



## CERTIFICATE OF STERILIZATION

Date: 4-Jun-14

This certification is provided as full assurance that the following product code was manufactured in accordance with prescribed procedures and specifications.

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|                             |                            |
|-----------------------------|----------------------------|
| Product/Material Number:    | C2-1212IR                  |
| Product Description:        | STERILESORB* C/P 12INx12IN |
| Lot Number:                 | 126383                     |
| Irradiation Run Number:     | 86487A                     |
| Irradiation Run Number:     | 86487B                     |
| Irradiation Dose Delivered: | 26.6kGy to 35.1kGy         |
| Irradiation Dose Delivered: | 27.2kGy to 35.8kGy         |
| Manufacture Date:           | 03/2014                    |
| Expiration Date:            | 03/2016                    |

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The above product has been Gamma Irradiated to Sterility Assurance Level of  $10^{-6}$  in accordance with the guidelines of the Association for the Advancement of Medical Instrumentation.

A handwritten signature in black ink, appearing to read "C. Inthavongsa".

Champagne Inthavongsa  
Quality Supervisor  
cinthavongsa@contecinc.com

# Certificate Of Processing

Prepared for ESSENTRA POROUS TECHNOLOGIES



Gamma Process Run ID 86487A

| <u>Product Code</u> | <u>Product Lot Number</u> | <u>Quantity</u> | <u>UOM</u> |
|---------------------|---------------------------|-----------------|------------|
| C-41212R            | 126383                    | 36              | CS         |

PO Number: 27964

|                                 |                         |                           |      |
|---------------------------------|-------------------------|---------------------------|------|
| Processing Run Start Date/Time: | 20-Mar-2014 03:05:00 am | Approx. Downtime (hours): | 0.13 |
| Processing Run End Date/Time:   | 20-Mar-2014 04:43:00 am |                           |      |

|                               |      |                               |      |
|-------------------------------|------|-------------------------------|------|
| Minimum Specified Dose (kGy): | 25.0 | Minimum Delivered Dose (kGy): | 26.6 |
| Maximum Specified Dose (kGy): | 40.0 | Maximum Delivered Dose (kGy): | 35.1 |

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

## Signature Manifest

Reviewed and E-Signed By:

*Francine Maranda (QS/RC Analyst)*

DocuSign Content Revision: 1

Signed On 3/20/2014 at 11:03 AM

UTC / GMT Offset (hh:mm) -4:00

## Processing Location:

STERIS Inc Medical Devices  
435 Whittey Street  
Northborough, MA 01532  
Phone: 508-393-8333  
Fax: 508-393-0588

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and CFRs) and provide services under a quality system which meets the requirements of FDA QSR, ENISO 13485:2003/2012, and in alignment with the applicable standard, EN ANSI/AAMI/ISO 11137:2006 or EN ANSI/AAMI/ISO 11135:2007. For items processed with gamma irradiation, STERIS Inc Medical certifies that these items received the indicated doses within the precision and accuracy of the dosimetry system used.

# Certificate Of Processing

Prepared for ESSENTRA POROUS TECHNOLOGIES

STERIS

Gamma Process Run ID 36487E

| Product Code | Product Lot Number | Quantity | UOM |
|--------------|--------------------|----------|-----|
| CL12121B     | 166383             | 54       | CS  |

PO Number: 27954

|                                 |                         |                           |      |
|---------------------------------|-------------------------|---------------------------|------|
| Processing Run Start Date/Time: | 20-Mar-2014 05:00:00 am | Approx. Downtime (hours): | 0.57 |
| Processing Run End Date/Time:   | 20-Mar-2014 07:04:00 am |                           |      |

|                                                                                                   |      |                               |      |
|---------------------------------------------------------------------------------------------------|------|-------------------------------|------|
| Minimum Specified Dose (kGy):                                                                     | 25.0 | Minimum Delivered Dose (kGy): | 27.2 |
| Maximum Specified Dose (kGy):                                                                     | 40.0 | Maximum Delivered Dose (kGy): | 35.8 |
| Product meets Customer specifications; zero nonconformities occurred during this irradiation run. |      |                               |      |

## Signature: Manifest

Reviewed and Signed By  
*Frazer Maranda (QC/QC Analyst)*  
Document Content Revision: 1

Signed On 3/20/2014 at 11:04 AM  
UTC / GMT Offset (hh:mm) -4:00

Processing Location:  
STERIS Komedy Services  
25 Walnut Street  
Southborough, MA 01832  
Phone: 508-393-9113  
Fax: 508-393-9117

Our long 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 13485:2003/2012, and in alignment with the applicable standard, EN ANSI/AAMI ISO 11137:2006 or EN ANSI/AAMI ISO 11135:2007. For items processed with gamma irradiation, STERIS Komedy Services' facilities have received the indicated doses within the precision and accuracy of the dosimetry system used.