PROFESSIONAL MEDICAL PRODUCTS

FILTRO PER CONTENITORI PER STERILIZZAZIONE,
DIAMETRO CA. 19 CM CON INDICATORE DI VAPORE DI TIPO 1

CONTAINER FILTER,
ROUND 19CM DIAMETER, WITH STEAM INDICATOR TYPE 1

FILTRU PENTRU RECIPIENTE DE STERILIZARE,
DIAMETRU APROX. 19 CM CU INDICATOR DE ABUR DE TIP 1

È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.

All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.

Orice accident grav produs, privitor la dispozitivul medical fabricat de firma noastră, trebuie semnalat producătorului și autorității competente în statul membru pe teritoriul căruia își are sediul utilizatorul.

- **Manuale d'uso e manutenzione**
- **Use and maintenance book**
- **Manual de utilizare și întreținere**

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

GIMA 37328

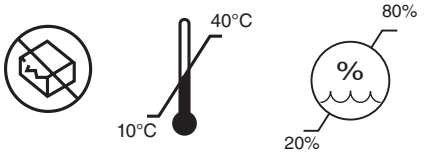
SP Medikal San Ltd. Sti
Yenidoğan Mahallesi, Erciyes Sokak No:16/2
34035, Bayrampaşa Istanbul Turkey
info@spmedikal.com
Made in Turkey

CE

REF **901.001.0500**



MD



Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com

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ENGLISH

Direction for use (DFU Container Filter 1-2026 version G)

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

Container Filter round:
901.001.0500 with steam indicator in the middle

⚠ Warnings:
Protect the filter from sharp objects to prevent them to damage the paper and thus the sterile barrier function of the filter.

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

Introduction:
The Container Filter is developed to use at rigid containers with a filter holder 190 mm diameter. The Container Filter is intended to form a Sterile barrier which is able to let steam in during sterilization conditions. It provides a steam indicator ISO 11140-1 Type 1 to distinct whether a container has undergone sterilization or not. The Type 1 steam indicator is not giving any conclusion on the sterility of the container nor its content.

Characteristics:
This Container Filter is composed of white medical grade Soft Crepe material and a special indicating steam ink which is turning into end color (brown) under steam sterilization conditions. 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 Filter is 190 mm diameter.

Intended use:
This Container Filter is recommended for steam sterilization cycles parameters between 121°C - 15 min and 134°C - 3,5 min.

⚠ Warning:
Do not use this Container Filter in any other sterilization cycle than Steam cycles with the SV as displayed above.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Instructions for use:
Place the Container Filter in the designated area of the rigid container.

Fixate it by the mechanical holder (this may differ per type and brand of the instrument container

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 Filters to sterilizing agents or other chemical products of any kind.

Compliancy to standards:

The filters are compliant to standard ISO 11607- 1: 2019 and ISO 11140 - 1: 2014 as well as EU MDR 2017/745 Class 1. The products carry a CE mark.

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 Filters have a shelf life of 5 years from manufacturing date, when stored in the recommended conditions. The manufacturing and expiry date as well as lot number are indicated on the packaging label. Do not use the Container Filters after the expiry date.

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
	Disposable device, do not re-use		Medical Device compliant with Regulation (EU) 2017/745
	Medical device		Don’t use if package is damaged
	Peel direction		Unique device identifier

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies