

DIRECTIONS FOR USE



GKE Steri-Record® single and double self-adhesive labels on roll with process indicator according to EN ISO 11140-1 Type 1

STEAM

EO

VH202

For steam sterilization processes:

211-142, 211-149, 211-148

211-278, 211-279, 211-282, 211-284, 211-285, 211-286, 211-287, 211-288, 211-289

211-389, 211-297, 211-338, 211-339, 211-341, 211-342, 211-344, 211-345, 211-346, 211-349, 211-358, 211-363, 211-365, 211-367, 211-369, 211-370, 211-373, 211-375, 211-376, 211-377, 211-379, 211-380, 211-382, 211-385, 211-386, 211-387, 211-388, 211-389, 211-390, 211-394, 211-396, 211-442, 211-448, 211-449, 211-467, 211-468, 211-469, 211-473, 211-475, 211-476, 211-479, 211-480, 211-482, 211-483, 211-486, 211-488, 211-489, 211-490, 211-494, 211-497, 211-549, 1045

For ethylene oxide sterilization processes:

212-349

For hydrogen peroxide (plasma) sterilization processes:

214-349, 214-358, 214-369, 214-373, 214-376, 214-380, 214-383, 214-390

Application

Instruments and other products to be sterilized in hospitals and clinics are wrapped before sterilization in containers that are made of metal, foil, non-woven or paper material. The goods have to be labelled on the outside for logistic information, containing content, sterilization and expiry date. The position of the label is eligible. The labels can be printed with any thermal transfer printers. By using endless labels, the label lengths can be adjusted according to the requirements.

Containers made of stainless steel, aluminium or plastic cannot be adhered with conventional labels since glue residues will remain on the surface. Therefore, many containers have openings where labels can slide-in. The labels need to have special dimensions and are mostly not big enough to add all data. Furthermore, the label is placed on a certain position and cannot be scanned without shifting the container. GKE has developed a single self-adhesive label which can be adhered onto the container without leaving any residues. Therefore, extensive cleaning with organic solvents is unnecessary. The use of under foil or film for easy removal of the label is also not anymore required.

The double self-adhesive labels are used for sterile packages made of foil, non-woven or paper material.

Product Description

The labels are single or double self-adhesive and can be used for documentation e.g. to be registered in a patient' data or operation book.

The labels are available in different sizes with process indicator for different sterilization processes. The sterilization process and the successful colour change of the indicator are mentioned on each label.

All GKE labels are wrapped to the outside on a paper core. The inner diameter of the core can be reduced by using reducing inserts from 3" to 2", 2" to 1" or 3" to 1".

Performance Characteristics

All GKE labels with process indicators comply with the standard EN ISO 11140-1 type 1 and provide logistic information, if a pack or container has been run through the sterilization process. The labels do not give any information about the sterility of the goods sterilized.

The materials used are not toxic and non-allergen.

Additional information for indicators for steam sterilization processes

Super-heated steam may be generated by a pressure reducing valve in the steam pipe before the sterilizer entrance due to high sterilizer wall temperatures or due to hygroscopic condensation inside cellulose packages in the sterilizer. Type 1 indicators indicate superheated steam by a greenish-brown colour change. This colour change of the indicator is no proof of an insufficient sterilization process and must be checked by a validation procedure. The same indicator showing super-heated conditions on a pack may show a black colour inside a pack because inside the pack load and condensate may compensate super-heat conditions.

The colour change to greenish-brown is no quality problem of the indicator. In contrast the indicator provides additional information about superheating conditions inside the sterilization chamber. The colour change also shows that the package has been exposed to a steam sterilization process. However, the indicator does not provide information about the result of the sterilization process, also see colour reference chart 720-007.

Handling Information

1. The label can be marked manually or with a printer.
2. Adhere labels on packs or containers. The container labels can be inserted onto containers.
3. Run the sterilization process.
4. The indicator changes its colour according the indicator and sterilization process used.

	Indicator colour (before sterilization)	Indicator colour (after sterilization)
Steam	blue	brown/black
EO	blue	green
VH2O2	blue	green
	purple	green

The indicator colour (before sterilization) and reference end colour are also printed in words on each label.

5. After opening the pack or container, the double self-adhesive labels can be used for patient documentation. The single self-adhesive labels for containers are removable and can also be used for documentation.

Storage and Disposal

1. Store indicators in a cool, dry place between 5-30°C or 41-86°F and a humidity of 5 - 80% RH and away from intense light inside its original packaging.
2. Do not store them together with other chemicals. The vapour of chemicals may destroy the indicator.
3. The indicators should not be used after expiry date and can be disposed with normal garbage.
4. Process indicators for hydrogen peroxide / plasma sterilization processes have to be stored away from the sterilizer (preferably in a separate room) and from sterilized goods including indicators used in advance since H₂O₂ gases may partially change the indicator colour without being sterilized.
5. If packages sterilized with hydrogen peroxide are stored with package sterilized with steam, the indicator for steam may change back its colour.

For further technical details please visit our website at www.gke.eu, contact your local dealer or the GKE application laboratory. We will assist you with any technical questions.

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