

PRODUCT CERTIFICATE

Product: Contec Sterile NeutraKlean
Product Code: SBC103NK
Product Description: Sterile Neutral Detergent in purified water (EP) 1L Capped
Batch Number: 201001543
Manufacture Date: OCT / 2020
Expiry Date: OCT / 2022

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: 2173-14326A
Irradiation Dose (kGy): > 25 kGy > 28.1

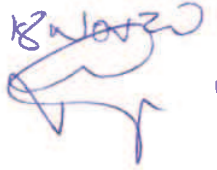
We certify that the notified goods have undergone irradiation by exposure to γ (Gamma) irradiation with an exposure of not less than 25 kGy to conform to the European Pharmacopoeia.

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: 0000557719
Sterility test result: No evidence of microbial growth
Test method as described in the current edition of the European Pharmacopoeia.

Name:	1: John Gray	2: Lee Rodgers
Position:	1: Quality Manager	2: Quality Supervisor
Date:	1: 18 Nov 20	2: 18 Nov 20
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: 2173-14326A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
1L Neutraklean DV5638	201001543	160	Case

Validation Reference Number: 5638

Processing Run Start Date: 21-Oct-20 08:28 PM

Processing Run End Date: 22-Oct-20 05:02 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	28.1
Reference Dose Range (kGy):	30.8 - 39.3	Calculated Max Dose (kGy):	41.8

PO Number: 113164

Gamma Process Run Approval authorized by STERIS

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
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Drayton Fields Industrial Estate
Daventry
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