

Certificate of Conformance 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: | PSME0001-BPR |
| Lot Number: | 1147598-0-0-1 |
| EU BPR Authorisation Number: | EU-0020460 0002 (1-2) |
| Manufacturing Date: | 05/06/2025 |
| Isopropyl Alcohol: | 70 ± 3% by volume with the remainder DI H2O. |
| Expiration Date: | 05/2027 |

Sterility

| | |
|-----------------------------|---|
| Gamma Processing Run ID: | 3761084 |
| Irradiation Dose Specified: | 25.0 kGy to 50.0 kGy |
| Irradiation Dose Delivered: | 28.9 kGy to 39.1 kGy |
| Validated Sterile Product: | Validation Sterile packets available upon request. |
| Sterility Assurance Level: | 10 ⁻⁶ (SAL determined by test method AAMI/ISO 11137) |



QC Supervisor
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Monday, May 19, 2025

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Certificate of Processing

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R55480102

05/16/2025 14:15:14 GMT

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| | | | | | |
|-----------------------|---------------------------|------------------------------|-------------------------------|--------------------------------|----------------|
| Customer Name: | Contec- PO Box 530 | Processing Facility: | Charlotte Gamma | Work Order # | 3761084 |
| P.O.# | 149812 | | | Sales Order # | 3806088 |
| 25-50 kGy | | CNT6, Gamma Treatment | Irradiation Date/Time: | 05/16/2025 04:24:00 GMT | |

| SO Line # | Qty | UOM | Customer Item Number | Customer Item Description | Customer Lot Number | Customer Load Number |
|-----------|------------|-----------|----------------------|---------------------------|---------------------|----------------------|
| 101.000 | 72 | CA | PSCS0009 | Clean Room Product | 1144413-0-0-1 | 149812 |
| 102.000 | 72 | CA | PSCS0009 | Clean Room Product | 1144414-0-0-1 | 149812 |
| 103.000 | 72 | CA | PSCS0009 | Clean Room Product | 1144415-0-0-1 | 149812 |
| 104.000 | 60 | CA | PSME0001-BPR | Clean Room Product | 1147597-0-0-1 | 149812 |
| 105.000 | 72 | CA | PSCS0009 | Clean Room Product | 1144416-0-0-1 | 149812 |
| 106.000 | 60 | CA | PSME0001-BPR | Clean Room Product | 1147598-0-0-1 | 149812 |
| 107.000 | 72 | CA | PSCS0009 | Clean Room Product | 1144417-0-0-1 | 149812 |
| | 480 | CA | Total | | | |

Quality Test Summary

| Op# | Quality Test Description | Minimum Spec | Maximum Spec | Result | Pass/Fail | -----Signed By----- User | Date /Time |
|--------|--------------------------|------------------|--------------|----------|-----------|-----------------------------|-------------------------|
| 450.00 | Minimum Dose | 25.0 kGy | 50.0 kGy | 28.9 KGY | Pass | GDIAZ | 05/16/2025 13:27:06 GMT |
| | | Reason Code Test | | | | FAUSTINO GERMAN DIAZ | |
| 450.00 | Maximum Dose | 25.0 kGy | 50.0 kGy | 39.1 KGY | Pass | GDIAZ | 05/16/2025 13:30:25 GMT |
| | | Reason Code Test | | | | FAUSTINO GERMAN DIAZ | |

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: BRITTANY LONG
Reason: Work Order Completions

Date: 05/16/2025 14:14:25 GMT