CROSSTEX A CANTEL MEDICAL COMPANY | PROTECTS®

10 Ranick Road
Hauppauge, NY 11788-4209
Tel: 888-276-7783 | Fax: 631-582-1726
crosstex.com

Geobacillus stearothermophilus and *Bacillus atrophaeus* Dual Species Biological Indicator Spore Strip Product Comparison

This document refers to standard dual species spore strips of *Geobacillus stearothermophilus,* ATCC® 7953 and *Bacillus atrophaeus*, ATCC® 9372 NAMSA Product Code: STN-065R in comparison to Crosstex's equivalent replacement Product Code: DS-100.

Product Code Reference and Shelf Life

Product Description	NAMSA		Crosstex	
	Product Code	Shelf Life	Product Code	Shelf Life
Geobacillus stearothermophilus 10^5 Spore Strip	STN-065R	30 months	DS-100	24 months
Bacillus atrophaeus 10^6 Spore Strip				

Product Lot Comparison: NAMSA STN-065R versus Crosstex DS-100

Product Characteristic	NAMSA			Crosstex		
	Lot Number			Lot Number		
	X912	X937	X938	D35	D36	D38
Population per strip	$1.9x10^5$	$1.2x10^5$	$1.1x10^5$	$2.0x10^5$	$2.2x10^5$	$1.9x10^5$
	$2.4x10^6$	$1.8x10^6$	$1.3x10^6$	$1.9x10^6$	$1.9x10^6$	$1.8x10^6$
Ethylene Oxide (EO) *D* value 600 mg/L, 54°C, 60% RH In Minutes	3.3	3.4	3.2	3.0	3.0	2.8
EO Survival Time In Minutes	14.5	14.5	13.2	Survives: 15 minutes		
EO Kill Time In Minutes	34.2	34.8	32.3	Killed: 120 minutes		
Dry Heat Survives 121°C	Not Certified			30 minutes		
Dry Heat *D* value at 160°C In Minutes	1.9	1.9	1.6	2.3	2.3	2.1
Dry Heat Survival Time at 160°C In Minutes	8.4	8.1	6.6	Not Certified		
Dry Heat Kill Time at 160°C In Minutes	19.7	19.4	16.1	Killed: 120 minutes		

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Product Characteristic	NAMSA			Crosstex		
	Lot Number			Lot Number		
	X912	X937	X938	D35	D36	D38
Dry Heat *z* value	Determined based on *D* values at 150°C, 160°C and 180°C			Not Certified		
	42°C	42°C	43°C			
Steam *D* value at 121°C In Minutes	2.4	2.3	2.2	1.9	1.9	2.1
Steam Survival Time at 121°C In Minutes	7.9	7.1	6.7	Survives: 5 minutes		
Steam Kill Time at 121°C In Minutes	22.2	20.8	19.8	Killed: 15 minutes		
Steam *D* value at 132°C In Minutes	Not Certified	Not Certified	0.2	Not Certified		
Steam Survival Time at 132°C In Minutes			0.7	Survives: 20 seconds		
Steam Kill Time at 132°C In Minutes			1.8	Killed: 2 minutes		
Steam z value	Determined based on *D* values at 119°C, 121°C and 130°C			Not Certified		
	10°C	10°C	11°C			

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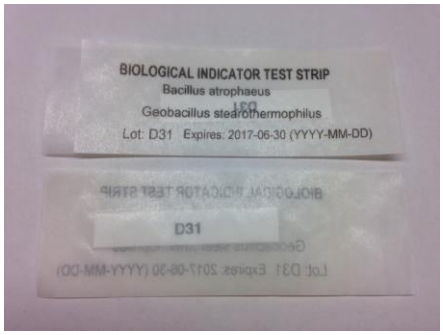

Crosstex is a FDA registered facility (registration number 1319130). Based on a product comparison and review of best practices, the Biological Indicator Spore Strips manufactured by Crosstex are equivalent to those manufactured by NAMSA Products Division and offer the following advantages:

- 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.

	NAMSA	Crosstex
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	4 Digits printed on glassine
Expiration Date	DD-MMM-YYYY	YYYY-MM-DD
Strip Dimension	6 mm x 30 mm	7 mm x 38 mm
Quantity	Boxes of 100	Boxes of 100
Population	1.0 to 6.0 x 10^x	1.0 to 5.0 x 10^x
EO *D* value	2.5 to 5.8 minutes	2.5 to 5.8 minutes
Dry Heat *D* value at 160°C	1.0 to 3.0 minutes	1.0 to 3.0 minutes
Dry Heat *z* value	≥20°C	≥20°C

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

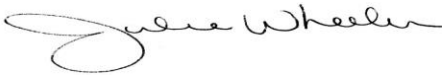
Ordering Information	
Telephone	1 (800) 860-1888
Fax	1 (419) 666-1715
Email	productorders@crosstex.com

We understand that our clients have different needs based on your internal quality system requirements or Standard Operating Procedures (SOP's). Because of this, if there is something specific that is required, such as completion of specific forms or documents, samples, etc., please do not hesitate to let us know.

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

If you have any questions, please do not hesitate to contact me.

Sincerely,



Julie Wheeler
Director Industrial Markets
jwheeler@crosstex.com
419-304-6535