

Secure. Tested. Certified.



Monitoring Products for Dry Heat



Steam-Formaldehyde



Chlorine Dioxide

CLO<sub>2</sub>

# CROSSTEX | INDUSTRIAL

Pouches and Tubes, Custom Indicator Labels, Face Masks

manufacturing/distribution facilities around the world – eight

### Sales, Service and R&D Office Manufacturing Facilities

959 Illinois Avenue, Suite B

6789 W. Henrietta Road

Visit our websites at: Fax: (419) 666-1715

Email: ProductOrders@crosstex.com

### Table of Contents

#### Biological Indicators for Dry Heat

Inoculated Carriers & Biological Indicators
Spore Suspensions
Chemical Indicators for Dry Heat
Chemical Process Indicators5
Chemical Indicator Strips5
Packaging for Dry Heat
Nylon Self-Seal Sterilization Pouches6
Nylon Sterilization Tubing6
Biological Indicators for Chlorine Dioxide
Biological Indicators
Biological & Chemical Indicators for Steam-Formaldehyde
Biological Indicators
Chemical Process Indicators7
Chemical Indicator Strips



#### Inoculated Carriers & Biological Indicators

Crosstex manufactures a comprehensive line of Inoculated Carriers and Biological Indicators (BIs) for use in monitoring Dry Heat sterilization processes. Our most popular inoculated carriers and biological indicators are packaged using state of the art equipment, which provides assurance that each glassine pouch contains a biological indicator.

- Convenient shelf packages of 100 units per box
- Products are accompanied by a Certificate of Analysis and are certified with population, purity, and resistance characteristics (*D* value, *z* value, survival and kill where applicable)

#### Biological Indicators – ISO 11138-4 Compliant

Crosstex manufactures a biological indicator for Dry Heat sterilization which is compliant with ISO 11138-4. The BI consists of a 7 mm x 38 mm filter paper strip inoculated with *Bacillus atrophaeus* spores, packaged in a white glassine pouch. The configuration offers an increased *D* value at 160°C of not less than 2.5 minutes meeting the requirements for dry heat resistance as outlined in ISO 11138-4.

- Place Bls into the most difficult area of the sterilizer or device/article to be sterilized. In general, a minimum of 10 Bls are utilized in each cycle
- Packaging allows for easy placement in sterilizer or device/article and transfer post-exposure

#### Biological Indicators – ISO 11138-4 Compliant

Bacillus atrophaeus Cell Line 9372 24 month shelf life

Crosstex Code	Population	Quantity
BG-106DH	10 <sup>6</sup>	100/box

#### Traditional Spore Strips

Consist of inoculated filter paper, each 7 mm x 38 mm, individually packaged in easy-to-handle glassine pouches.

- The strips can be easily removed from the glassine pouch by tearing or peeling the pouch open for transfer to culture media or challenge device assembly
- Compliant with ISO 11138-1



#### Mini Spore Strips

Consist of inoculated filter paper, each 2 mm  $\times$  10 mm, packaged in a variety of options. The small size of the Mini Spore Strips allows them to fit into areas of a device where standard sized spore strips cannot be used, such as within a syringe barrel, inside tubing or under a cap.

- Crosstex Mini Spore Strips are available packaged in glassine envelopes of two sizes: a larger envelope 25 mm x 50 mm (STN-062) or a mini glassine envelope 25 mm x 25 mm (STN-062MG)
- The product is also available as an inoculated carrier in bulk (no glassine packaging - STN-062B)
- Compliant with ISO 11138-1



#### Traditional Spore Strips

Bacillus atrophaeus Cell Line 9372 24 month shelf life

Crosstex Code	Population	Quantity
BG-104	104	100/box
BG-105	10 <sup>5</sup>	100/box
BG-106	10 <sup>6</sup>	100/box

#### Mini Spore Strips

Bacillus atrophaeus Cell Line 9372 30 month shelf life

Crosstex Code	Packaging	Population	Quantity
STN-062	Glassine envelopes	10 <sup>6</sup>	100/box
STN-062B	Bulk	10 <sup>6</sup>	100/box
STN-062MG	Mini glassine envelope	s 10 <sup>6</sup>	100/box

# Biological Indicators for Dry Heat

#### Spore Discs

Crosstex Spore Discs are available in two different sizes, 6 mm and 3 mm diameters. The discs are designed to be utilized as an inoculated carrier for placement directly into areas of a device which are the most difficult to sterilize.

- The Inoculated Carriers are packaged in easy-to-access and handle bulk packaging
- Crosstex Spore Discs will fit into small areas of a device where a standard-sized spore strip cannot be used, such as within a syringe barrel, inside tubing and vials or under a cap
- Compliant with ISO 11138-1







#### **Spore Discs**

Bacillus atrophaeus Cell Line 9372 24 month shelf life (BG-106D) / 30 month shelf life (DN18-06)

Crosstex Code	Disc Diameter	Packaging	Population	Quantity
BG-106D	6 mm	Bulk	10 <sup>6</sup>	100/box
DN18-06	3 mm	Bulk	10 <sup>6</sup>	100/box

#### Spore Threads

- Ideal for use in tubing, lumens and other devices/instruments where larger BIs and carriers cannot be utilized
- Compliant with ISO 11138-1

#### Spore Threads

Bacillus atrophaeus Cell Line 9372 24 month shelf life

Crosstex Code	Description	Packaging	Population	Quantity
THN-06	Cotton Thread, 25 mm x 0.1 mm	Bulk	10 <sup>6</sup>	100/box

#### Spore Suspensions

Crosstex manufactures Spore Suspensions utilized in Dry Heat sterilization processes. The Spore Suspensions are pure suspensions of spores with known resistance characteristics and a variety of population levels standardized per 0.1 mL. The Spore Suspensions allow for direct inoculation of products, typically to verify sterility of devices where a traditional biological indicator spore strip cannot be used. They can also be used for a variety of other microbiological tests including cleaning effectiveness studies, Bioburden percent recovery and Bacteriostasis/Fungistasis (BF) testing.

- Each vial contains 10 mL of suspension. Diluent contains 20%
- Pharmaceutical grade glass vials with screw cap and septum
- Spore Suspensions require storage under refrigerated conditions (2°C to 8°C)
- ISO 11138-1 Compliant



#### Spore Suspensions

Bacillus atrophaeus Cell Line 9372 18 month shelf life

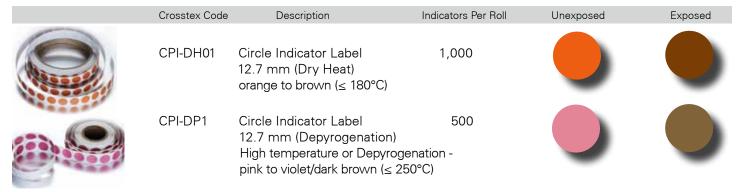
Crosstex Code	Population per 0.1 mL
VBA-102	10 <sup>2</sup>
VBA-103	10 <sup>3</sup>
VBA-104	104
VBA-105	10 <sup>5</sup>
VBA-106	10 <sup>6</sup>
VBA-107	10 <sup>7</sup>
VBA-108	10 <sup>8</sup>

#### Chemical Process Indicators

Crosstex Dry Heat Chemical Process Indicators (CPIs) meet the requirements of Crosstex's Quality System (ISO 13485) and have been validated per standard cycles outlined in ISO and USP for Depyrogenation processes. Our Chemical Process Indicators provide a fast and consistent visual check on items there were exposed to Dry Heat processes.

#### Chemical Process Indicators

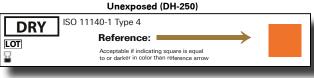
#### 24 month shelf life



36 month shelf life				
Crosstex Code	Description	Indicators Per Roll	Unexposed	Exposed
DIL -1000	Circle Indicator Label 19 mm	1,000	Indicator Label	Indicator Label
DTL-125	Indicator Label with operator and date 19 mm x 32 mm	125	Dry Heat Indicator	Dry Heat Indicator
Chemical Indicator Strips			OPERATOR	OPERATOR

#### Chemical indicator Strips

Crosstex Dry Heat Chemical Indicator Strips are innovative indicator strips which demonstrate exceptional performance and are customized for the most widely utilized Dry Heat processes. Crosstex evaluates the performance of every lot to ensure consistent and reliable performance. Each shipment includes a Certificate of Analysis for assurance of product quality and performance.





- Lead & latex free
- Irreversible color transition from orange to brown
- ISO 11140-1 Type 4 Compliant

#### Unexposed (DIS-100)



# Exposed (DIS-100) DRY HEAT INDICATOR STRIP

- Provides a distinct color change from green to dark when processed
- Writable strip for record keeping
- ISO 11140-1 Type 1 Compliant

#### Chemical Indicator Strips

#### 24 month shelf life

Crosstex Code	Description	Dimensions	Quantity
DH-250	Chemical Indicator Strip – Type 4	115 mm x 19 mm	250/box
DIS-100	Chemical Indicator Strip – Type 1	100 mm x 16 mm	100/box

# Packaging for Dry Heat

#### Nylon Self-Seal Sterilization Pouches and Roll Stock Tubing

Crosstex Nylon Self-Seal Sterilization Pouches and Roll Stock Tubing are manufactured for use in Dry Heat processes up to 215°C. Nylon material is clear, strong and puncture resistant, maintaining a durable barrier for instrumentation until point of use.

- Pouches have built-in adhesive tape which eliminates the need for a heat sealer or indicator tape
- Each pouch is notched for ease of opening after processing, and complimentary external chemical indicator labels are included
- Roll stock tubing is designed to be cut to any length prior to packaging and then mechanically sealed or taped closed
- Latex free

#### Nylon Self-Seal Sterilization Pouches

Crosstex Code	Dimensions	Quantity
NSP-400	2" x 10" (5 x 25 cm)	100/bx
NSP-405	3" x 10" (8 x 25 cm)	100/bx
NSP-410	$4" \times 10"$ (10 x 25 cm)	100/bx
NSP-420	$7" \times 10.5"$ (18 $\times$ 25 cm)	100/bx
NSP-430	9.5" x 13" (24 x 25 cm)	100/bx



#### Nylon Sterilization Tubing

Crosstex Code	Dimensions	Quantity
SN2	2" x 100 ft (5 cm x 30 m)	16 rolls/cs
SN3	3" x 100 ft (8 cm x 30 m)	12 rolls/cs
SN4	$4'' \times 100 \text{ ft } (10 \text{ cm} \times 30 \text{ m})$	12 rolls/cs
SN6	6" x 100 ft (15 cm x 30 m)	12 rolls/cs



# Biological Indicators for Chlorine Dioxide

#### Biological Indicators - Traditional Spore Strips

Crosstex manufactures Biological Indicators (BIs) for use in monitoring Chlorine Dioxide sterilization processes. Our BIs are manufactured using precise care, which provides assurance that each pouch contains a biological indicator consistent in population and purity.

- Consist of inoculated filter paper, each 7 mm x 38 mm, individually packaged in easy-to-handle Tyvek®/Tyvek® pouches
- The strips can be easily removed from the pouch for transfer to culture media
- Convenient shelf packages of 100 units per box
- Products are accompanied by a Certificate of Analysis and are certified with population and purity
- Compliant with ISO 11138-1

#### Traditional Spore Strips

Geobacillus stearothermophilus Cell Line 7953 30 month shelf life

Crosstex Code	Packaging	Population	Quantity
TCDS-06	Tyvek®/ Tyvek®	10 <sup>6</sup>	100/box

Tyvek® is a registered trademark of E.I. du Pont de Nemours and Company.



# Biological & Chemical Indicators for Steam-Formaldehyde

#### Biological Indicators - Traditional Spore Strips

Crosstex manufactures Biological Indicators (BIs) for use in monitoring Steam-Formaldehyde sterilization processes. Our BIs are manufactured using precise care, which provides assurance that each glassine pouch contains a biological indicator consistent in population and purity.

- Consist of inoculated filter paper, each 7 mm x 38 mm, individually packaged in easy-to-handle glassine pouches
- The strips can be easily removed from the glassine pouch by tearing open for transfer to culture media
- Convenient shelf packages of 100 units per box
- Products are accompanied by a Certificate of Analysis
- Compliant with ISO 11138-1



#### Traditional Spore Strips

Geobacillus stearothermophilus Cell Line 7953 30 month shelf life

Crosstex Code	Population	Quantity
STSF-05	10 <sup>5</sup>	100/box
STSF-06	10 <sup>6</sup>	100/box

#### Chemical Process Indicators

Crosstex Steam-Formaldehyde Chemical Process Indicators (CPIs) are manufactured to meet performance specifications as outlined in ISO 11140-1 Sterilization of health care products - Chemical indicators - Part 1: General requirements, for Type 1 Process Indicators. Our CPIs provide a fast and consistent visual check on items that were sterilized by Steam-Formaldehyde.

• Consistent and irreversible color transition from violet to green

CPI-SF01

- No light sensitivity issues
- Permanent pressure-sensitive adhesive

- Room temperature storage (15°C to 30°C)
- Each shipment is accompanied by a Certificate of Analysis to ensure product quality and consistency



### Chemical Process Indicators

12.7 mm

Crosstex Code Description

60 month shelf life

escription Indicators Per Roll

Circle Indicator Label 5

5.000



Unexposed



Exposed

#### Chemical Indicator Strips

Crosstex Steam-Formaldehyde Chemical Indicator Strips demonstrate exceptional performance and are customized for the most widely utilized Steam-Formaldehyde sterilization processes and provide a distinct color change. Crosstex evaluates the performance of every lot to ensure consistent and reliable performance.

- Indicator turns from red to green when processed
- Each shipment includes a Certificate of Analysis for assurance of product quality and performance
- ISO 11140-1 Type 4 Compliant

# Unexposed

Steam Formaldehyde Indicator

Indicator turns GREEN with processing.

with processing. SFS-250

Exposed

Steam Formaldehyde Indicator

FORM

FORM

Indicator turns GREEN with processing.

SFS-250

#### Chemical Indicator Strip

24 month shelf life

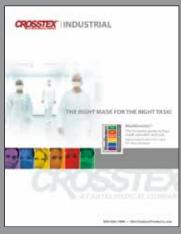
Crosstex Code Description Dimensions Quantity
SFS-250 Chemical Indicator Strip – Type 4 100 mm x 16 mm 250/box

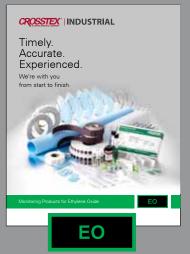
Colors shown are representations of printed ink initial and signal colors but may vary from actual use.

# Our Product Literature











**FORM** 

Authorized Distributor:

CLO<sub>2</sub>



**DRY** 





# 959 Illinois Avenue, Suite B

959 Illinois Avenue, Suite B Maumee, OH 43537 USA SterilizationProducts.com crosstex.com (567) 803-1220 | (800) 860-1888 Fax: (419) 666-1715