

Biological Indicator Spore Strips - Manufacturing Transfer Summary

With the acquisition of NAMSA's Sterilization Monitoring Products Division, all manufacturing processes will be transferred to Crosstex. Biological Indicator Spore Strips 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 Biological Indicator Spore Strips manufactured by Crosstex are equivalent to those manufactured by NAMSA Products Division and offer the following advantages:

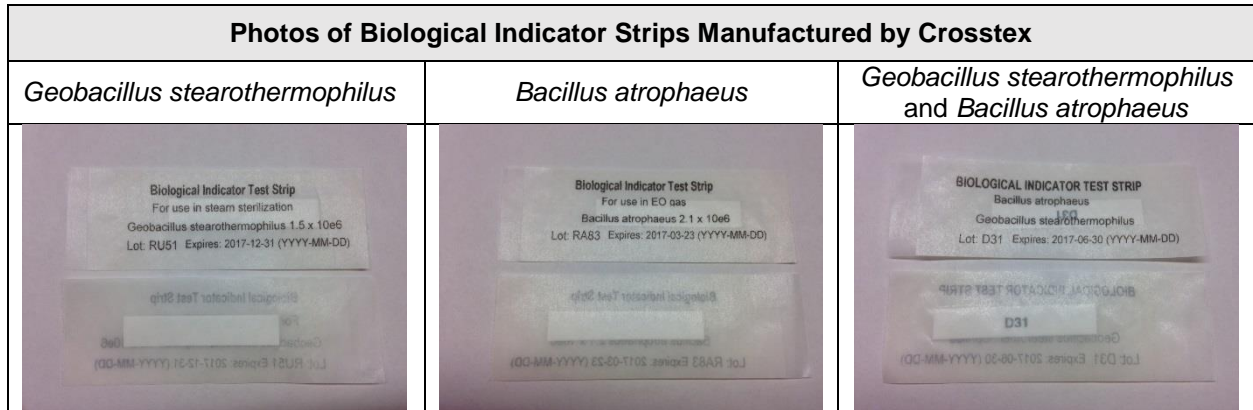
- An improved peel area which allows for the Spore Strip to be more easily accessed and removed from the glassine packaging.
- Natural glassine material which does not contain dye.
- Lot Number printed on the glassine packaging.
 - On the Dual Spore Strips only, Lot Number is printed on both the Spore Strip and the glassine packaging.

Information important to the transfer of the Biological Indicator Spore Strip manufacturing process is outlined below:

Organisms	NAMSA Cell lines	Crosstex Cell lines
<i>Geobacillus stearothermophilus</i>	7953	7953
<i>Bacillus atrophaeus</i>	9372	9372
<i>Bacillus pumilus</i>	27142	27142
<i>Bacillus subtilis</i>	5230	5230

	NAMSA	Crosstex
Packaging		
Glassine Material	30# Blue	25# White
Worldwide sources for glassine material are limited; thus, the material utilized by NAMSA and Crosstex-SPSmedical are the same with the exception of a blue dye. It is this dye which causes the glassine material NAMSA has utilized to appear blue, whereas Crosstex-SPSmedical utilizes the natural form of the material without the addition of the dye. Crosstex-SPSmedical switched from the dyed material to the natural white version several years ago without any negative impact to the product or its performance.		
Peel Area	Edges of glassine material align with indication to "PEEL HERE".	Edges of glassine material are offset, creating an obvious peel area which requires no indication.
Lot Number	6-7 Digits printed on glassine.	Single species: 4 Digits printed on glassine. Dual species: 3 Digits printed on Spore Strip and glassine.
Expiration Date	DD-MMM-YYYY	YYYY-MM-DD

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Strip Dimension	6 mm x 30 mm	6 mm x 30 mm
Quantity		
Single Species Spore Strips	Boxes of 100	Boxes of 100
Dual Species Spore Strips	Boxes of 100	Boxes of 100 500 and 1,000 packaged in bulk
Population	1.0 to 6.0 x 10 ^x	1.0 to 5.0 x 10 ^x

Product Code Reference and Shelf Life

Product Description	NAMSA		Crosstex	
	Product Code	Shelf Life	Product Code	Shelf Life
<i>Geobacillus stearothermophilus</i>				
10 ² Spore Strip	STS-02	30 months	BS-102	24 months
10 ³ Spore Strip	STS-03	30 months	BS-103	24 months
10 ⁴ Spore Strip	STS-04	30 months	BS-104	24 months
10 ⁵ Spore Strip	STS-05	30 months	BS-105	24 months
10 ⁶ Spore Strip	STS-06	30 months	BS-106	24 months
10 ⁷ Spore Strip	STS-07	30 months	BS-107	24 months
10 ⁸ Spore Strip	STS-08	30 months	BS-108	24 months
<i>Bacillus atrophaeus</i>				
10 ² Spore Strip	STN-02	30 months	BG-102	24 months
10 ³ Spore Strip	STN-03	30 months	BG-103	24 months
10 ⁴ Spore Strip	STN-04	30 months	BG-104	24 months
10 ⁵ Spore Strip	STN-05	30 months	BG-105	24 months
10 ⁶ Spore Strip	STN-06	30 months	BG-106	24 months
10 ⁷ Spore Strip	STN-07	30 months	BG-107	24 months
10 ⁸ Spore Strip	STN-08	30 months	BG-108	24 months



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Product Description	NAMSA		Crosstex	
	Product Code	Shelf Life	Product Code	Shelf Life
<i>Bacillus pumilus</i>				
10 ² Spore Strip	STP-02	24 months	PM-102	24 months
10 ³ Spore Strip	STP-03	24 months	PM-103	24 months
10 ⁴ Spore Strip	STP-04	24 months	PM-104	24 months
10 ⁵ Spore Strip	STP-05	24 months	PM-105	24 months
10 ⁶ Spore Strip	STP-06	24 months	PM-106	24 months
10 ⁷ Spore Strip	STP-07	24 months	PM-107	24 months
10 ⁸ Spore Strip	STP-08	24 months	PM-108	24 months
<i>Bacillus subtilis</i>				
10 ⁶ Spore Strip	BS52306	15 months	BS52306	15 months
Dual Species <i>Geobacillus stearothermophilus</i> and <i>Bacillus atrophaeus</i>				
10 ⁵ and 10 ⁶ Spore Strip	STNS-65	30 months	DS-100 (100/box) DS-500 (500/bulk bag) DS-1000 (1,000/bulk bag)	24 months

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.