

Trusted. Tailored. Precise.

We can help you ensure the safety of your product.



Monitoring Products for Gamma & E-Beam Sterilization



Chemical Process Indicators

Crosstex Gamma & E-Beam Chemical Process Indicators (CPIs) are manufactured with Crosstex's Eco Friendly Indicating Inks and 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 Chemical Process Indicators provide a fast and consistent visual check on materials that have been processed by Gamma or E-Beam sterilization processes.

- Consistent and irreversible color transition from yellow to red (≥10 kGy dose) or green to dark (≥1 kGy dose)
- Permanent pressure-sensitive adhesive
- 24 month shelf life
- 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						
24 month shelf life	e Crosstex Code	Description	Dose Level	Indicators Per Roll	Unexposed	Exposed
	CPI-R01	Circle Indicator Label 12.7 mm	≥10kGy	5,000		
	CPI-R03	Circle Indicator Label 12.7 mm with imprinted text "RED IS EXPOSED	≥10kGy ″	5,000	RED IS	RED G
	SP-R58	Circle Indicator Label 12.7 mm with imprinted text "RED IS γ EXPOSE	≥10kGy ED″	5,000	PPOSE	RED IS FtpoSC
	CPI-F01	Circle Indicator Label 12.7 mm	≥1kGy	5,000		
	CPI-R02	Indicator Labels for hand-held labeling systems 25 mm x 12 mm	≥10kGy	1,000		
	CPI-R06	Indicator Labels for hand-held labeling systems with indicator 25 mm x 12 mm	≥10kGy	1,000		
	SP-RXX	Custom Indicator Labels. Please Inquire	Custom	Varies		

Example of Label with Indicator

Biological Indicators

Biological Indicators - Traditional Spore Strips

Crosstex offers Biological Indicators (BIs) for use in monitoring Gamma & E-Beam sterilization processes. Our biological indicators are manufactured using precise care, which provides assurance that each glassine pouch contains a biological indicator consistent in population, purity and resistance.

- 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 or challenge device assembly
- 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
- Compliant with ISO 11138-1

Traditional Spore Strips

Bacillus pumilus Cell Line 27142 24 month shelf life

Crosstex Code	Population	Quantity
PM-106	106	100/box
PM-107	10 ⁷	100/box
PM-108	10 ⁸	100/box



Spore Suspensions

Crosstex manufactures Spore Suspensions utilized in Gamma & E-Beam sterilization processes. The Spore Suspensions are pure suspensions of spores with known radiation 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.

- Each vial contains 10 mL of suspension. Diluent contains 20% ethanol
- Pharmaceutical grade glass vials with screw cap and septum
- Spore Suspensions require storage under refrigerated conditions (2°C to 8°C)
- Each vial of Spore Suspension is accompanied by a Certificate of Analysis detailing the source, assayed population, resistance characteristics on paper carrier and expiration date
- ISO 11138-1 Compliant

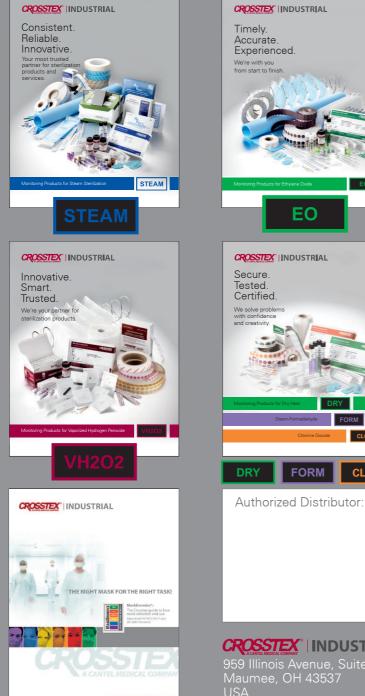


Spore Suspensions

Bacillus pumilus Cell Line 27142 24 month shelf life

Crosstex Code	Population per 0.1 mL
VBP-106	10 ⁶
VBP-107	107
VBP-108	10 ⁸

Our Product Literature







FORM

CLO₂



CROSSTEX INDUSTRIAL 959 Illinois Avenue, Suite B Maumee, OH 43537 USA

crosstex.com (567) 803-1220 | (800) 860-1888 Fax: (419) 666-1715