

TDS-1601-2 / Rev.00 / 09-2021



Class 6 Emulating Indicator, Single Big Indicator, Self-Adhesive 134 °C - 3.5 min.

Ref Code:C-1601-SA

Product Description

Class 6 Emulating Indicators are cycle verification indicators that confirm the presence or absence of specific time and temperature parameters during a cycle and integrate all the critical parameters of the steam sterilization cycle. Emulating indicators can be placed inside each pack or pouch during sterilization of supplies or equipment in a validated pre-vacuum cycle. These emulating indicators can be used for routine monitoring of steam sterilization cycles. The indicators color transition from pink to dark brown/black. With the Self-Adhesive feature it can be used as a permanent record for traceability purposes.

Physical Parameters

Process	Steam
Dimensions	6,5 cm x 2,5 cm
Packaging	250 indicators / pack
Chemical Indicator	Initial color: Pink Signal color: Dark brown / Black %100 Toxic Heavy Metals Free

Intended Use

The indicators are for use in all Steam sterilization processes.

Class 6/Type 6 Process Indicator Requirements


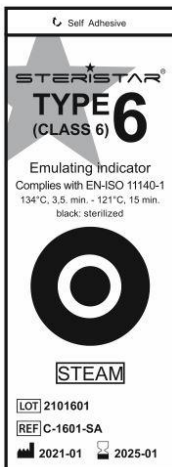
- 134 °C 3,5 min. – 121 °C 15 min.

Instructions for Use

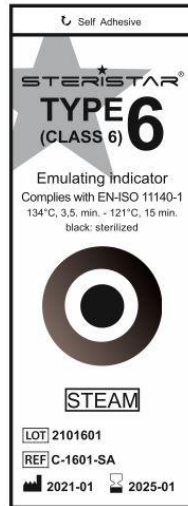
Use an indicator on each item, pack, peel pouch, or tray intended for steam sterilization. Place at a location considered most challenging for the steam penetration.

Process the packages/items as instructed in the sterilizer validation or manual. Upon exposure, the indicator will transition from pink to dark brown/black. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from pink to a shade of dark brown/black provides indication of exposure. If the signal color is not achieved immediately following exposure, allow the indicator to aerate for 1 minute. If the signal color is still not achieved, this suggests ideal sterilization conditions may not have been met.

Performance Characteristics

Results Availability	Immediately following exposure to Steam processes
Unexposed*	Exposed to 134°C 3,5 min. – 121 °C 15 min. *
	

Potential Fail Color



*Colors shown are representations of printed ink initial and signal colors but may vary from actual use.





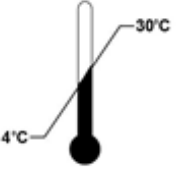
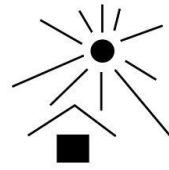

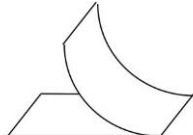


The signal color achieved from exposure to steam may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature, etc.). For a Type 6 Process Indicator, any color change produced during exposure to steam which is close to signal color is considered acceptable.

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical Indicators

ISO 13485:2016 Medical devices - Quality management systems

Storage and Shelf Life

	<p>Do not reuse</p>		<p>Keep dry</p>
	<p>4°C to 30°C</p>		<p>Keep away from sunlight</p>
	<p>10% - 40% RH</p>		<p>Self-Adhesive</p>
	<p>Shelf life 4 years from the date of manufacture</p>		
	<p>Keep away from sterilants. Do not use damaged Indicators or Indicators which have transitioned to green. Do not use after expiration date. Do not expose this product to Dry Heat, EO, H2O2 or any sterilization processes other than Steam,</p>		

Disposal

Discard as general waste.