

PCD 5.8

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_{ETO} 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.