SteriTec Cross-Checks EO
REF CI 106

Directions For Use

INDICATIONS FOR USE
Steritec *Cross-Checks EO* chemical indicator/integrator strips are designed to be used in ethylene oxide gas sterilizers. When used as directed, SteriTec *Cross-Checks EO* Integrators give visual confirmation that the item being sterilized has been subjected to the following parameters to cause color change to brown with exposure to EO gas mixture of 88 ½ with gas concentration fo 600 mg/L. temperature at 130°F and relative humidity at 45% for between 30 and 45 minutes. Sterilization conditions have been achieved if the check mark at the end of the strip turns from yellow to brown.

COLOR CHANGE
During EO sterilization, the check mark at the end of the strip changes from Yellow to Brown.

CRITICAL PARAMETERS: (in a standard hospital EO sterilizer)
60 minutes or longer at 600 mg/l, 130° F (54° C), 40-60% R.H.

STATED VALUES: (as determined in an EO sterilization resistometer)
45 minutes at 600 mg/l, 130 F (54 C), 40-60% R.H.

INSTRUCTIONS FOR USE
1. Place a SteriTec *Cross-Checks EO* strip in each pack, peel pouch or tray to be ethylene oxide gas sterilized. For larger packs use several strips placed at different locations.
2. Sterilize package as usual in the ethylene oxide gas sterilizer.
3. After sterilization and aeration are completed, visually verify that the indicator check marks have changed from yellow to brown.

SAFETY PRECAUTIONS
- *If there is any doubt about sterility of item, it must be considered NOT sterile.*
- *Do not use any strips whose indicator marks are not yellow in color prior to exposure to EO sterilization processing.*
- *Cross-Checks EO indicator 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
Steritec *Cross-Checks EO* sterilization indicator strips should be stored between 50° - 100°F (10° - 38°C) in the re-sealable bag provided. No special storage conditions are necessary after exposure to sterilization conditions.

EXPIRY DATE
The expiry date is printed 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
SteriTec Products Mfg. Co., Inc. declares that the *Cross-Checks EO integrator* conforms to all applicable portions ISO 11140-1:2005 pertaining to Class 4 multi-variable indicators and FDA requirements for Integrator status.

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