

## PCD 2.43 - Mesa Laboratories EZTest EZG/6 SCBI

PCD 2.43 is an external Process Challenge Device for Ethylene Oxide (EO) sterilization containing a MESA EZ Test EZG/6 SCBI. 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 custom PCD features a double pouch configuration using our Type 2 pouch to yield maxim EO resistance. These pouches are formed from proprietary multi-layer plastic films that yield consistent resistance to EO sterilization.

**Biological Indicator:** Mesa EZTest EZG/6 SCBI



### PCD EO Performance

The nominal Deo value for this PCD is approximately 58 minutes. This Deo value was derived from multiple studies performed in an 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](http://biologicalindicators.mesalabs.com)

### Packaging

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