

PRODUCT CERTIFICATE

Product: Contec Sterile NeutraKlean
Product Code: SBC503NK
Product Description: Sterile Neutral Detergent in purified water (EP) 5L Capped
Batch Number: 210801815
Manufacture Date: AUG / 2021
Expiry Date: AUG / 2023

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:	6.5 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: 2173-21889A
Irradiation Dose (kGy): > 25 kGy > 28.3

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: 0000618686
Sterility test result: No evidence of microbial growth
Test method as described in the current edition of the European Pharmacopoeia.

Name:	1: Marie Thompson	2: John Gray
Position:	1: Quality Administrator	2: Quality Manager
Date:	1: 28 Sep 21	2: 28 Sep 21
Authorised Signature:	1: 	2: 

For and on behalf of Contec Inc

COA019 Rev 3

Manufactured by:
 Contec Cleanroom (UK) Ltd
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 UK

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STERIS: Gamma Certificate Of Processing

Prepared for: CONTEC CLEANROOM UK LTD (8250)

Gamma Process Run ID: 2173-21889A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
NEUTRAKLEAN 5L DV5342	210801815	95	Case

Validation Reference Number: 5342

Processing Run Start Date: 29-Aug-2021 9:04 PM

Processing Run End Date: 30-Aug-2021 5:34 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	28.3
Reference Dose Range (kGy):	30.4 - 39.8	Calculated Max Dose (kGy):	39.7

PO Number: 120023

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

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 30-Aug-2021 6:54 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
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Drayton Fields Industrial Estate
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Mari Thompson
28 SEP 21

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Rel Date: 13-Aug-2018

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