

# Instructions for Use

## Seal Test for daily routine control of sealing seams and for operational qualification (OQ) of sealing machines according to EN ISO 11607-2

Art.-No.	Quantity [pc]	Product Code	Product Description
200-311	100	SEAL-TEST	Seal indicator (173 x 76,2 mm) to check paper/plastic film pouches in rotary sealing machines
200-312	250		
200-321	100	HDPE-SEAL-TEST	Seal indicator (173 x 76,2 mm) to check Tyvek® pouches in rotary sealing machines
200-331	100	BAR-SEAL-TEST	Seal indicator (250 x 76,2 mm) to check paper/plastic film pouches in bar sealing machines

### Application

The GKE SEAL-TEST indicator is used for daily routine control of sealing seams and for the operational qualification of different sealing machines in accordance with EN ISO 11607-2:

- Rotary sealing machines for pouch material made of:
  - paper/foil
  - Tyvek®
- Bar sealing machines

The test ensures that the sealing machine is working properly, is correctly adjusted and that the sealing seams are tightly sealed, the continuous monitoring of which is required by DIN 58953-7. The SEAL test shows the quality of the adhesive quality to the seam by visually inspection the contrast on the inserted indicator.

### Product Description




The GKE SEAL-TEST indicator is manufactured in two dimensions and two materials. It is made of either medical paper according to EN 868-3 or uncoated Tyvek®/film material (HDPE) according to EN 868-9 and is printed with a gridded indicator field. The seal indicator for bar sealers (BAR-SEAL-TEST) is wider so that the entire width of the bar can be tested. The indicator does not release any toxic substances.

### Handling Information

- Switch on the sealing machine and wait until the correct temperature is reached and the sealing machine is ready for operation.
- Place GKE SEAL-TEST indicator in a sterilization pouch so that the black print pattern is visible through the transparent surface and covers the sealing seam.
- Insert the sterilization pouch (foil on top) with the inserted SEAL-TEST indicator into the sealing machine so that the created seal seam runs approximately centrally over the entire width of the test area.
- Check GKE SEAL-TEST indicator visually.

Has the film layer fused correctly together with the underlying material and does the sealing seam have a uniform full-surface area? The sealing seam must not have any irregularities or imperfections. As a result, the sealing machine is set to the correct temperature, contact pressure and speed.

With the correct fusing together of the inner foil layer and the correct contact pressure on the pouch, a full-area or grooved sealing seam is created.

CORRECT SEAL SEAM	ERROR 1	ERROR 2
		
A correctly produced sealing seam is uniformly discoloured and visible over the entire area.	Detachment of the foil due to low sealing temperature or low contact pressure.	Seal seam is interrupted and not continuous.

- After successful testing, label the GKE SEAL-TEST indicator. The results can be documented directly on the sealing indicator in the predefined areas with information on the machine, location, release, date and remarks. Archive the seal indicator for documentation.

### Storage and Disposal

- Store GKE SEAL-TEST always between 5-30 °C or 41 - 86°F and a humidity of 5 - 80% RH.
- Do not use after expiry date and dispose with normal waste.

For further technical details please contact your local dealer or GKE application laboratory. We will assist you with any technical questions. Visit our website [www.gke-healthcare.com](http://www.gke-healthcare.com) for more information.