

**kayoCheck**[®]

TECHNICAL AND SAFETY DATA SHEET

Circular Chemical Process Indicator for Ethylene Oxide Gas

CAT. NO.: EO-BD-GB-P-5000

Product Description

KayoCheck Ethylene Oxide (EO) Circular Chemical Process Indicator Dots for EO are manufactured to monitor whether EO exposure conditions were met at the point of application using pressure sensitive adhesive.

EO-BD-GB-P-5000 are intended for use with individual units (e.g. packs, containers) to indicate that the unit has been directly exposed to EO process and to distinguish between processed and unprocessed units.

The indicators color transition from Blue to Golden/Brown.

Physical Properties

Circular Indicator Dots	
Process	EO
Dimensions	12.7 mm (diameter circle)
Packaging	5,000 Indicator dots Per Roll
Chemical Indicator	Initial Color: Blue Signal Color: Golden / Brown

Intended Use

The indicators are for use in all EO sterilization processes.

Type 1 Process Indicator Requirements:

600 mg/L at 54°C and 60% RH for 20 minutes (Hot Cycle)

600 mg/L at 38°C and 60% RH for 30 minutes (Cold Cycle)

Instructions For Use

- 1) Use an indicator on each item, pack, peel pouch, or tray intended for EO sterilization. Place at a location considered most challenging for EO gas to reach.
- 2) Process the packages/products as instructed in the sterilizer validation or manual.
- 3) Upon exposure to EO, the indicator will transition from Blue to Golden/Brown. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from Blue to a shade of Golden/Brown provides indication of exposure to EO.
- 4) If the signal color is not achieved immediately following exposure, allow the indicator to aerate for 20 minutes. If the signal color is still not achieved, this suggests ideal sterilization conditions may not have been met. Determine if the load was successfully sterilized by examining a biological indicator, or re-sterilize the load using a new chemical indicator.

Kayo Research and Innovation Corporation

Neminath Industrial Estate No. 1, Gala No. 102 & 107, 1st Floor, Navghar, Vasai Road (East), Dist. Palghar - 401 210, Maharashtra (India)

+91 (0) 250-2392186 / 2392187

info@LadoKayo.com

kayoresearch@gmail.com

www.LadoKayo.com

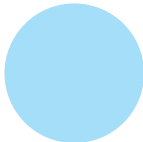

**kayoCheck[®]**

TECHNICAL AND SAFETY DATA SHEET

Circular Chemical Process Indicator for Ethylene Oxide Gas

CAT. NO.: EO-BD-GB-P-5000

Performance Characteristics

Result Availability	Immediately following exposure to EO processes
Unexposed*	Exposed to 54°C, 20 minutes, 60% RH, 600 mg/L EO gas*
	

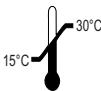

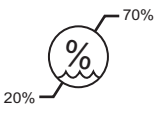


*Colors shown are representations of printed ink initial and signal colors but may vary from actual use.

The signal color achieved from exposure to EO may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature, etc.). For a Type 1 Process Indicator, any color change produced during exposure to EO which is different from the initial color is considered acceptable.

Compliance

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

Storage And Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 70% relative humidity		Keep dry
Shelf Life	2 years from the date of manufacture The date of manufacture is based on the day the indicating ink is applied to the substrate.		
	Keep away from sterilants. Do not use damaged Indicators or Indicators which have transitioned to green. Do not use after expiration date		

Disposal

Discard as general waste.

Kayo Research and Innovation Corporation

Neminath Industrial Estate No. 1, Gala No. 102 & 107, 1st Floor, Navghar, Vasai Road (East), Dist. Palghar - 401 210, Maharashtra (India)

+91 (0) 250-2392186 / 2392187

info@LadoKayo.com

kayoresearch@gmail.com

www.LadoKayo.com