

PRODUCT CERTIFICATE

Product: Contec Sterile NeutraKlean
Product Code: SBC103NK
Product Description: Sterile Neutral Detergent in purified water (EP) 1L Capped
Batch Number: 220302003
Manufacture Date: MAR / 2022
Expiry Date: MAR / 2024

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	1.001
pH:	6.5 to 8.0	7.5

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: 2173-27385A
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:

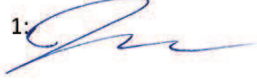
ISO 13485:2016 Quality Management System – Medical Devices
ISO 11137:2015 Sterilisation of Healthcare Products – Requirements for Validation & Routine Control – Radio-sterilisation

STERILITY

Sterility test number: 0000675871
Sterility test result: No evidence of microbial growth
Test method as described in the current edition of the European Pharmacopoeia.

Name: 1: Declan O'Connor 2: Nicole Kelly
Position: 1: R&D Associate 2: QC Supervisor

Date: 1: 28 Jun 22 2: 29 Jun 22

Authorised Signature: 1:  2: 
For and on behalf of Contec Inc

STERIS: Gamma Certificate Of Processing

Prepared for: CONTEC CLEANROOM UK LTD (8250)
Gamma Process Run ID 2173-27385A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
1L Neutraklean DV5638	220302003	160	Case
Validation Reference Number: 5638			

Processing Run Start Date: 12-Apr-2022 9:17 PM

Processing Run End Date: 13-Apr-2022 6:17 AM

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):	42.7

PO Number: 124767

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 13-Apr-2022 12:00 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
NN11 8RB
Phone: + 44(0) 1327 706 111

Mare Thompson
23 Jun 22

Document ID: 108794

N/A

Last Revised in Rel 2.0.0.0

Rel Date: 13-Aug-2018

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