



STERAFFIRM™ STEAM CLASS 6 EMULATING INDICATORS FOR EXPOSURE PARAMETERS 134°C (273°F) FOR 3.5 MINUTES TECHNICAL DATA

GENERAL DESCRIPTION

The Steraffirm Steam Class 6 Emulating Indicators are chemical indicators intended to verify exposure to the steam sterilization cycle parameters of 134°C (273°F) for 3.5 minutes. Each Emulating indicator is approximately 143 x 22 mm (5-5/8 x 7/8") and is manufactured from high quality pulp board substrate. A circular area of yellow indicator ink is printed near one end of each indicator. The indicator ink changes from yellow to blue/purple, when exposed to saturated steam at 134°C (273°F) for 3.5 minutes. The indicator ink contains no lead or heavy metal salts, and the ink area is totally encapsulated in a specialised polymeric membrane. The membrane is semi-permeable to steam and only allows steam in excess of 110°C (230°F) to permeate. The Steraffirm Steam Class 6 Emulating Indicators conform to International Standard ISO 11140-1 Class 6 and European Standard EN867-1 Class D.

APPLICATION

Steraffirm Steam Class 6 Emulating Indicators are chemical indicators intended for use inside individual packs, trays, or pouches to verify exposure to the specified steam sterilization cycle parameters of 134°C (273°F) for 3.5 minutes. The Steraffirm Steam Class 6 Emulating Indicators are cycle verification indicators which integrate all the critical parameters of the steam sterilization cycle (temperature, saturated steam, and exposure time). The indicators must be checked by the end user (prior to use of the processed item) to confirm that the specific sterilizing parameters have been attained at the location of each indicator. The Steraffirm Steam Class 6 Emulating Indicators are for Life Sciences applications and international use and are not approved for use in healthcare facilities in the United States.

FEATURES

Abrupt and distinctive color change from yellow to blue/purple

Endpoint color standard is present on each indicator strip

No lead or other heavy metals

Indicator can be kept as a permanent record

Lot number on each indicator strip and on each box

Conforms to EN 867-1 Class D and ISO 11140-1 Class 6

BENEFITS

Vivid indication when time/temperature parameters are achieved

Facilitates color comparison

No concern over exposure to lead or other heavy metals

Valuable documentation of the efficacy of the sterilizer cycle

Enhances traceability

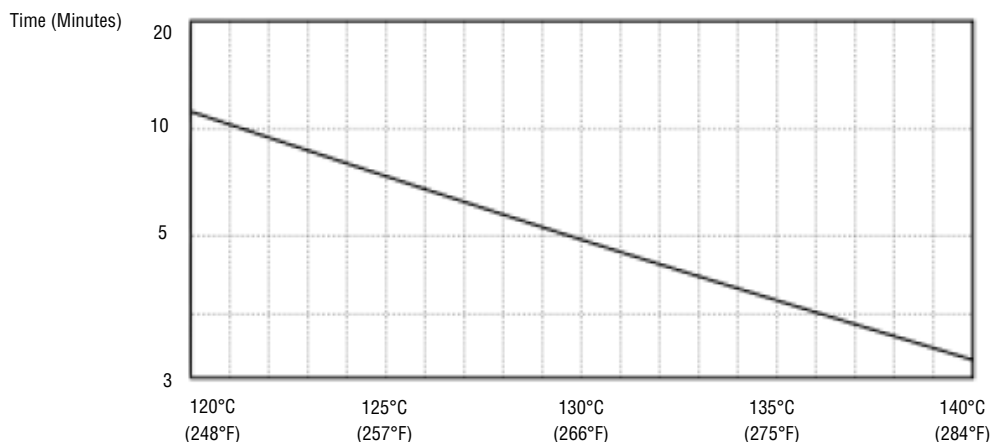
Meets critical standards as an indicator for monitoring specific cycle parameters

TECHNICAL PROPERTIES

The indicator ink area changes from yellow to blue/purple, when exposed to saturated steam at 134°C +0/-1°C (273°F +0/-1.8°F) for 3.5 minutes +0/-12.6 seconds (or equivalent) as shown in Figure 1.

Figure 1

A Blue/Purple Steraffirm Steam Class 6 Emulating Indicator Result Verifies Exposure to the Stated or Equivalent Sterilization Parameters



Steraffirm Steam Class 6 Emulating Indicator performs within the tolerances stated in Table 1 when tested in specialized test equipment (resistometers) meeting the international standard ISO 11140 part 2. Testing using other equipment may give different or misleading results.

Table 1: Critical Parameter Performance Characteristics of the Steraffirm Steam Class 6 Emulating Indicator

Sterilization Method	Time Minutes	Temperature °C
Steam	Sv +0/-6%	Sv +0/-1°C (-1.8°F)

Sv = stated value: reaction value identified for the product with respect to a critical parameter.

Each Steraffirm Steam Class 6 Emulating Indicator is clearly marked with the type of sterilization process for which it is intended, e.g., steam and the classification of indicator (Class 6/D).

The use of TST Control™ Cycle Verification (emulating) Indicators is limited to specific sterilization cycles and this information is stated on the product, e.g., 134°C (273°F) for 3.5 minutes steam.

DIRECTIONS FOR USE

Place the Steraffirm Steam Class 6 Emulating Indicator in the center of the pack, drum, tray, or pouch to be sterilized. After the sterilizing cycle, and prior to use of the contents of the pack, drum, tray, or pouch, the Emulating Indicator should be inspected. If the color change has not reached a complete blue/purple then the process should be considered suspect and the items should be re-sterilized using a fresh Emulating Indicator. The Steraffirm Steam Class 6 Emulating Indicator should only be used to monitor steam sterilization cycles operating at the performance tolerances stipulated on the indicator and/or the indicator packaging. See the instructions enclosed in the product packaging for detailed use-directions.

STORAGE CONDITIONS

The Steraffirm Steam Class 6 Emulating Indicator should be stored in unopened or resealed packages in cool (0-30°C [32-86°F]) dry (20-60% RH) conditions away from direct sunlight.

Cool, dry conditions should be maintained after use when kept as part of a documentation system.

SERVICE

Sales

Service is one of the most important ways to verify consistent quality of the facility's performance and operation. A tailored service program by STERIS provides effective, trouble-free operations.

Technical

STERIS is pleased to provide a completely staffed and equipped technical service laboratory capable of performing needed tests and providing both telephone and on-site assistance when needed. More details on how this service can benefit a facility's particular situation can be provided upon request.

ORDERING INFORMATION

Description	Quantity	Reorder Number
Steraffirm Steam Class 6 Emulating Indicator For exposure parameters 134°C (273°F) for 3.5 minutes	100/Box	PCC013

For further information, please contact:

STERIS[®]



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