PCD 3.9 - 3M Attest™ 1294-S RRBI

PCD 4.9 is an Ethylene Oxide (EO) sterilization external Process Challenge Device containing a 3M Attest™ 1294-S RRBI. 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 3 pouch material configuration. This pouch is a proprietary multi-layer plastic film that yields consistent resistance to the EO sterilization process.

Biological Indicator: 3M Attest™ 1294-S RRBI offers a 4 hour incubation and release time.

**PCD EO Performance**
The $D_{EO}$ value for this PCD is unknown but is estimated to be about 5 minutes. PCD $D_{EO}$ values are obtained in a laboratory BIER vessel using the 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.