



# Colour Reference Chart

**GKE Steri-Record® Process and Batch Monitoring of ethylene oxide sterilization processes**

**EO**

## PASS RESULTS

The batch can be released when all four colour bars of the indicator have turned blue (see image) and all other critical process parameters such as temperature, pressure and sterilization time correspond to the specifications.

Ethylene oxide sterilization processes vary in EO concentration, temperature, pressure, inert gases and the indicator colour may come out slightly different under pass conditions. Please check the indicator colour change without PCD first.



Sufficient ethylene oxide penetration  
All colour segments are blue

## FAIL RESULTS



Insufficient ethylene oxide penetration  
all colour segments are blue-grey



Ethylene oxide penetration  
all colour segments are yellow (starting colour)

### Technical notes:

A failure is no conclusive proof that the fault is necessarily associated to the sterilizer itself (insufficient air removal or leakages). A sterilizer defect may result in insufficient ethylene oxide supply due to separation of ethylene oxide and inert gases, changing temperatures or unpurged supply pipes at the start of the process,

If an indicator is placed unprotected inside a sterilizer and not inside a process challenge device (PCD) with fully pass conditions, this is a clear proof that the ethylene oxide concentration is sufficient. However, the process may not be able to penetrate ethylene oxide into the PCD and in inner lumens of hollow devices, e.g. tubes etc.

If the indicator shows a clear blue colour before usage, the indicator was improperly stored or the expiry date has passed. Those indicators should not be used anymore.

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