

3M™ Comply™ SteriGage™

1243A, 1243B and 1243E

Steam Chemical Integrators

STEAM Class 5 Integrating Indicator as classified by ANSI/AAMI/ISO 11140-1:2005

Stated Values: See Stated Values listed in the table on the front of the package. The table lists the time in minutes at the corresponding temperature for chemical indicators in this lot to reach their endpoint when tested in a steam resistometer under highly controlled conditions with saturated steam.

This compares with a 1×10^6 spore population of *Geobacillus stearothermophilus* with a D-value of 1.6 minutes at 121°C and a z-value of 10.0°C.

The lot in a box and the hourglass symbols represent expiration date and lot number. The hourglass is followed by a year and month that represent the expiration date (year and month: 2012-12). All of the information to the right of the hourglass symbol represents the lot number (2012-12AZ).

Product Description

3M Comply 1243A, 1243B, and 1243E Steam Chemical Integrators are chemical indicators consisting of a paper wick and steam and temperature sensitive chemical pellet contained in a paper/film and paper/film/foil laminate. The chemical pellet melts and migrates as a dark color along the paper wick. The migration is visible through a window marked ACCEPT or REJECT; the extent of migration depends on steam, time, and temperature.

This product is also available with an extender strip affixed to one end of a Comply 1243 steam chemical integrator and is labeled as Comply 1243E steam chemical integrator. The affixed extender is a 19 cm (7.5 in) long by 1 cm (0.375 in) wide rigid, paperboard strip that serves as a handle to retrieve processed integrators from inner packs.

Indications for Use

Use Comply 1243A, 1243B, and 1243E steam chemical integrators for pack control monitoring of all 118-138°C (245-280°F) steam sterilization cycles.

Contraindications

None.

Precautions

Do not use Comply 1243A, 1243B, or 1243E steam chemical integrators to monitor dry heat, ethylene oxide, or other low temperature sterilization processes.

Instructions for Use

1. To preserve as much package area as possible for folding and resealing, use scissors on the marked area at the top of the foil package to make the initial opening. Remove only the number of Comply 1243A, 1243B, or 1243E steam chemical integrators needed. Reseal the package by folding the opened end over at least two times.
2. Place a Comply 1243A or 1243B steam chemical integrator in each pack, peel pouch, container system or tray to be steam sterilized in the area determined to be the least accessible to steam penetration. If using a Comply 1243E steam chemical integrator, position the unattached end of the extender so that it extends slightly beyond the inner contents of the pack. This will permit integrator retrieval without touching the pack contents.
3. Process the load according to established procedures.
4. After processing, the dark color should have entered the ACCEPT window of the Comply 1243A, 1243B, or 1243E steam chemical integrator. If the dark color has not entered the ACCEPT window, a REJECT result is indicated and the items in the pack, peel pouch, container system, or tray were not exposed to sufficient steam sterilization conditions. These items should be returned for reprocessing.

Storage and Shelf Life

- Store unopened and resealed packages at 40-60% relative

humidity condition at room temperature [15-30°C (59-86°F)].
Store away from direct sunlight. Do not store near strong
alkaline or acidic products such as cleaning/disinfecting
agents.

- After use, the indicator will not change visually within 6 months when stored at above conditions.
- Comply 1243A, 1243B, and 1243E steam chemical integrators contained in an unopened package have a 5 year shelf life from the date of manufacture when stored at recommended conditions. The expiration date is printed on the package label.

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