

3M™ Comply™ Thermalog™ Steam Chemical Integrators 2134MM

Product Description

3M™ Comply™ Thermalog™ Steam Chemical Integrators 2134MM 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. 3M™ Comply™ Thermalog™ Steam Chemical Integrators are Class 5 Integrating Indicators 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 1×10^6 spore population of *Geobacillus stearothermophilus* with a D-value of 1.6 minutes at 121°C and a z-value of 10.0°C.

Indications for Use

Use 3M™ Comply™ Thermalog™ Steam Chemical Integrators 2134MM for pack control monitoring of all 121-135°C (250-275°F) steam sterilization cycles.

Contraindications

None.

Precautions

Do not use 3M™ Comply™ Thermalog™ Steam Chemical Integrators 2134MM to monitor dry heat, ethylene oxide, or other low temperature sterilization processes.

Directions 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 3M™ Comply™ Thermalog™ Steam Chemical Integrators 2134MM needed. Reseal the package.
2. Place a 3M™ Comply™ Thermalog™ Steam Chemical Integrator 2134MM 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 3M™ Comply™ Thermalog™ Steam Chemical Integrator 2134MM. 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

- Best stored at normal room temperature conditions, 15-30°C (59-86°F) and 40-60% relative humidity. 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.

Explanation of Symbols:

 Catalogue Number

 Caution, see instructions for use

 Do not reuse

 Use by date

 Batch code

 Manufacturer

 Date of manufacture

 Product is designed for use with steam sterilization cycles.

Made in U.S.A. by

 **3M Health Care**

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3M.com/infectionprevention

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