PCD 4.19 - Mesa A2X10/6G BI Mini Strip

PCD 4.19 is an external Process Challenge Device for Ethylene Oxide (EO) sterilization containing a glassine wrapped Mesa A2X10/6G BI Mini Strip. The unique, patented packaging is convenient to use and demonstrates consistent sterilization resistance for a wide range of medical devices in industrial EO cycles.

Component Materials
Product Label: Polyolefin plastic with removable pressure sensitive adhesive test tube label.

Mounting Card: PVC plastic with a pressure sensitive adhesive strip for mounting on the outside of sterilizer load boxes.

EO Resistant Barrier Pouch: This PCD uses our type 4 pouch material configuration. This pouch is formed from a proprietary multi-layer plastic film that yields consistent resistance to EO sterilization processes.

Biological Indicator: Mesa A2X10/6G BI Mini Strip in glassine

PCD EO Performance
The nominal $D_{\text{EO}}$ value for this PCD is approximately 32 minutes. This $D_{\text{EO}}$ value was derived from multiple studies performed in ISO certified laboratory BIER vessels using the standard Stumbo-Murphy Carr (SMC) Fraction Negative method. Commercial results will differ depending on EO product/process variables.

Quality Systems Conformance
Every PCD lot is supplied with a Certificate of Quality Conformance and the BI manufacturer’s certification. Mesa’s biological indicator manufacturing facilities are in compliance with ISO-13485 manufacturing standards.

Shelf Life and Storage Conditions
Storage conditions and expiry are based on the biological manufacturer’s certificate supplied with every PCD lot. Do not use PCDs if they are past the BI manufacturer’s labeled expiration date.

PCD EO Process Validation
Please review our Validation Guideline at biologicalindicators.mesalabs.com

Packaging
All PCDs are packaged in corrugated shippers with appropriate cushioning to assure clean, damage free transport to the customer.