PCD 5.8 - NAMSA STN-062 Mini-Strip

PCD 5.8 is an Ethylene Oxide (EO) sterilization Process Challenge Device containing a NAMSA STN-062 Mini-Strip *Bacillus atrophaeus* biological indicator (BI). The unique, patented packaging is convenient to use and demonstrates consistent sterilization resistance for a wide range of medical devices in industrial EO process 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 5 pouch material configuration. This pouch is a proprietary combination of two multi-layer plastic films that yields consistent resistance to the EO sterilization process.

Biological Indicator: NAMSA STN-062 Mini-Strip; Glassine wrapped

**PCD EO Performance**

A $D_{10}$ value range for this PCD has not been established in a laboratory BIER vessel. Customer testing has established acceptable resistance in a commercial industrial EO process.

**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.