PCD 4.7 - Steris BI Spore Strip in Glassine, NA005

PCD 4.7 is an external Process Challenge Device for Ethylene Oxide (EO) sterilization containing a glassine wrapped Steris BI Spore Strip, NA 005. The unique, patented packaging is convenient to use and consistently 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: Steris BI Spore Strip in glassine, NA005

**PCD EO Performance**

The nominal $D_{EtO}$ value for this PCD is approximately 32 minutes. This $D_{EtO}$ 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.