

3M™ Comply™ SteriGage™

Steam Chemical Integrators 1243A and 1243B

Product Description

3M™ Comply™ SteriGage™ Steam Chemical Integrators 1243A and 1243B 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. 3M™ Comply™ SteriGage™ Steam Chemical Integrators are Type 5 (Category i5) Integrating Indicators as categorized by ISO 11140-1:2014.

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 the lot contained in the package to reach their endpoint when tested in a steam resistometer under highly controlled conditions with saturated steam. The Stated Values are determined for each lot at the time of manufacture and are reproducible only under the exact conditions in which they were determined.

The Stated Values compare 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.

This Product Is Not Made With Lead.

Indications for Use

Use 3M™ Comply™ SteriGage™ Steam Chemical Integrators 1243A and 1243B for pack control monitoring of all 118-138°C (245-280°F) steam sterilization cycles.

Contraindications

None.

Precautions

Do not use 3M™ Comply™ SteriGage™ Steam Chemical Integrators 1243A or 1243B to monitor dry heat, ethylene oxide, or other low temperature sterilization processes.

Directions 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 3M™ Comply™ SteriGage™ Steam Chemical Integrators 1243A or 1243B needed. Reseal the package.

Place a 3M™ Comply™ SteriGage™ Steam Chemical Integrator 1243A or 1243B 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.

Process the load according to established procedures.

After processing, the dark color should have entered the ACCEPT window of the 3M™ Comply™ SteriGage™ Steam Chemical Integrator 1243A or 1243B. 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

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.



British Standards Institution (BSI) Kitemark License for conformance to ISO 11140-1:2014 Type 5 (Category i5) Integrating Indicators

Made in U.S.A. by

3M Health Care

2510 Conway Ave.

St. Paul, MN 55144

1-800-228-3957

3M.com/Medical

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Issue Date: 2016-12

34-8720-5834-1