

Instructions for Use

Chemical Indicator for Ethylene Oxide according to EN ISO 11140-1 Type 4 +5

Art.-No.	Quantity [pc]	Product Code	EN ISO 11140-1	Color Change	Stated Value (SV)	Product Description
212-360	3.200	C-E-P-4-SV3	Type 4	Blue → Green	600 mg/L EO, 54 °C, 20 min, RH > 30 %	Multivariable Indicator (internal indicator) 65 x 14 mm
212-224	400	C-E-P-5	Type 5	Yellow → Blue	600 mg/L EO, 54 °C, 50 min, RH = 60 %	Integrating Indicator 65 x 14 mm
212-226	3.200					

Application

The GKE type 4 and type 5 indicators are used in packages to monitor ethylene oxide sterilization processes.

Product Description

The type 4 indicators consist of a carrier made of paper and the type 5 made of plastic. Both contain an indicator dot that fulfills the different requirements and are self-adhesive for documentation. The chemical substances of the indicator are protected to bleed by a polymer binder coating and therefore, do not release toxic substances.

Performance characteristics

Type 4 indicators check more than two but not all critical variables, while type 5 indicators monitor all critical variables. Both indicators are in accordance with EN ISO 11140-1.

Handling Information

1. Take out indicator from the sheet.
2. Place indicator at the most difficult location inside of the package.
3. Run the sterilization process.
4. After completion remove the indicator and check the result. Use the reference color chart for interpretation.

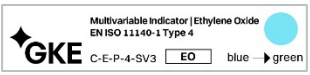
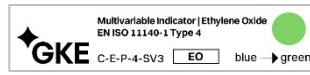
5. The indicator is self-adhesive and shall be adhered in the documentation sheet.

Storage and Disposal

1. Store all indicators in the closed foil pouch and in the outer packaging, away from sterilizer or sterilizing agent. Ideally, keep in a separate room.
2. Store indicators always between 5-30 °C or 41 - 86°F and a humidity of 5 - 80% RH.
3. The vapour of chemicals, especially hydrogen peroxide, may change the indicator before or after sterilization. Therefore, do not store them together with other chemicals.
4. The indicators should not be used after expiry date. They may be disposed with normal waste.

For further technical details please contact your local dealer or GKE directly. We will assist you with any technical questions. Visit our website www.gke-healthcare.com for more information.

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Art.-No.	Indicator starting color	Indicator final color
212-360		
212-224 212-226	