

PRODUCT CERTIFICATE

Product: Contec Sterile NeutraKlean
Product Code: SBC103NK
Product Description: Sterile Neutral Detergent in purified water (EP) 1L Capped
Batch Number: 210201671
Manufacture Date: FEB / 2021
Expiry Date: FEB / 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	7.4

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: 2173-17903A
Irradiation Dose (kGy): > 25 kGy > 27.9

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: 0000590972
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: 04 May 21	2: 04 MAY 21
Authorised Signature:	1: <i>Marie Thompson</i>	2: <i>[Signature]</i>

For and on behalf of Contec Inc

COA54 Rev 2

Manufactured by:
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STERIS: Gamma Certificate Of Processing

Prepared for: CONTEC CLEANROOM UK LTD (8250)

Gamma Process Run ID: 2173-17903A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
1L Neutraklean DV5638	210201671	159	Case

Validation Reference Number: 5638

Processing Run Start Date: 22-Mar-21 04:59 PM

Processing Run End Date: 23-Mar-21 02:17 AM

Specified Dose Range (kGy):	25.0 - 45.0	Calculated Min Dose (kGy):	27.9
Reference Dose Range (kGy):	30.8 - 39.3	Calculated Max Dose (kGy):	41.1

PO Number: 116476

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

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
Limited, a STERIS Company
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M. Thompson
23 Mar 21.

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