

SEFAR® PHARMA GMP BAGS

The certified filter bag solution

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SEFAR® PHARMA GMP BAGS

GMP compliant filter bags for powder processing in the life science market.

Integrated production in clean controlled environment.

Choice between different levels of certification.

Unique manufacturing solutions.

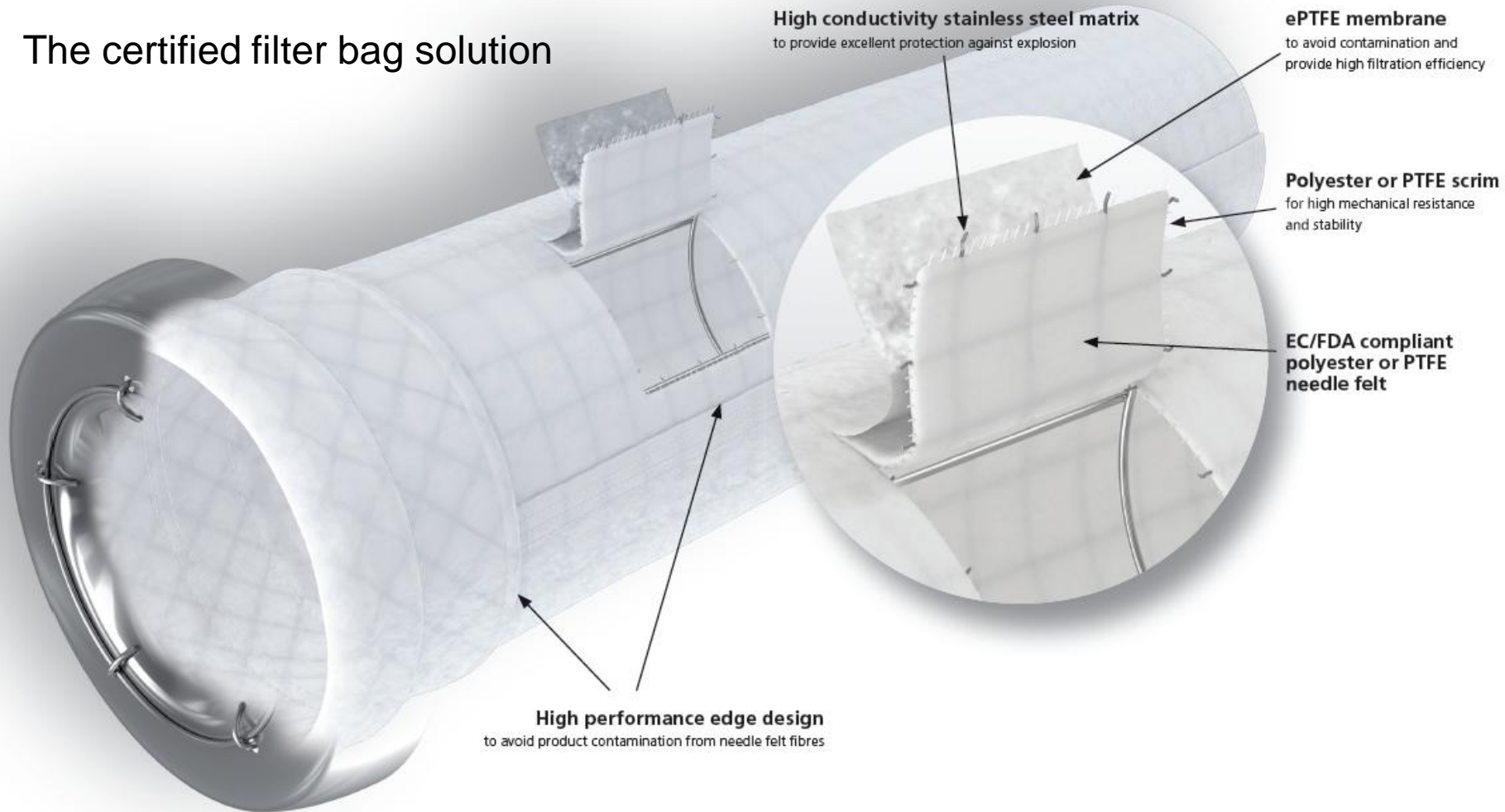
High filtration performance.

Taylor made manufacturing (no standard sizes).



Unique Selling Proposition

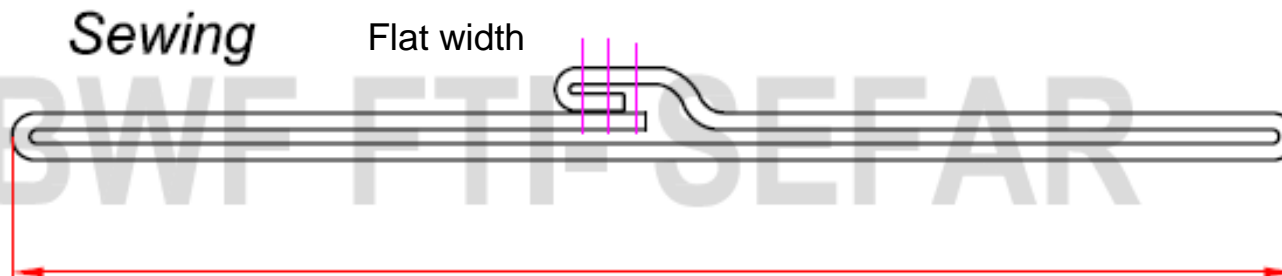
The certified filter bag solution



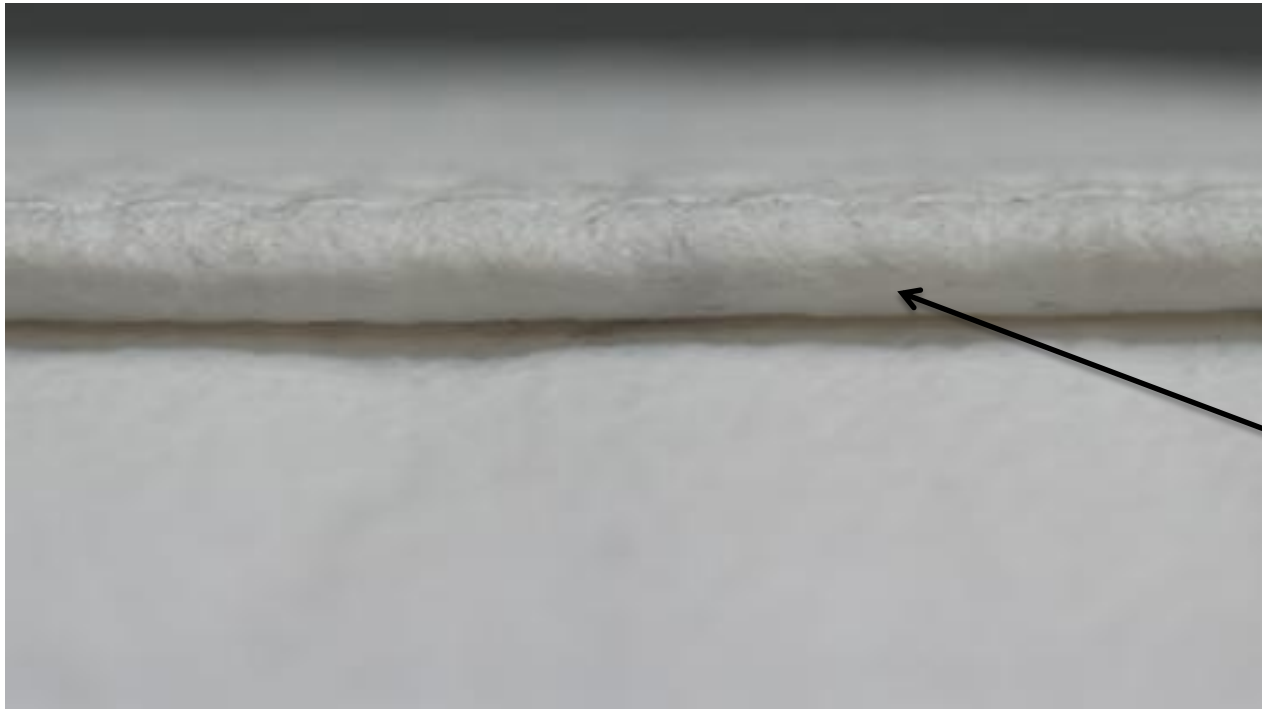
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High performance edge design

All the cut edges of the needle felt are folded in the sewing, to avoid contact between the customer's product and the felt staple fibers. This will give the guarantee of avoiding possible contamination of the product by the fibers. The product will be in contact only with the ePTFE membrane (No releasing particles). The sewing thread material is always PTFE, FDA and EU compliant. The stitches are produced with a special needle to avoid leakage.



High performance edge design

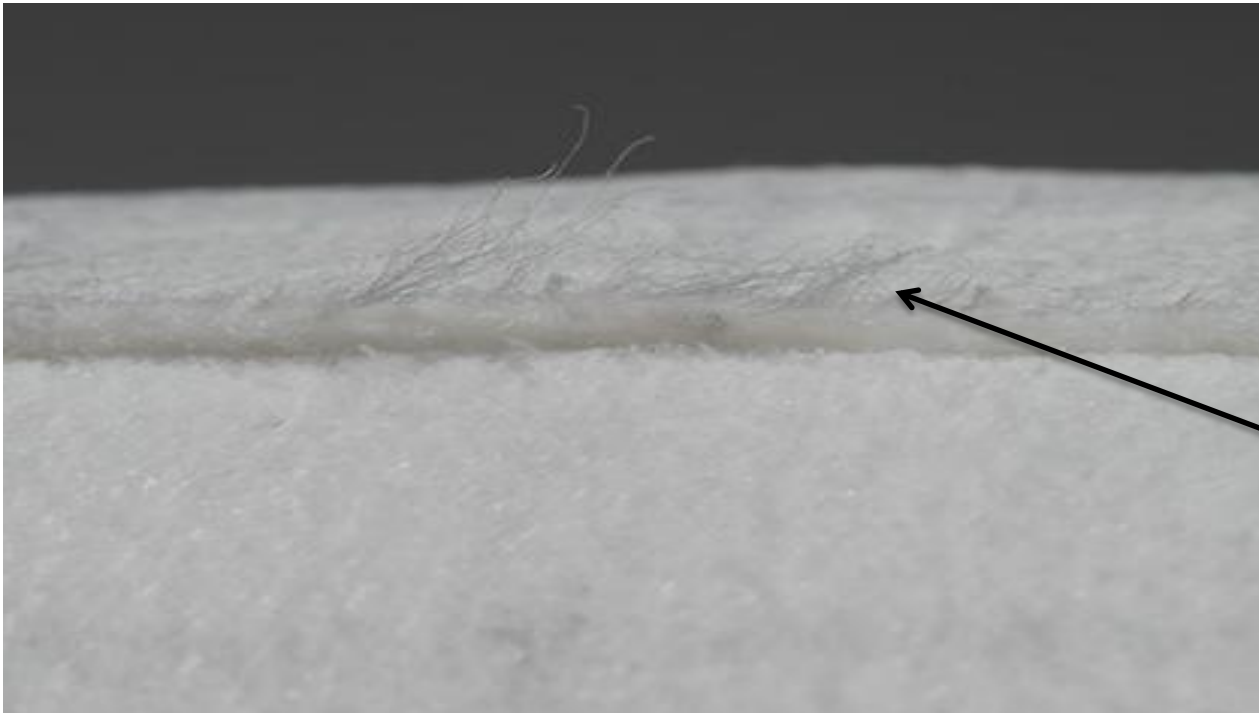


PTFE Membrane

Sefar solution (Mandatory for SEFAR® PHARMA GMP level – Folded edge)

The folded edge avoid any possible contact between the product and the needle felt so that there is no possibility of powder contamination from the staple fibers. Moreover this solution guarantee that particles of valuable product can be clogged in the needle felt section.

High performance edge design



Needle felt open edge

Competitor's solution – Thermo welded or flat sewn

The thermo welded longitudinal seam is one of the most used solution by competitors. In this case it's not possible to avoid that fibers from the needle felt get in contact with the product, with high risk of contamination

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High performance edge design



Competitor's Pharma bottom

This is an example of bottom proposed by the competition (Heimbach in this case). To obtain this bottom design is needed to produce the bag with the membrane on the internal part, and pull the finished bag inside out, with the high risk to damage the membrane during the operation.



Sefar Pharma bottom

This is the Sefar Pharma bottom, with folded open edges to avoid needle felt staple fibers to be in contact with the product.



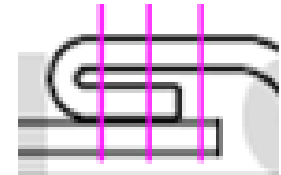
Sewings



Sewing are a always made using EU/ FDA PTFE threads.

Special needles are used to avoid having holes that let the product pass through.

In the folded seams there are always 3 layers of felt and membrane, that ensure to avoid leakage through the holes:



This sewing has been tested in the field in critical conditions, with positive results (No leakage).

At the end of the manufacturing process all the sewing are controlled, to eliminate eventual exceeding threads.



ePTFE Membrane: Functional principle

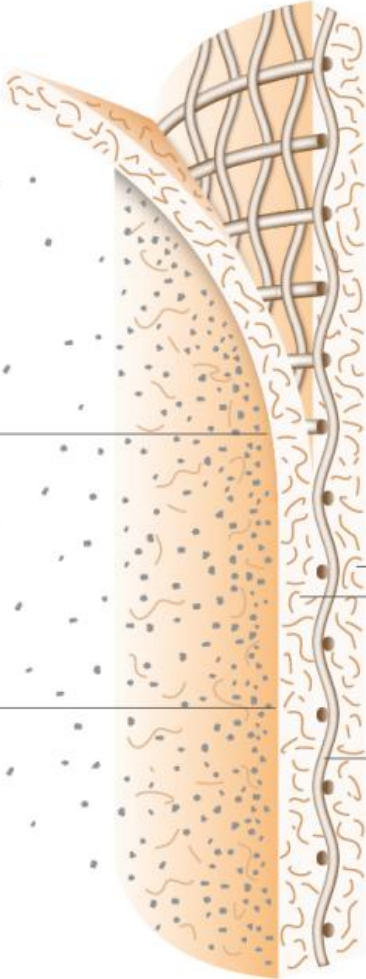
Rohgasseite
Raw Gas Side

Reingasseite
Clean Gas Side

Staub
Dust Particles

Membrane
Membrane

Ausrüstung
Finishing

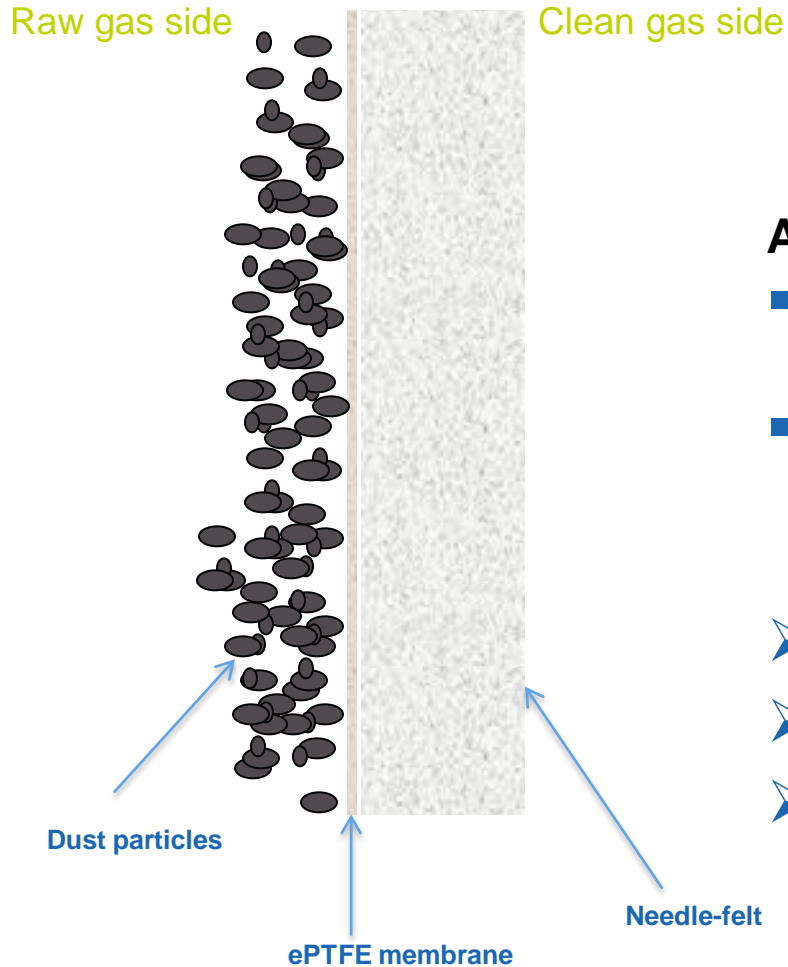


Faserauflage
Fibre Web

Stützgewebe
Supporting Scrim



Surface filtration

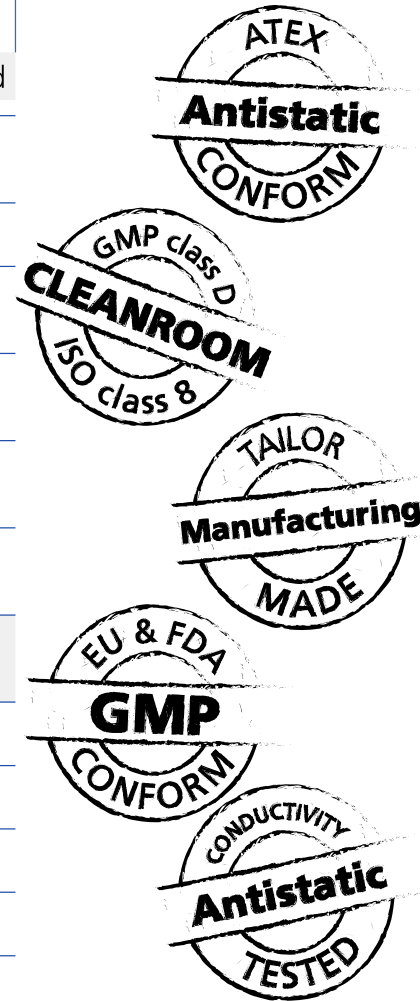


Advantages of surface filtration:

- Particles do not embed themselves in the support medium
- The dust is removed from the support medium during each cleaning
- Constant differential pressure behavior
- Constant gas volumetric flow
- Hence minimum emission

SEFAR® PHARMA GMP – Product positioning

	Available quality levels		
	PHARMA GMP	PHARMA	Standard
Food and Drug conformity for complete filter	✓	✗	✗
FDA and EC regulation compliance for all components	✓	✗	✗
All production processes and fabrication according to EC 2023/2006 or corresponding cGMP	✓	✗	✗
Fabrication processes in dedicated cleanroom (GMP class D or ISO class 8)	✓	✗	✗
Food and drug conformity for filter media	✓	✓	✗
Tested for extractables and migration values according to EC 10/2011	✓	✓	✗
Food and drug conformity for filter media polymers	✓	✓	✓
ISO 9001 Quality control procedures	✓	✓	✓
Dedicated sales staff, including on-site sales support	✓	✓	✓
Products backed by engineering support staff	✓	✓	✓
PHARMA labels (where applicable)	✓	optional	optional
Conductivity certificate for complete filter (where applicable)	✓	optional	optional

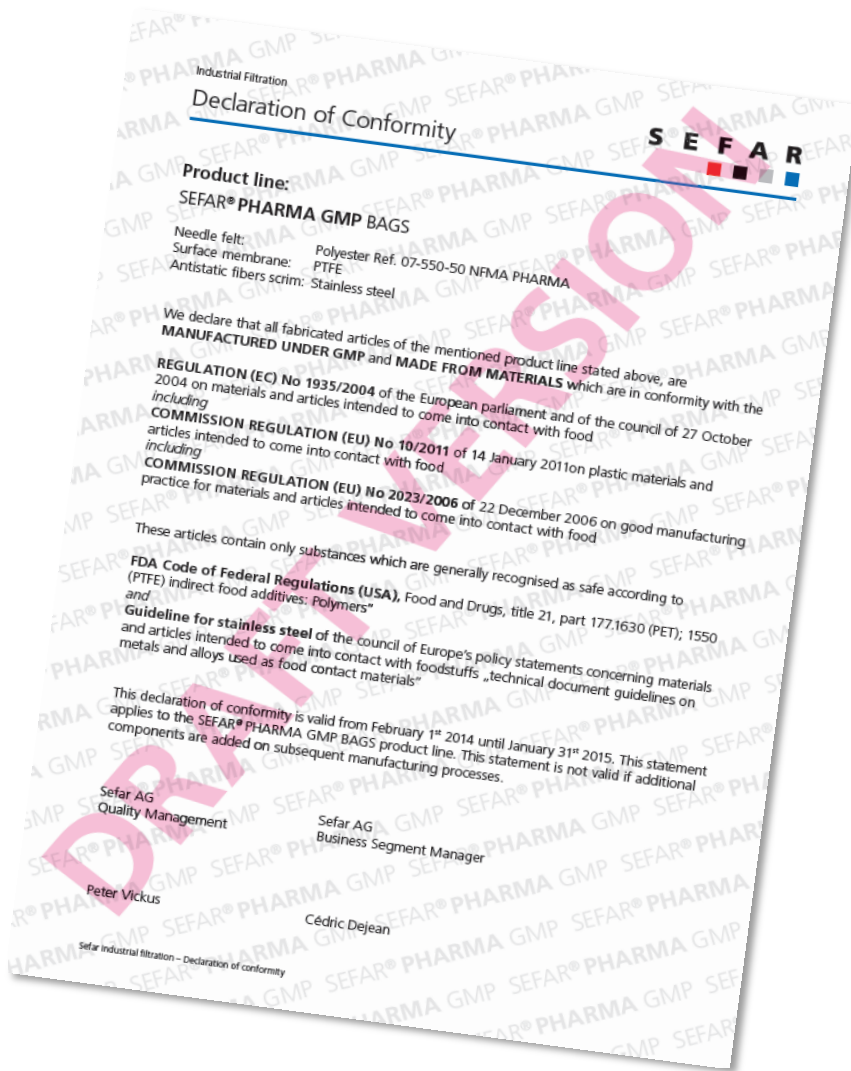


Documentation



	Material certifications FDA CFR, EU 10/2011, EC 1935/2004	Material data sheet	ATEX certification for conductive material	Process following GMP guidelines + Single packing	Test report with values upon request(*) (final inspection)
Top Level SEFAR PHARMA GMP BAGS					
Mid Level SEFAR PHARMA BAGS					
Low level SEFAR DUST BAGS					

SEFAR® PHARMA GMP Declaration (Top Level)



SEFAR® PHARMA Declaration (Mid Level)



Industrial Filtration
Declaration of Conformity

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Product line:
SEFAR® PHARMA BAGS

Needle felt: Polyester Ref. 07-550-50 NFMA PHARMA
Surface membrane: PTFE
Antistatic fibers scrim: Stainless steel

We declare that all articles stated above, **ARE MADE FROM MATERIALS** which are in conformity with the

REGULATION (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food.
COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

These articles contain only substances which are generally recognised as safe according to

FDA Code of Federal Regulations (USA, Food and Drugs, title 21, part 177.1630 (PET); 1550 (PTFE) indirect food additives: Polymers

and
Guideline for stainless steel of the council of Europe's policy statements concerning materials and articles intended to come into contact with foodstuffs „technical document guidelines on metals and alloys used as food contact materials“

This declaration of conformity is valid from February 1st 2014 until January 31st 2015. This statement applies to the SEFAR® PHARMA BAGS article only. This statement is not valid if additional components are added on subsequent manufacturing processes.

Sefar AG
Quality Management

Peter Vickus

Sefar AG
Business Segment Manager

Cédric Dejean

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Sefar Industrial Filtration - Declaration of conformity



ATEX Declaration

Industrial Filtration
SEFAR
SEFAR PHARMA BAGS ATEX

Declaration of Conformity

ATEX Directive 94/9 - Compatibility:

Customer: To whom it may concern

Product: Dust Filter Bags made out of Polyester Needle Felt

Sales no.: SEFAR® PHARMA 07-550-100 NFMA

Date: 3.March 2014

Validity: 05.2014 to 05.2015

Herewith, Sefar AG confirms the safety assessment against electrostatic chargeability based on the ATEX Directive EC 94/9 (Class Components).

Statement after a careful examination of the compounds of interest:
The filter material can be used in hazardous dust areas of zones 20, 21 and 22 as well as in hazardous areas by fuel gas/air or solvent vapor-air mixtures of zones 0,1 and 2 for the explosion groups II A, II B and II C.

This statement is valid only for the mentioned Felt Quality with permanent conductive support structure, resistance $<10^6$ ohms (according to DIN 54345 Part1 and Part 5).

Sefar AG
Sefar AG
Quality Management
Peter Vickus

Sefar AG
Business Segment Manager
Cédric Dejean

Sefar Industrial filtration - Declaration of conformity



Single packing for top level



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Design your bag



Window for filter media selection:

Filter Media	07-550-50 NFMA (Antistatic polyester with PTFE Membrane)
Quantity per Order	07-550-50 NFM (Polyester with PTFE Membrane) 24-750-50 NFMA (Antistatic PTFE with PTFE Membrane) 24-750-50 NFM (PTFE with PTFE Membrane)

Window for level selection:

Manufacturing Level	PHARMA.GMP
Filter Media	PHARMA None
Quantity per Order	Quantity per Year

Window for top connection selection:

Top	Snap ring Stainless steel ring Silicon ring Strina ring Cut + hem (15mm)
Bottom	

Window for bottom selection

Bottom	Open Closed Flat
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Brochure



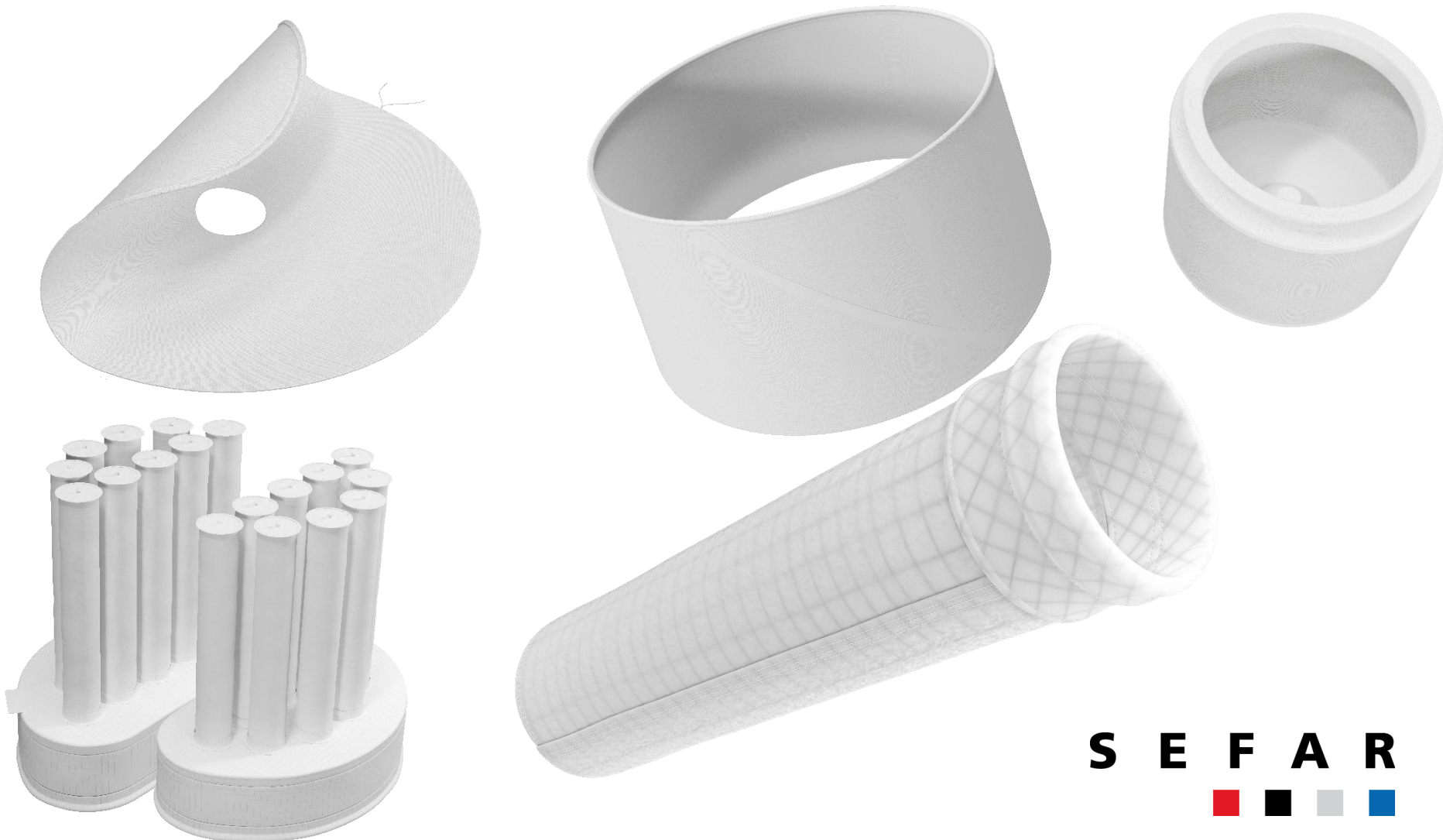
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To explore the complete SEFAR® PHARMA product line
(Fluid bed dryers, centrifuge bags and liners, filter disks...)
and more, visit our website www.sefar.com



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