

TECHNICAL DATA SHEET

Product Name: PTFE Container Filter Steam

Product Description:

Our product MEDSTER PTFE Container Filter Steam is a 2000 cycles usable PTFE filter. PTFE filters are porous membranes used in steam sterilization reusable rigid containers as sterile barrier against the penetration of microorganisms. Our products are designed for use in STEAM sterilization cycles. The indicator on it works with color change and instantly provides reliable and accurate information that sterilization has occurred. After an effective full sterilization cycle, the indicator ink will change from pink to black. The indicator color resulting from exposure to steam may be darker due to differences in sterilization parameters (load content, cycle time, temperature, etc.).

There is LOT and SKT (Expiration Date) information on the product label.

The shelf life of our products; for 3 years.

Relevant Harmonized Standards

EN ISO 13485:2016

EN 15223-1: 2021

EN ISO 20417: 2021

EN ISO 14971:2019

EN 868-8:2018

EN ISO 11607-1:2017

Relevant Regulations


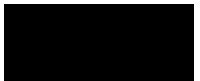
Medical Devices Regulation (EU) 2017/745

Product Properties:

Product Code	Product Name	Product Type	Sterilization Type	Material Type	Dimensions
80.400	PTFE Container Filter Steam	Chemical Indicator*	Steam Sterilization	PTFE	Ø: 194mm

*Does not contain lead and other heavy metals.

Indicator Properties:

Product Code	Product Description	Printed Indicator Type	Indicator Initial Color	Indicator Conversion Color
80.400	PTFE Container Filter	Steam		

Technical Properties:

Properties	Unit	Method	Tolerance	Typical Value
Pore Size	μ	-	-	10
Porosity	% 50	-	-	50
Airflow	L/min/47mmØ/10mBar	-	-	Min 0.8
Water Intrusion Pressure	bar	-	-	Min 0.24
Thickness	mm	-	± 0.063	0.63
Maximum number of use	cycles	-	-	2000

Packaging Information:

Product Code	Product Description	Number of Packages	Box Quantity (Pack)
80.400	PTFE Container Filter Steam	1	-



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Preservation, Storage and Disposal Information:

- Do not expose to direct sunlight and keep dry.
- Replace the Steam Container Filter after each use.
- Between 0°C and 40°C and Max. Store at 70% RH humidity.
- Check before each use. Do not use the filters when they are wet or damp. Never use filters that are torn, cracked or show other signs of damage.
- Store in its original packaging.
- Dispose of it in accordance with the place of use and local regulations.
- Keep away from sterilants, alkaline chemicals and acids.
- Do not use after the expiration date.



TECHNICAL DATA SHEET

Product Name: Container Label Steam

Product Description:

Our 'MEDSTER SafeCheck Container Label Steam' is designed to ensure that sterilized materials are accurately recorded. There are four lines on the product to record sterilization date, sterilization number, operator name information. When exposed to steam sterilization conditions, the indicator ink will change from the initial color to the reference color.

LOT and expiry date information can be found on the product label. The shelf life of our product is 3 years.

Complying Harmonized Standards

EN ISO 13485: 2016	EN ISO 14971: 2019	ISO TR 24971:2020
ISO 20417:2021	ISO 15223-1:2021	ISO 11140-1:2014



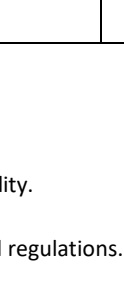

Other Regulations, Directive and Guidelines

Medical Devices Regulation (EU) 2017/745

Product Properties:

Product Size:	3,6cm x 6,6cm
Paper Type:	American Bristol
Sticky Feature:	Available
Cellophane:	N/A
Environmental impact:	Lead and metal free
Sterilization Type:	Steam

Indicator Properties:

Product Code	Product Description	Printed Indicator Type	Indicator Initial Color	Indicator Conversion Color
80.100	Container Label Steam	Steam	 	 

Chemical Components:

Chemical Ingredients Name	% of ingredients	CAS No
Water	%35	7732-18-5
Diacetone Alcohol	%3	123-42-2
Proprietary Combination	%62	N/A

Packaging Information:

Product Code	Product Description	Package Contents	Inner Box Quantity
80.100	Container Label Steam	100 pcs	50 packs

Storage, Storing, and Disposal Information:

- Do not expose to direct sunlight and keep it dry.
- Between 0°C and 40°C and Max. Store at 70% RH humidity.
- Store in its original packaging.
- Dispose of in accordance with the place of use and local regulations.



TECHNICAL DATA SHEET

Product Name: Paper Container Filter Steam

Product Description:

Our product MEDSTER Paper Container Filter Steam is a single-use paper filter. It has a heat and steam sensitive indicator print on it. Our products are designed for use in STEAM sterilization cycles. The indicator on it works with color change and instantly provides reliable and accurate information that sterilization has occurred. After an effective full sterilization cycle, the indicator ink will change from pink to black. The indicator color resulting from exposure to steam may be darker due to differences in sterilization parameters (load content, cycle time, temperature, etc.).

There is LOT and SKT (Expiration Date) information on the product label.

The shelf life of our products; for 3 years.

Relevant Harmonized Standards

EN ISO 13485:2016	EN 15223-1: 2021	EN ISO 20417: 2021
EN ISO 14971:2019	EN 868-8:2018	EN ISO 11607-1:2017

Relevant Regulations



Medical Devices Regulation (EU) 2017/745

Product Properties:

Product Code	Product Name	Product Type	Sterilization Type	Material Type	Dimensions
80.300	Paper Container Filter Steam	Chemical Indicator*	Steam Sterilization	Paper	Ø: 184mm

*Does not contain lead and other heavy metals.

Indicator Properties:

Product Code	Product Description	Printed Indicator Type	Indicator Initial Color	Indicator Conversion Color
80.300	Steam Container Filter	Steam		

Technical Properties:

Properties	Unit	Method	Tolerance	Typical Value
Basis Weight	GSM	EN ISO 536	± 2	73
Thickness	mm	UNE 20534	± 0.005	0.285
Density	g/cm ³	UNE-EN 20534	-	0.256
Filtration 180 c.c	s	Intern	-	40-60
Resistance in passing of air	s	Gurley Method / UNE 57065	-	1
Air Permeability	cm ³ /Ns	UNE 57066	-	140
Traction Resistance	kN/m	UNE 57028 / ISO 1924/1	-	SL ≥ 1.57 ST ≥ 1.57
Break Length	km	UNE 57028 / ISO 1924/1	-	SL ≥ 2.19 ST ≥ 2.19
Elongation	%	UNE 57028 / ISO 1924/1	-	SL ≥ 11 ST ≥ 3.8
Break Load Wet	kN/m	UNE 57030 / ISO 3781	-	SL ≥ 0.379 ST ≥ 0.379
Retetion Wet/Dry	%	UNE 57030 / ISO 3781	-	24.1



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Capillary Water	mm	Klemm Method / UNE 57044	-	SL \geq 56 ST \geq 74
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Packaging Information:

Product Code	Product Description	Number of Packages	Box Quantity (Pack)
80.300	Paper Container Filter Steam	100	-

Preservation, Storage and Disposal Information:

- Do not expose to direct sunlight and keep dry.
- Replace the Steam Container Filter after each use.
- Between 0°C and 40°C and Max. Store at 70% RH humidity.
- Check before each use. Do not use the filters when they are wet or damp. Never use filters that are torn, cracked or show other signs of damage.
- Store in its original packaging.
- Dispose of it in accordance with the place of use and local regulations.
- Keep away from sterilants, alkaline chemicals and acids.
- Do not use after the expiration date.

