

PRODUCT CERTIFICATE

Product: Contec HydroKlean
Product Code: SBT34HK6IR
Product Description: Sterile filled, 6% stabilized Hydrogen Peroxide in water for injection 1L Trigger Spray
Batch Number: 191101278
Manufacture Date: NOV / 29 / 2019
Expiry Date: NOV / 2021

ANALYSIS

Test	Specification	Results
Color:	Colorless	Complies
Clarity:	Clear	Complies
Filtration:	Filtered to 0.2 microns	Complies
Endotoxins:	<0.25 EU/ml	Complies
SG at 20°C:	1.021 – 1.025	1.002
Concentration of H ₂ O ₂ :	6.0% - 6.9%	6.9

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.

STERILITY

Sterility test number: 0000505155 0000505156 0000505157

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: Snr. Quality Technician
Date: 1: 31 Jan 20 2: 31 Jan 20
Authorized Signature: 1:  2: 
For and on behalf of Contec Inc

COA023 Rev4

Manufactured by:
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STERIS: Gamma Certificate Of Processing

Prepared for: CONTEC CLEANROOM UK LTD (8250)

Gamma Process Run ID: 2173-6853A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
PRIMARY PACKAGING 1L GAPLAST DV4781	191101278	22	Case

Validation Reference Number: 4781

Processing Run Start Date: 11-Dec-19 11:52 AM

Processing Run End Date: 11-Dec-19 07:06 PM

Specified Dose Range (kGy):	25.0 - 95.0	Calculated Min Dose (kGy):	33.1
Reference Dose Range (kGy):	26.1- 88.8	Calculated Max Dose (kGy):	37.5

PO Number: 105292

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

Signature Manifest

Reviewed and E-Signed By: **Bhavya Ramisetty (Quality Engineer)**

Date/Time E-Signed: 2019-12-12 12:47 PM

Document Content Revision: 1

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

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