1:  2: 
For and on behalf of Contec Inc

COA13 Rev 5

Manufactured by:
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STERIS: Gamma Certificate Of Processing

Prepared For CONTEC CLEANROOM UK LTD (8250)
Gamma Process Run ID 2173-51578A

| <u>Product Code</u> | <u>Lot Number</u> | <u>Quantity</u> | <u>UOM</u> |
|-----------------------------------|-------------------|-----------------|------------|
| Sterile 70% Alcohol DV5508 | 241002909 | 1120 | Case |
| Validation Reference Number: 5508 | | | |

Processing Run Start Date 02-Nov-2024 9:23 PM
Processing Run End Date 03-Nov-2024 3:59 PM

| | | | |
|----------------------------|-------------|---------------------------|------|
| Specified Dose Range (kGy) | 25.0 - 95.0 | Calculated Min Dose (kGy) | 53.1 |
| Reference Dose Range (kGy) | 31.1 - 83.0 | Calculated Max Dose (kGy) | 77.8 |

PO Number: 145085

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

Gamma Process Run Approval authorized by STERIS
DateTime Esigned 03-Nov-2024 5:16 PM

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
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18 Nov 24