

## Spore Discs - Manufacturing Transfer Summary

With the acquisition of NAMSA's Sterilization Monitoring Products Division, all manufacturing processes will be transferred to Crosstex. Spore Discs 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 Spore Discs manufactured by Crosstex are equivalent to those manufactured by NAMSA Products Division.

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

### Spore Discs for Steam:

NAMSA Product Codes: DS-05 and DS-06

	NAMSA	Crosstex
<b>Product Codes</b>	DS-05 (Population 10 <sup>5</sup> )	BS-105D (Population 10 <sup>5</sup> )
	DS-06 (Population 10 <sup>6</sup> )	BS-106D (Population 10 <sup>6</sup> )
<b>Cell Line Number</b> ( <i>Geobacillus stearothermophilus</i> )	7953	7953
<b>Packaging</b>	100/box (bulk)	100/box (bulk)
<b>Shelf Life</b>	30 months	24 months
<b>Disc Dimensions</b>	0.24"(6.0 mm) to 0.26"(6.6 mm)	0.25" (6.4 mm)
<b>Population</b>	≥1.0 x 10 <sup>x</sup>	1.0 to 5.0 x 10 <sup>x</sup>

### Spore Discs for Ethylene Oxide (EO):

NAMSA Product Code: DN-06

	NAMSA	Crosstex
<b>Product Codes</b>	DN-06	BG-106D
<b>Cell Line Number</b> ( <i>Bacillus atrophaeus</i> )	9372	9372
<b>Packaging</b>	100/box (bulk)	100/box (bulk)
<b>Shelf Life</b>	30 months	24 months
<b>Disc Dimensions</b>	0.24"(6.0 mm) to 0.26"(6.6 mm)	0.25" (6.4 mm)
<b>Population</b>	≥1.0 x 10 <sup>6</sup>	1.0 to 5.0 x 10 <sup>6</sup>