

PRODUCT CERTIFICATE

Product: Contec Sterile Neutraklean
Product Code: SBC503NK
Product Description: Sterile Neutral Detergent in purified water (EP) 5L Capped
Batch Number: 250403070
Manufacture Date: Apr / 2025
Expiry Date: Apr / 2027

ANALYSIS

Test	Specification	Results
Colour:	Colourless	Complies
Clarity:	Clear	Complies
Filtration:	Filtered to 0.2 microns	Complies
SG at 20°C:	0.995 - 1.010	1.000
pH:	6.0 to 8.0	7.90

Manufactured product via a quality system certified to ISO 9001:2015 tested in accordance with documented quality procedures and approved when required specifications are met.

IRRADIATION

Irradiation certificate number: 2173-56771A

Irradiation Dose (kGy): > 25 kGy > 32.4

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 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: 0000940499

Sterility test result: No evidence of microbial growth

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

Name: 1: Nicola Hunter 2: Kobey Robson
Position: 1: Quality Assurance Officer 2: Quality Assurance Officer
Date: 1: 30 Jun 25 2: 30 JUN 25
Authorised Signature: 1:  2: 
For and on behalf of Contec Inc

COA019 Rev 4

Manufactured by:
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STERIS: Gamma Certificate Of Processing

Prepared For CONTEC CLEANROOM UK LTD (8250)
Gamma Process Run ID 2173-56771A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
Neutraklean 5L DV6097	250403070	95	Case

Validation Reference Number: 6097

Processing Run Start Date 25-May-2025 10:11 AM

Processing Run End Date 25-May-2025 7:43 PM

Specified Dose Range (kGy)	25.0 - 50.0	Calculated Min Dose (kGy)	32.4
Reference Dose Range (kGy)	31.3 - 46.4	Calculated Max Dose (kGy)	45.0

PO Number: 149884

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

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 26-May-2025 5:52 AM

Operating facilities are in compliance with applicable state and federal regulations providing services under a certified quality system which meets the following requirements (if applicable): FDA QSR (will be updated to QMSR), ISO 9001, EN/ISO 13485 current certified version, national pharmaceutical GMP and is in alignment with EN ISO 11137 current certified version. STERIS AST certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

Processing Location

Synergy Health Sterilisation UK
Limited, a STERIS Company
Brunel Close
Drayton Fields Industrial Estate
Daventry
Northants
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W 02 JUN 25

Document ID: 209881

N/A

Last Revised in Rel 2.0.0.0

Rel Date: 13-Aug-2018

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