



# GIMA

PROFESSIONAL MEDICAL PRODUCTS

**SIGILLI IN PLASTICA CON INDICATORE DI VAPORE**

**PLASTIC SECURITY SEAL WITH STEAM INDICATOR**

**SCEAU DE SÉCURITÉ EN PLASTIQUE AVEC INDICATEUR DE VAPEUR**

**SELLO DE SEGURIDAD PLÁSTICO CON INDICADOR DE VAPOR**

**SELO DE SEGURANÇA EM PLÁSTICO COM INDICADOR DE VAPOR**

**SIGILLARE DE SECURITATE DIN PLASTIC CU INDICATOR DE ABUR**

**MŰANYAG BIZTONSÁGI TÖMÍTÉS GŐZJELZŐVEL**

- Manuale d'uso e manutenzione

- Use and maintenance book

- Instructions de fonctionnement et entretien

- Manual de uso y mantenimiento

- Manual de uso e manutenção

- Manual de utilizare și întreținere

- Kezelési és karbantartási útmutató

**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.

**CUIDADO:** Os operadores devem ler e compreender este manual completamente antes de usar o produto.

**ATENȚIE:** Operatorii trebuie să citească și să înțeleagă complet acest manual înainte de a utiliza produsul.

**VIGYÁZAT:** A kezelőknek el kell olvasniuk és meg kell érteniük ezt a kézikönyvet a termék használata előtt.

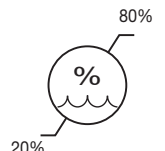
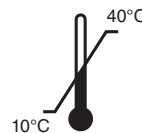
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GIMA 37330	902.111.1000
GIMA 37332	902.112.1000
GIMA 37340	902.113.1000
GIMA 37341	902.115.1000
GIMA 37343	902.114.1000



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**Direction for use  
(DFU Container Seal 1-2025 version C)**

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

**Container Seal**

- 902.111.1000 Container seal 2,7cm Blue
- 902.112.1000 Container seal 2,7cm Blue with steam indicator
- 902.113.1000 Container seal 2,7cm Red
- 902.114.1000 Container seal 2,7cm Red with steam indicator
- 902.115.1000 Container seal 2,7cm Orange
- 902.116.1000 Container seal 2,7cm Orange with steam indicator
- 902.117.1000 Container seal 2,7cm Green
- 902.118.1000 Container seal 2,7cm Green with steam indicator

** Warnings:**

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

**Introduction:**

The Container Seal is developed to use at rigid containers to secure the lock before sterilization is taking place. It provides proof that the container is not opened in between sterilization and point of use. It provides a steam indicator Type 1 to distinct whether a container has undergone sterilization or not (if provided).

The Type 1 Steam indicator is not giving any conclusion on the sterility of the container nor its content.

**Characteristics:**

The Container Seal are produced from a special PP material (DEHP free) which softening point is above 150° Celsius. The container seals are available with or without steam indicator.

Each Container Seal measures approx. 30 x 50 mm (closed). The chemical indicator changes from violet into green when sterilized by a steam sterilizer: Cycle parameter: 134° Celsius for 3,5 minutes or

121° Celsius for 15 minutes. The inks used are non-toxic, heavy metal free inks.

For more details please refer to the technical data sheet.

The dimensions of the Container Seal pin is 27 mm.

#### Intended use:

This Container Seal is recommended for steam sterilization cycles parameters between 121°C - 15 min and 134°C - 3,5 min but can be used for other sterilization methods as well (the ones without indicator)



#### Warning:

Do not use this Container Seal in Steam cycles with a different SV as the SV displayed above

Any serious incident that has occurred in relation to the Container Seal should be reported to the manufacture.

#### Instructions for use:

Place the Container seal with its pin through the lock of the rigid container and close it.

Place the rigid container inside the sterilizer and run the cycle.

After sterilization the steam indicator should have reached the end color (green).

#### 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 Container Seals to sterilizing agents or other chemical products of any kind.

#### Compliance to standards

The Container seals are compliant to standard EN 868-8 and ISO 11140 - 1: 2014 (in case of steam indicator)

#### Technical Data Sheet.













For these products technical data sheets 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 Container Seals have not a limited shelf life but need to be stored in the recommended conditions. The manufacturing date as well as lot number are indicated on the packaging label.

#### Symbols:

	Date of manufacture		Keep in a cool, dry place
	Manufacturer		Keep away from sunlight
	Product code		Temperature limit
	Lot number		Humidity limit
	Expiration date		Caution: read instructions (warnings) carefully
	Imported by		Consult instructions for use

#### GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies