

PRODUCT CERTIFICATE

Product: Contec Sterile NeutraKlean
Product Code: SBT103NK
Product Description: Sterile Neutral Detergent in purified water (EP) 1L Trigger Spray
Batch Number: 241202951
Manufacture Date: DEC / 2024
Expiry Date: DEC / 2026

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	7.0

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: 2173-54068A
Irradiation Dose (kGy): > 25 kGy > 28.2



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: 0000920932
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: 01 MAY 25	2: 01 May 25
Authorised Signature:	1: 	2: 

For and on behalf of Contec Inc

COA018 Rev 4

Manufactured by:
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STERIS: Gamma Certificate Of Processing

Prepared For CONTEC CLEANROOM UK LTD (8250)
Gamma Process Run ID 2173-54068A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
1L Neutraklean DV5638	241202951	154	Case

Validation Reference Number: 5638

Processing Run Start Date 19-Feb-2025 1:48 PM

Processing Run End Date 19-Feb-2025 10:46 PM

Specified Dose Range (kGy)	25.0 - 45.0	Calculated Min Dose (kGy)	28.2
Reference Dose Range (kGy)	30.8 - 39.3	Calculated Max Dose (kGy)	41.9

PO Number: 147620

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


Gamma Process Run Approval authorized by STERIS

DateTime Esigned 20-Feb-2025 5:21 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
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27 Feb 25