



# GIMA

PROFESSIONAL MEDICAL PRODUCTS

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## SEAL CHECKER

### User manual

**ATTENTION:** The operators must carefully read and completely understand the present manual before using the product.

ENGLISH

#### Seal Check manual

##### Introduction

The ISO 11607 - 2 is describing the IQ, OQ and PQ procedures which are applicable to Medical Heat sealers. For Operational Qualification (OQ) and daily testing of your sealing device in accordance with EN ISO 11607-2 the Seal Checker can be used as a indicator placed in between the layers of medical pouches and seal it. By its unique printed pattern of the black area the inspection of the seal and the detection of minor or bigger problems are easily detected.

##### Procedure

Place the Seal Check inside a 20 cm wide pouch in between the paper and the film. The printed side should be facing the film to be visible at all times. Only the black printed area should be inside the pouch enabling the operator to make notes on the designated area.

Switch on the heat sealer and let it heat up till the pre-set value. (In most cases the heat sealer will be set in between 160 and 180 degrees Celsius depending on the pouch manufacturers recommendations).

Heat seal the combination in a normal way once the heat sealer has indicated it reached the pre-set temperature. Make sure the seal is made over the dark part of the seal check.

Inspect the dark seal part of the seal check. The seal made should be:

- Uniform without any distortion
- Without gaps or spots

In case of low sealing temperature, pressure or interruptions of the seal the Seal Check will show it clearly by a lighter area at the sealing area.

When the seal is been tested and ok, please fill in the related data on the Seal check and place it in a folder for future references.

Now the heat sealer can be released for usage for the day.

##### Restrictions for use:

The Seal Check can only be used for Paper/Film pouches and rolls to be tested. The Seal Check is not suitable for testing the Heat sealer in combination with a Tyvek Pouch.

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