



Certificate of Conformance, Analysis, and Sterility

This certification is provided as full assurance that the following product code and lot number were manufactured in accordance via a Quality System certified to ISO 9001 with prescribed procedures and specifications.

Product Code:	SBC3702PX
Lot Number:	GH081104241D
Product Description:	Contec Sterile PeridoxRTU, hydrogen peroxide and peracetic acid in deionised water, capped, 3.78L, for Europe Only
EU BPR Authorisation Number:	EU-0023658-0001 (1-1)
Manufacturing Date:	02/10/2025
Expiration Date:	02/2027

Analysis

Properties	Min	Max	Actual	Pass/Fail
%w Hydrogen Peroxide	4.00	4.80	4.51	Pass
%w Peroxyacetic Acid	0.17	0.29	0.23	Pass
Appearance	Liquid with white to grey tinge		Liquid with white to grey tinge	Pass
Odor	Vinegar		Vinegar	Pass
Additional Comments	N/A			

Sterility

Gamma Processing Run ID:	1153-12293A
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	30.7 kGy to 41.0 kGy
Validated Sterile Product:	Validation Sterile packets available upon request.
Sterility Assurance Level:	10 ⁻⁶ (SAL determined by test method AAMI/ISO 11137)

Thursday, February 27, 2025

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DID: 20643A



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STERIS: Gamma Certificate Of Processing

Prepared For CONTEC INC (1963)

Gamma Process Run ID 1153-12293A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
SBC3702PX	GH081104241D	80	Case
CR85336IR	GH081104241C	320	Case
HC85366IR	GH091204241B	80	Case

Processing Run Start Date 17-Feb-2025 10:28 PM

Processing Run End Date 18-Feb-2025 3:39 PM

Minimum Specified Dose (kGy)	25.0	Minimum Delivered Dose (kGy)	30.7
Maximum Specified Dose (kGy)	50.0	Maximum Delivered Dose (kGy)	41.0

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

Signature Manifest

Reviewed and E-Signed By: **Pachy Thor (Senior Quality Technician)**

DateTime Esigned 19-Feb-2025 6:34 AM

Document Content Revision 1

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485:2016, and in alignment with EN ANSI/AAMI/ISO 11137-1:2015.

Processing Location

2072 Southport Road
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