

**CERTIFICATE OF STERILIZATION**

Date: 2-Oct-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:	C2-99IR/25
Product Description:	STERILESORB* C/P 9x9
Lot Number:	132585
Irradiation Run Number:	89361C
Irradiation Dose Delivered:	27.6kGy to 37.2kGy
Manufacture Date:	09/19/2014
Expiration Date:	09/2016

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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.



Champagne Inthavongsa  
Quality Supervisor  
cinthavongsa@contecinc.com

# Certificate Of Processing

Prepared for **ESSENTRA POROUS TECHNOLOGIES**



STERIS Isomedix Services

Gamma Process Run ID **89361C**

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
C2-991R/25	132585	35	CS

PO Number: 29005

Processing Run Start Date/Time: 19-Sep-2014 06:52:00 am      Approx. Downtime (hours): 0.00  
Processing Run End Date/Time: 19-Sep-2014 08:13:00 am

<b>Minimum Specified Dose (kGy):</b> 25.0	<b>Minimum Delivered Dose (kGy):</b> 27.6
<b>Maximum Specified Dose (kGy):</b> 40.0	<b>Maximum Delivered Dose (kGy):</b> 37.2

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

### Signature Manifest

Reviewed and E-Signed By  
**Francine Maranda (QS/RC Analyst)**

Document Content Revision: 1

Signed On 9/19/2014 at 12:43 PM  
UTC / GMT Offset (hh:mm): -4:00

**Processing Location:**  
STERIS Isomedix Services  
435 Whitney Street  
Northborough, MA 01532  
Phone: 508-393-9323  
Fax: 508-393-3685

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 13485:2003/2012, 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 Isomedix certifies that these items received the indicated doses within the precision and accuracy of the dosimetry system used.