



# **Directions For Use**

## INDICATIONS FOR USE

The ProChem SSI strips are designed for Industrial Use Only in steam sterilization cycles operating at 132°C -135°C (270°F - 276°F) for 3 minutes or longer. When used as directed, the ProChem SSI gives visual indication that sterilizing conditions were met at point of placement.

## COLOR CHANGE

During steam sterilization, the indicator at the end of the strip changes from white to black.

## **STATED VALUES** (As determined in a steam sterilization resistometer)

135°C – 2.25 minutes 134° C – 2.5 minutes 132° C – 3 minutes 121°C – 9 minutes

## INSTRUCTIONS FOR USE

- Place ProChem SSI strips in each pack, peel-pouch or tray for sterilization. Place strip at a location in the package considered most difficult for steam to reach. For larger packs, place strips in multiple locations in the pack. Strips may be cut in half.
  Steriliza package as usual in a steam sterilization.
- 2. Sterilize package as usual in a steam sterilizer.
- 3. Following sterilization cycle, verify that indicator on the ends of the strip have turned from white to black. This change is indicative that sterilization conditions were met at point of placement.
- 4. If the indicator is white or not as dark as or darker than the reference arrow, consider the cycle failed and the items non-sterile. Follow in-house protocol for failed cycle.

# SAFETY PRECAUTIONS

- If there is any doubt about sterility of item, it must be considered NOT sterile.
- Do not use any strips whose indicators are not white in color prior to exposure to steam sterilization processing.
- ProChem SSI Strips must NOT be used in place of a biological indicator, but can be used in conjunction with a standard infection control monitoring protocol such as that described by the AAMI Standards and Recommended practices: Good Hospital Practice: Sterilization and Sterility Assurance.

#### STORAGE

ProChem SSI strips should be stored between 50°-100°F (10°- 38°C) 10-60% R. H. in the re-sealable bag provided. No special storage conditions are necessary after exposure to steam sterilization conditions.

# **EXPIRY DATE**

The expiry date is printed on the product packaging. Do not use after the expiration date listed on the product packaging.

#### LOT NUMBER

A unique identification code, LOT, is printed on each indicator strip and packaging labeling.

# INTERFERING SUBSTANCES OR CONDITIONS

There are NO KNOWN INTERFERING SUBSTANCES OR CONDITIONS that could affect the intended use of the indicator or adversely affect the indicator performance.

#### **RELEASE OF TOXIC SUBSTANCES**

The indicator releases NO KNOWN TOXIC SUBSTANCES in sufficient quantities to cause either a health hazard, or a hazard to the intended properties of the product being sterilized before, during or after the sterilization process.

#### **DECLARATION OF CONFORMITY**

Mesa Labs declares that the ProChem SSI Indicator conforms to all applicable portions ISO 11140-1 Type 4 Multicritical Process Variable Indicators. The ProChem SSI indicator is for Industrial Use Only.

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