



GIMA

PROFESSIONAL MEDICAL PRODUCTS

TEST PER SIGILLATRICI SEAL CHECKER CONTRÔLE DE SCEAU CONTROLADOR DE SELLADO

Manuale d'uso - User manual - Manuel de l'utilisateur - Guía de uso

ATTENZIONE: Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.

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

AVIS: Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.

ATENCIÓN: Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.

GIMA 35957



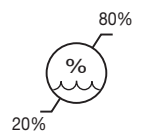
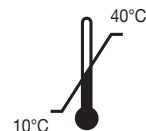
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ENGLISH

Direction for use (DFU Seal Checker 1-2026 version B)

This direction for use is applicable for the following Sterintech™ products:

Seal Checker:

No	Catalog Number	Name	Spec	Description
1	909.001.0250	Seal Checker	175x75 mm	For Medical Grade paper pouch

**Warnings:**

Upon receipt of goods please check whether the package was undamaged and ensure you about the expiry date of the materials.

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 Sterintech™ 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.

Characteristics:

This Seal Checker is composed of a special paper strip with a specific length to check the whole pressure roll area of the heat sealer. A special black ink which is showing the imprint of the sealing machine pressure roller.

For more details please refer to the technical data sheet. The dimensions of the Seal Checker is displayed above.

Intended use:

The Seal Checker are used in combination with a Medical grade paper / Film pouch and a Medical rotary heat sealer.

**Warning:**

Do not use this Seal Checker with other materials (like f.i. Tyvek) then displayed above.

Any serious incident that has occurred in relation to the Seal Checker should be reported to the manufacturer.

Instructions for use:

Place the Seal Checker 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 Checker 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 Checker and place it in a folder for future references.

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

Storage conditions:

Please take into consideration the storage conditions provided for at the box label of the product . Only in case the storage conditions were met, SP Medikal guarantee products compliance to standard within the expiry date.

Do not expose the Seal Checker to sterilizing agents or other chemical products of any kind.

Compliance to standards:

The Seal Checkers are compliant to standard EN ISO 11607-2













Technical Data Sheet:

For this product a technical data sheet are available in which reference to standards, packaging, certificates etc. are enclosed. This Direction for Use may be changed in the future.

Shelf life:

The Seal Checker is not having an expiry date

Simboli - Symbols - Symboles - Simbolos

	IT - Fabbricante GB - Manufacturer FR - Fabricant ES - Fabricante
	IT - Conservare in luogo fresco ed asciutto GB - Keep in a cool, dry place FR - À conserver dans un endroit frais et sec ES - Conservar en un lugar fresco y seco
	IT - Conservare al riparo dalla luce solare GB - Keep away from sunlight FR - À conserver à l'abri de la lumière du soleil ES - Conservar al amparo de la luz solar
	IT - Data di scadenza GB - Expiration date FR - Date d'échéance ES - Fecha de caducidad
	IT - Data di fabbricazione GB - Date of manufacture FR - Date de fabrication ES - Fecha de fabricación
	IT - Numero di lotto GB - Lot number FR - Numéro de lot ES - Número de lote
	IT - Limite di temperatura GB - Temperature limit FR - Limite de température ES - Límite de temperatur
	IT - Limite umidità GB - Moisture limitation FR - Limites d'humidité ES - Limitación de humedad
	IT - Codice prodotto GB - Product code FR - Code produit ES - Código producto
	IT - Importato da GB - Imported by FR - Importé par ES - Importado por
	IT - Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso GB - Caution: read instructions (warnings) carefully FR - Attention: lisez attentivement les instructions (avertissements) ES - Precaución: lea las instrucciones (advertencias) cuidadosamente
	IT - Leggere le istruzioni per l'uso GB - Consult instructions for use FR - Consulter les instructions d'utilisation ES - Consultar las instrucciones de uso