CONTEC

CERTIFICATE OF STERILIZATION

Date: 6-Apr-15

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

Product/Material Number:	C2-99IR/25
Product Description:	STERILESORB* C/P 9x9
Lot Number:	137935
Irradiation Run Number:	92381A
Irradiation Run Number:	92381B
Irradiation Run Number:	92381C
Irradiation Dose Delivered:	26.3kGy to 38.2kGy
Irradiation Dose Delivered:	26.6kGy to 36.2kGy
Irradiation Dose Delivered:	27.5kGy to 36.6kGy
Manufacture Date:	03/24/2015
Expiration Date:	03/2017

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
Contec, Inc.
cinthavongsa@contecinc.com

Certificate Of Processing

Prepared for **ESSENTRA POROUS TECHNOLOGIES**

STERIS
Isomedix Services

Gamma Process Run ID **92381A**

Product Code	Product Lot Number	Quantity	UOM
C2-99IR/25	137935	6	CS

PO Number: P029943

Processing Run Start Date/Time:	23-Mar-2015 02:19:00 pm	Approx. Downtime (hours):	0.85
Processing Run End Date/Time:	23-Mar-2015 04:37:00 pm		

Minimum Specified Dose (kGy):	**25.0**	**Minimum Delivered Dose (kGy):**	**26.3**
Maximum Specified Dose (kGy):	**40.0**	**Maximum Delivered Dose (kGy):**	**38.2**

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

Signature Manifest

Reviewed and E-Signed By
Bryan Sposato (QS/RC Analyst)
Document Content Revision: 1

Signed On 3/24/2015 at 7:38 AM
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.

Certificate Of Processing

Prepared for **ESSENTRA POROUS TECHNOLOGIES**

Gamma Process Run ID **92381B**

STERIS
Isomedix Services

Product Code	Product Lot Number	Quantity	UOM
C2-99IR/25	137935	216	CS

PO Number: P029943

Processing Run Start Date/Time:	23-Mar-2015 04:47:00 pm	Approx. Downtime (hours):	0.42
Processing Run End Date/Time:	23-Mar-2015 06:36:00 pm		

Minimum Specified Dose (kGy):	**25.0**	**Minimum Delivered Dose (kGy):**	**26.6**
Maximum Specified Dose (kGy):	**40.0**	**Maximum Delivered Dose (kGy):**	**36.2**

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

Signature Manifest

Reviewed and E-Signed By
Bryan Sposato (QS/RC Analyst)
Document Content Revision: 1

Signed On 3/24/2015 at 7:38 AM
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.

Certificate Of Processing

Prepared for **ESSENTRA POROUS TECHNOLOGIES**

STERIS
Isomedix Services

Gamma Process Run ID **92381C**

Product Code	Product Lot Number	Quantity	UOM
C2-99IR/25	137935	78	CS

PO Number: P029943

Processing Run Start Date/Time:	23-Mar-2015 06:46:00 pm	Approx. Downtime (hours):	0.28
Processing Run End Date/Time:	23-Mar-2015 08:28:00 pm		

Minimum Specified Dose (kGy):	**25.0**	**Minimum Delivered Dose (kGy):**	**27.5**
Maximum Specified Dose (kGy):	**40.0**	**Maximum Delivered Dose (kGy):**	**36.6**

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

Signature Manifest

Reviewed and E-Signed By
Bryan Sposato (QS/RC Analyst)
Document Content Revision: 1

Signed On 3/24/2015 at 7:37 AM
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.