# PCD 8.13 - Mesa Laboratories EZTest EZH/6 SCBI

PCD 8.13 is an external Process Challenge Device for H2O2 sterilization containing a EZTest EZH SCBI. The unique, patented packaging is convenient to use and consistently demonstrates consistent sterilization resistance for medical devices in industrial H2O2 sterilization processes.

#### **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 pouch is formed from a combination of proprietary plastic films that yield consistent resistance to H2O2 sterilization processes.

Biological Indicator: Mesa Laboratories EZTest EZH/6 SCBI



#### **PCD EO Performance**

PCD performance is dictated by the particular combination of product, equipment and process variables. D value resistance is typically confirmed by the user during validation. PCD pouches have been documented to be very consistent in their resistance in other gas sterilization processes.

### **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.

