

PRODUCT CERTIFICATE

Product:

Contec ProChlor

Product Code:

SBC502PC

Product Description:

Sterile Stabilised Hypochlorous Acid in purified water (EP) 5L Capped

Batch Number:

250202995

Manufacture Date:

Feb / 2025

Expiry Date:

Feb / 2027

ANALYSIS

Test

Specification

Results

Colour:

Colourless

Complies

Clarity:

Clear

Complies

Filtration:

Filtered to 0.2 microns

Complies

SG at 20°C:

0.990 - 1.010

1.002

Available chlorine:

>1000ppm

2245

pH at 20°C:

3.0 - 6.0

3.79

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:

0000928885, 0000928886, 0000928887

Sterility test result:

No evidence of microbial growth

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

Name:

1: Nicola Hunter

2: Kobey Robson

Position:

1: Quality Assurance Officer

2: Quality Assurance Officer

Date:

1: 21 May 25

2. 21May 25

Authorised Signature:

For and on behalf of Contec Inc

Τ;

America

Contec Inc

P.O.Box 530

Spartanburg SC

2:

COA10 Rev 4

Manufactured by: Contec Cleanroom (UK) Ltd Unit 6A Wansbeck Business Park Ashington

s Park

Europe Contec Inc ZI du Prat RP 3707 56037 VANNES China
Contec Cleanroom Technology (Suzhou) Co. Ltd
No. 17 Longyun Road
Suzhou 215024
China

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STERIS: Gamma Certificate Of Processing

Prepared For

CONTEC CLEANROOM UK LTD (8250)

Gamma Process Run ID

2173-55195A

Product Code

Lot Number

Quantity

<u>UOM</u>

PRIMARY PACKAGING 5L DV4794

250202995

Validation Reference Number: 4794

Case

Processing Run Start Date 30-Mar-2025 5:05 PM

Processing Run End Date 31-Mar-2025 1:32 AM

Calculated Min Dose (kGy)

31.8

Specified Dose Range (kGy) Reference Dose Range (kGy)

25.0 - 95.0 26.2 - 87.9

Calculated Max Dose (kGy)

39.7

PO Number: 148525

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

Gamma Process Run Approval authorized by STERIS

DateTime Esigned 31-Mar-2025 4:39 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 **Brunel Close Drayton Fields Industrial Estate Daventry** Northants **NN11 8RB**

Phone: + 44(0) 1327 706 111