



## 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:       | PS-911EB                                     |
| Lot Number:         | 834908-0-0-1                                 |
| Description:        | PROSAT sterile pre saturated wipes           |
| Manufacturing Date: | 05/24/2021                                   |
| Isopropyl Alcohol:  | 70 ± 3% by volume with the remainder DI H2O. |
| Expiration Date:    | 05/2023                                      |

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### Analysis

|                                 |                                |
|---------------------------------|--------------------------------|
| Quantity of Particles Po 0.5µM: | 12.797 millions/m <sup>2</sup> |
|---------------------------------|--------------------------------|

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### Sterility

|                             |   |
|-----------------------------|---|
| Gamma Processing Run ID:    | 2894273   |
| Irradiation Dose Specified: | 18.2 kGy to 40 kGy  |
| Irradiation Dose Delivered: | 21.0 kGy to 34.0 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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Monday, June 07, 2021

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DID: 221G



## Certificate of Processing

STERIGENICS 10811 Withers Cove Park Dr. Charlotte NC 28278  
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R55480102

06/02/2021 12:51:43 GMT  
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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>2894273</b>                 |
| <b>P.O.#</b>          | <b>118105</b>             |                              |                               | <b>Sales Order #</b> | <b>2780149</b>                 |
|                       | <b>18.2-40.0 kGy</b>      | <b>CNT4, Gamma Treatment</b> | <b>Irradiation Date/Time:</b> |                      | <b>06/01/2021 23:38:00 GMT</b> |

| SO Line # | Qty | UOM | Customer Item Number | Customer Item Description | Customer Lot Number | Customer Load Number |
|-----------|-----|-----|----------------------|---------------------------|---------------------|----------------------|
| 101.000   | 448 | CA  | PS-911EB             | Clean Room Product        | 834908-0-0-1        | 118105               |
|           | 448 | CA  | Total                |                           |                     |                      |

### Quality Test Summary

| Op#    | Quality Test Description | Minimum Spec | Maximum Spec | Result   | Pass/Fail | -----Signed By -----<br>User | Date /Time              |
|--------|--------------------------|--------------|--------------|----------|-----------|------------------------------|-------------------------|
| 450.00 | Minimum Dose             | 18.2 kGy     | 40.0 kGy     | 21.0 KGY | Pass      | DHOWELL                      | 06/02/2021 07:14:33 GMT |
|        | Reason Code Test         |              |              |          |           | DEREK HOWELL                 |                         |
| 450.00 | Maximum Dose             | 18.2 kGy     | 40.0 kGy     | 34.0 KGY | Pass      | DHOWELL                      | 06/02/2021 07:14:44 GMT |
|        | Reason Code Test         |              |              |          |           | DEREK HOWELL                 |                         |

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: 06/02/2021 12:50:13 GMT