

3M™ Comply™ SteriGage™ Steam Chemical Integrator 1243RE



STEAM Class 5 Integrating Indicator as classified by ANSI/AAMI/ISO 11140-1:2005/(R) 2010

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 lot number and expiration date. The hourglass is followed by a year and month that represent the expiration date (year and month: 2015-12). All of the information to the right of the lot in a box symbol represents the lot number (201512AZ).

Product Description

3M™ Comply™ 1243RE 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 ACCEPT or REJECT; the extent of migration depends on steam, time, and temperature. This product comes with an extender strip affixed to one end of a Comply™ 1243R steam chemical integrator. The affixed extender is a 17.8 cm (7 in) long by 1.8 cm (0.7 in) wide rigid, paperboard strip that serves as a handle to retrieve processed integrators from inner packs.

Indications for Use

Use Comply™ 1243RE steam chemical integrators for pack control monitoring of the following steam sterilization cycles:

Cycle Type	Temperature	Exposure Time
Gravity	250°F/121°C	≥ 30 minutes
Gravity	270°F/132°C	≥ 3 minutes
Vacuum-assisted (prevacuum)	270°F/132°C	≥ 4 minutes (wrapped) ≥ 3 minutes (unwrapped)
Vacuum-assisted (prevacuum)	273°F/134°C	≥ 4 minutes (wrapped) ≥ 3.5 minutes (unwrapped)
Vacuum-assisted (prevacuum)	275°F/135°C	≥ 3 minutes

The Minimum Stated Values for Comply™ 1243RE steam chemical integrators as determined using a resistometer are shown in the table below.

Minimum Stated Values			
250°F/121°C	270°F/132°C	273°F/134°C	275°F/135°C
16.5 minutes	2.0 minutes	1.4 minutes	1.1 minutes

Contraindications

None.

Precautions

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

Instructions for Use

- 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™ 1243RE steam chemical integrators needed. Reseal the package.
- Place a Comply™ 1243RE 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. 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.
- Process the load according to established procedures.
- After processing, the dark color should have entered the ACCEPT window of the Comply™ 1243RE 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

- Unopened and resealed packages are best stored 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™ 1243RE 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.

Explanation of Symbols

Caution, see instructions for use

Do not reuse

Use by date

Batch code

Manufacturer

CE For France and other countries that
recognize the CE mark for this device.

Made in U.S.A. by

3M Health Care

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