

Geobacillus stearothermophilus Biological Indicator Spore Strip Product Comparison

This document refers to standard spore strips of *Geobacillus stearothermophilus*, ATCC® 7953
NAMSA Product Codes: STS-02, STS-03, STS-04, STS-05, STS-06, STS-07 and STS-08 in
comparison to Crosstex's equivalent replacement Product Codes: BS-102, BS-103, BS-104, BS-105,
BS-106, BS-107 and BS-108.

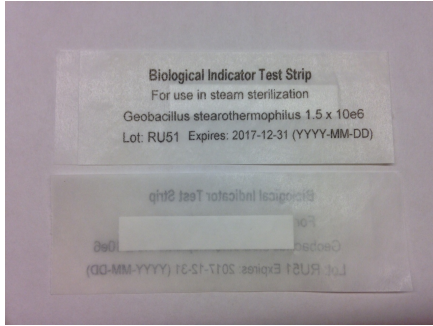
Product Code Reference and Shelf Life

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

Product Lot Comparison: NAMSA STS-06 versus Crosstex BS-106

Product Characteristic	NAMSA			Crosstex		
	Lot Number			Lot Number		
	S87403	S98202	S98600	RU48	RU50	RU51
Population per strip	5.1x10 ⁶	2.1x10 ⁶	1.5x10 ⁶	1.3x10 ⁶	1.5x10 ⁶	1.5x10 ⁶
Steam <i>D</i> value at 118°C In Minutes	Not Certified	Not Certified	Not Certified	4.9	6.6	5.1
Steam Survival Time at 118°C In Minutes				20.2	27.6	21.2
Steam Kill Time at 118°C In Minutes				49.5	67.1	51.8

Product Characteristic	NAMSA			Crosstex		
	Lot Number			Lot Number		
	S87403	S98202	S98600	RU48	RU50	RU51
Steam <i>D</i> value at 121°C In Minutes	1.8	1.9	2.5	1.7	2.5	1.7
Steam Survival Time at 121°C In Minutes	8.5	8.3	10.5	7.0	10.5	7.1
Steam Kill Time at 121°C In Minutes	19.2	19.6	25.4	17.1	25.4	17.2
Steam <i>D</i> value at 126°C In Seconds	Not Certified	Not Certified	Not Certified	26	33	23
Steam Survival Time at 126°C In Seconds				107	138	97
Steam Kill Time at 126°C In Seconds				262	335	234
Steam <i>z</i> value	Determined based on <i>D</i> values at 110°C, 119°C and 121°C			Determined based on <i>D</i> values at 118°C, 121°C and 126°C		
	9.0°C	12°C	11°C	7.7°C	7.4°C	7.2°C



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
<p>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.</p>		
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
Steam D value at 121°C	1.5 to 3.0 minutes	1.5 to 3.0 minutes
Steam z value	≥6°C	≥6°C

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

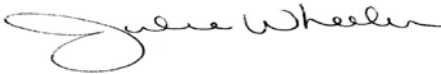
Ordering Information	
Telephone	1 (800) 860-1888
Fax	1 (419) 666-1715
Email	productorders@crosstex.com

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
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