# DIRECTIONS FOR USE



# GKE Steri-Record® Autoclave Tape with process indicator to wrap packages

STEAM VH2O2 EO

For steam sterilization processes:

211-354 (10 rolls), 211-355 (50 rolls)

For ethylene oxide sterilization processes:

212-354 (10 rolls), 212-355(50 rolls)

For hydrogen peroxide sterilization processes:

214-354 (2 rolls), 214-355 (10 rolls)

## **Application**

The autoclave tape or indicator tape is adhered to the packaging or packages and used to differentiate between sterilized and non-sterilized goods. However, the indicator only provides information about the sterilizing gas effect on the surface of the package. Since it is known that the sterilization conditions inside the package and in hollow devices can be completely different depending on the sterilization process, the air removal and the steam quality, the use of a process indicator is no substitute for sterilization monitoring. The process indicator merely provides the logistical information that the package has been subjected to a sterilization process in order to avoid confusion between sterilized and non-sterilized goods.

The use of autoclave tape does not provide any information about the sterility of the load. To monitor the sterility of the load, a type 5 or 6 indicator must be placed in each pack at the worst-case penetration location. For hollow goods, such as minimally invasive surgical (MIS) instruments, a validated type 2 indicator system shall be used to demonstrate sterile agent penetration and sterility.

#### **Product Description**

The indicator tape is self-adhesive available on roll for steam, ethylene oxide and hydrogen peroxide sterilization processes. Each roll contains 50 m indicator tape, 19 mm widths.

#### **Performance Characteristics**

Each autoclave tape contains a process indicator according to EN ISO 11140-1 Type 1 for its sterilization process.

## **Handling Information**

- 1. Adhere indicator tape on disposable wraps.
- 2. The indicator turns colour when exposed to proper sterilization conditions. Please check for colour change after sterilization, see table below. The indicator only provides information on the surface of the package.

	Indicator colour lines (before sterilization)	Indicator colour lines (after sterilization)
Steam	Yellow	Black
EO	Red	Green
VH2O2	Blue	Pink

# Storage and Disposal

- 1. Store indicator tape always between 5-30 °C or 41-86 °F and a humidity of 5-80% RH.
- 2. The vapour of chemicals especially hydrogen peroxide may change the indicator before or after sterilization. Therefore, do not store them together with other chemicals.
- 3. The indicator tape should not be used after expiry date. It 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. Also visit our website www.gke.eu for more information.

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