



## 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.

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|                              |                       |
|------------------------------|-----------------------|
| Product Code:                | PSPP0039-BPR          |
| Lot Number:                  | 1147616-0-0-1         |
| EU BPR Authorisation Number: | EU-0020460 0002 (1-2) |
| Manufacturing Date:          | 05/06/2025            |
| Expiration Date:             | 05/2027               |

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### Analysis

|                           |                               |
|---------------------------|-------------------------------|
| Quantity of Particles Po: | 4.407 millions/m <sup>2</sup> |
|---------------------------|-------------------------------|

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### Sterility

|                             |   |
|-----------------------------|---|
| Gamma Processing Run ID:    | 3759451   |
| Irradiation Dose Specified: | 25.0 kGy to 50.0 kGy  |
| Irradiation Dose Delivered: | 27.0 kGy to 40.6 kGy  |
| Validated Sterile Product:  | Validation Sterile packets available upon request.              |
| Sterility Assurance Level:  | 10 <sup>-6</sup> (SAL determined by test method AAMI/ISO 11137) |

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QC Supervisor  
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Tuesday, May 20, 2025

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DID: 20601A



## Certificate of Processing

STERIGENICS 10811 Withers Cove Park Dr. Charlotte NC 28278  
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|                       |                           |                              |                               |                                |                |
|-----------------------|---------------------------|------------------------------|-------------------------------|--------------------------------|----------------|
| <b>Customer Name:</b> | <b>Contec- PO Box 530</b> | <b>Processing Facility:</b>  | <b>Charlotte Gamma</b>        | <b>Work Order #</b>            | <b>3759451</b> |
| <b>P.O.#</b>          | <b>149745</b>             |                              |                               | <b>Sales Order #</b>           | <b>3803957</b> |
|                       | <b>25-50 kGy</b>          | <b>CNT1, Gamma Treatment</b> | <b>Irradiation Date/Time:</b> | <b>05/16/2025 09:25:00 GMT</b> |                |

| SO Line # | Qty        | UOM       | Customer Item Number | Customer Item Description | Customer Lot Number | Customer Load Number |
|-----------|------------|-----------|----------------------|---------------------------|---------------------|----------------------|
| 101.000   | 54         | CA        | PSPS0076             | Clean Room Product        | 1140121-0-0-1       | 149745               |
| 102.000   | 360        | CA        | PSPP0039-BPR         | Clean Room Product        | 1147616-0-0-1       | 149745               |
| 103.000   | 30         | CA        | PSPS0077             | Clean Room Product        | 1146302-0-0-1       | 149745               |
| 104.000   | 66         | CA        | PS-LPP-7030IR-BPR    | Clean Room Product        | 1145865-0-0-1       | 149745               |
|           | <b>510</b> | <b>CA</b> | <b>Total</b>         |                           |                     |                      |

### Quality Test Summary

| Op#    | Quality Test Description | Minimum Spec     | Maximum Spec | Result   | Pass/Fail | -----Signed By-----<br>User | Date /Time              |
|--------|--------------------------|------------------|--------------|----------|-----------|-----------------------------|-------------------------|
| 450.00 | Minimum Dose             | 25.0 kGy         | 50.0 kGy     | 27.0 KGY | Pass      | BPOSTON                     | 05/16/2025 18:54:45 GMT |
|        |                          | Reason Code Test |              |          |           | BRANTT POSTON               |                         |
| 450.00 | Maximum Dose             | 25.0 kGy         | 50.0 kGy     | 40.6 KGY | Pass      | BPOSTON                     | 05/16/2025 18:55:08 GMT |
|        |                          | Reason Code Test |              |          |           | BRANTT POSTON               |                         |

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: 05/19/2025 13:14:01 GMT