

## 2134MM Steam Chemical Integrators

**STEAM**

Class 5 Integrating Indicator as classified by ANSI/AAMI/ISO 11140-1:2005 and EN/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  $1 \times 10^6$  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: 2012-10). All of the information to the right of the hourglass symbol represents the lot number (2012-10AZ).

### Product Description

3M Comply 2134MM Steam Chemical Integrators are chemical indicators consisting of a paper wick and steam and temperature sensitive chemical pellet contained in a 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 SAFE or UNSAFE; the extent of migration depends on steam, time, and temperature.

### Indications for Use

Use Comply 2134MM steam chemical integrators for pack control monitoring of all 121-135°C (250-275°F) steam sterilization cycles.

### Contraindications

None.

### Precautions

Do not use Comply 2134MM steam chemical integrators to monitor dry heat, ethylene oxide, or other low temperature sterilization processes.

### Instructions for Use

1. Carefully tear or use scissors at the tear notch at the top of the foil package to make the initial opening. Remove only the number of Comply 2134MM steam chemical integrators needed. Reseal the package.
2. Place a Comply 2134MM steam chemical integrator in the center of each pack, peel pouch or unwrapped tray to be steam sterilized. Place a chemical integrator in at least two opposing/diagonal corners of rigid containers or in the area determined by product testing to be the greatest challenge.
3. Process the load according to established procedures.
4. After processing, the dark color should have entered the SAFE window of the Comply 2134MM steam chemical integrator. If the dark color has not entered the SAFE window, an UNSAFE result is indicated and the items in the pack, peel pouch, unwrapped tray, or rigid container were not exposed to sufficient steam sterilization conditions. These items should be returned for reprocessing.
5. If several packs, peel pouches, or trays in a load contain integrators with UNSAFE results, review the biological indicator results. Check all areas of the process for cause of failure.

### Storage and Shelf Life

Store unopened and resealed packages containing Comply 2134MM steam chemical integrators in a dry (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.

Comply 2134MM steam chemical integrators contained in an unopened package have a 3 year shelf life from the date of manufacture when stored at recommended conditions. The expiration date is printed on the package label.

After use, the indicator will not change visually within 6 months when stored at 40-60% relative humidity and 15-30°C (59-86°F).

Made in U.S.A. by

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