

Self-Contained Biological Indicators - Manufacturing Transfer Summary

With the acquisition of NAMSA's Sterilization Monitoring Products Division, all manufacturing processes will be transferred to Crosstex. Self-Contained Biological Indicators (SCBIs) have been manufactured by Crosstex for several years; thus, the validated processes and equipment currently being used to manufacture these products will continue to be utilized once the transition is complete.

Crosstex is a FDA registered facility (registration number 1319130). Based on a product comparison and review of best practices, the SCBIs manufactured by Crosstex are equivalent to those manufactured by NAMSA Products Division and offer the following advantages:

- For Steam sterilization, SporView®10 is available. The SCBIs offer a validated reduced incubation time of 10 hours. The SCBI is utilizing a conventional spore growth readout for rapid and reliable monitoring of steam sterilization processes without the use of enzyme based technology or specific and specialized incubators or monitoring devices.
- Vial labels have an enhanced substrate and adhesive which allows the labels to be peeled off more easily post sterilization.

Information important to the transfer of the SCBIs manufacturing process is outlined below:



Mini SCBIs for Ethylene Oxide (EO):

NAMSA Product Code: MSCE-06

- NAMSA's Mini SCBIs for EO sterilization will be available under new Crosstex product codes.

	NAMSA	Crosstex
Product Codes	MSCE-06	SCA-100
Cell Line Number <i>(Bacillus atrophaeus)</i>	9372	9372
Population	≥1.0 x 10 ⁶	1.0 to 5.0 x 10 ⁶
Vial Dimensions	9 mm x 50 mm	8.4 mm x 45.5 mm
Incubation Time	48 hours	48 hours
Media Transitioning (Positive)	Green to Yellow	Green to Yellow
Packaging	100/box	100/box
Shelf Life	24 months	24 months
Cap Color	Green	Green
Chemical Indicator	Violet to Green	White to Brown
Compliance	USP, ISO 11138-1, ISO 11138-2	USP, ISO 11138-1, ISO 11138-2

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Below Photos Illustrate the Chemical Indicator Location and Color Transition on EO SCBIs Manufactured By Crosstex (Product Code: SCA-100)	
Before Exposure to EO	After Exposure to EO
	

Mini SCBIs for Steam:



NAMSA Product Codes: MSCS-05 and MSCS-06

- NAMSA's Mini SCBIs for Steam sterilization will be available under Crosstex product codes.

	NAMSA	Crosstex
Product Codes	MSCS-05 (Population 10 ⁵)	SCS-100 (Population 10 ⁵)
	MSCS-06 (Population 10 ⁶)	SCS-106 (Population 10 ⁶)
Cell Line Number (<i>Geobacillus stearothermophilus</i>)	7953	7953
Population	≥1.0 x 10 ⁶	1.0 to 5.0 x 10 ^x
Vial Dimensions	9 mm x 50 mm	8.4 mm x 45.5 mm
Incubation Time	24 hours	24 hours
Media Transitioning (Positive)	Purple to Yellow	Purple to Yellow
Packaging	100/box	100/box ¹
Shelf Life	24 months	24 months
Cap Color	Purple	Brown
Chemical Indicator	Yellow to Dark	Blue to Dark
Compliance	USP, ISO 11138-1, ISO 11138-3	USP, ISO 11138-1, ISO 11138-3

¹ Boxes of 25 units are also available.

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Below Photos Illustrate the Chemical Indicator Location and Color Transition on Steam SCBIs Manufactured By Crosstex (Product Codes: SCS-100 and SCS-106)	
Before Exposure to Steam	After Exposure to Steam
	



Mini SCBIs for Hydrogen Peroxide (VH₂O₂):

NAMSA Product Code: MSCH-06

- NAMSA's Mini SCBIs for VH₂O₂ sterilization will be available under Crosstex product codes.

	NAMSA	Crosstex
Product Codes	MSCH-06	VH50
Cell Line Number (<i>Geobacillus stearothermophilus</i>)	7953	7953
Population	≥1.0 x 10 ⁶	1.0 to 5.0 x 10 ⁶
Vial Dimensions	9 mm x 50 mm	8.4 mm x 45.5 mm
Incubation Time	24 hours	24 hours
Media Transitioning (Positive)	Purple to Yellow	Purple to Yellow
Packaging	100/box	50/box
Shelf Life	18 months	18 months
Cap Color	Clear	White
Chemical Indicator	Red to Yellow	Red to Blue
ISO Compliance	USP, ISO 11138-1	USP, ISO 11138-1

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Below Photos Illustrate the Chemical Indicator Location and Color Transition on VH ₂ O ₂ SCBIs Manufactured By Crosstex (Product Codes: VH50)	
Before Exposure to VH ₂ O ₂	After Exposure to VH ₂ O ₂
	

The ordering information associated with the products, during and post transition will remain the same and as outlined below.

Ordering Information	
Telephone	1 (800) 860-1888
Fax	1 (419) 666-1715
Email	productorders@crosstex.com

As manufacturing activities begin to transfer to Crosstex, product may be branded under NAMSA or Crosstex and will be shipped from one of two locations depending on the branding of the product. NAMSA branded product will ship from the existing NAMSA facility (6750 Wales Road, Northwood, OH 43619) and Crosstex branded product will be shipped from the Rush, NY, facility (6789 W Henrietta Road, Rush, NY 14543).

Thank you for being a valued client and we look forward to continuing to serve you.