

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: 190301058
Manufacture Date: MAR / 26 / 2021
Expiry Date: MAR / 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	1.023
Concentration of H ₂ O ₂ :	6.0% - 6.9%	6.7%


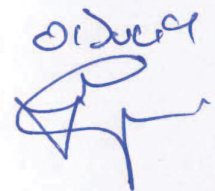
Manufactured product via a Quality System certified to ISO 9001:2015, tested in accordance with documented quality procedures and approved when required specifications are met.

STERILITY

Sterility test number: 0000464990, 0000464991, 0000464992

Sterility test result: No evidence of microbial growth

Test method as described in the current edition of the European Pharmacopoeia.

Name:	1: Barry Hollinshead	2: John Gray
Position:	1: Quality Technician	2: Quality Manager
Date:	1: 01 Jul 19	2: 01 Jul 19
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: 2173-2534A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
PRIMARY PACKAGING 1L GAPLAST DV4781	190301058	16	Case

Validation Reference Number: 4781

Processing Run Start Date: 09-Apr-19 08:48 PM

Processing Run End Date: 10-Apr-19 02:36 AM

Specified Dose Range (kGy):	25.0 - 95.0	Calculated Min Dose (kGy):	30.0
Reference Dose Range (kGy):	26.1- 88.8	Calculated Max Dose (kGy):	34.2

Other Information

190301058, 2 PLTS

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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