

This Specification Guideline is designed to assist in the specification of Donaldson sterile air filters. As a market leader in compressed air and gas filtration products, Donaldson has set forth the following performance and material specifications as a guideline for sterile air filtration. These are minimum, product-related requirements that do not represent the full range of requirements that your system may need and may not identify all potential considerations.

SECTION 1 – QUALITY ASSURANCE

- 1.1 *Filter elements must be completely staged, assembled, tested, and packaged in a facility whose quality management system is approved by an accredited registering body to the appropriate ISO9000 quality systems standard.*
- 1.2 *All component materials used must be FDA listed for food contact use in accordance with CFR Title 21 as well as EEC/1935/2004. All plastic or elastomeric component materials shall meet the criteria for USP Class VI testing.*
- 1.3 *Filter elements must be non-fiber releasing as defined in 21 CFR 210.3 (b) (6) and fabricated without the use of binders, adhesives, additives, or surface-active agents.*
- 1.4 *Sterile filter elements must be rated using the most penetrating pore size (MPPS) and be 100% integrity tested during production relative to the MPPS.*

SECTION 2 – PERFORMANCE SPECIFICATIONS

P- SRF N Filter Performance and Operating Specifications		
Filter Specification	Value	Measure
Retention Efficiency (Gas)	≥99.99998%	0.2 μm
Retention Efficiency (Gas)	≥99.9999998%	0.01 μm
Bacterial/Viral Retention	≥7	LRV of B. diminuta / cm ² media
	≥9	LRV of MS-2 Coliphages / cm ² media
Media Air Permeability	2.75	ft ³ /(min*ft ²) @ 0.5 in. H ₂ O ΔP
Cumulative Sterilization Time	≥180	30 min. cycles, 250°F sat. steam
	≥150	20 min. cycles, 270°F sat. steam
	≥150	10 min. cycles, 290°F sat. steam
	≥50	hours H ₂ O ₂ exposure @ 1,000ppm / 266°F
Integrity Test	≥99.99998% @ 0.2 μm	DOP Test per ASTM D2986-91
Operating Temperature Range	-4 to 300	Degrees Fahrenheit
Max Pressure Differential	75	lb/in ² (either direction)

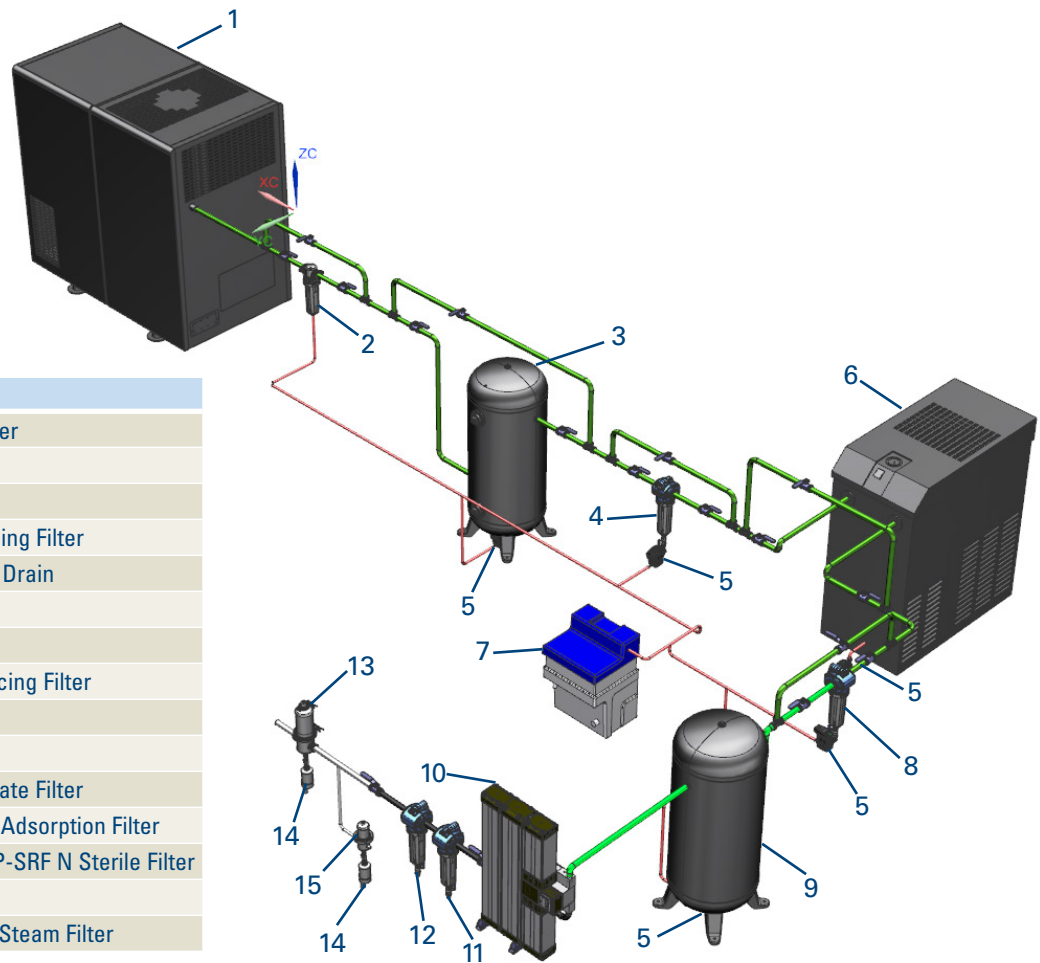
SECTION 3 – INSTALLATION AND USE SPECIFICATIONS

- 3.1 *Sterile air filters are to be installed in sanitary design free-draining housings made of SAE 300 series having an interior surface finish =/ <RA 32 microinch with an associated drain.*
- 3.2 *Sterile air filters must be supplied with clean, dry, air pre-treated with coalescing filters.*
- 3.3 *Sterile air filter assemblies must be sterilized regularly in order to inactivate captured microorganisms.*
- 3.4 *Sterile air filter integrity should be checked on a regular basis, for example after steam sterilization. The integrity test used shall be correlating to an actual bacterial retention test challenge.*
 - 3.4.1 *Sterile depth filters must be tested using a Paraffin aerosol challenge according to ASTM D 2986-91 using oil approved for food contact by FDA under 21 CFR 175.250.*
 - 3.4.2 *Sterile membrane filters should be tested using bubble point, diffusion, and/or water intrusion test methods.*

SECTION 4 – MATERIALS SPECIFICATIONS

P- SRF N Filter Materials of Construction		
Part	Material	CFR Title 21
Filtering Media	Borosilicate	177.2260
Coating	Polydimethylsiloxane	177.2260
Scrim	SAE grade 304	211.56
Cage & Core	SAE grade 304	211.56
End Caps	SAE grade 304	211.56
O-rings	Silicone	177.2600
Potting Compound	Silicone	177.2600

RECOMMENDED STERILE AIR SYSTEM



No.	Description
1	Air Compressor with Aftercooler
2	DF-C Cyclone Separator
3	Wet Storage Tank
4	DF Filter with V-Grade Coalescing Filter
5	UFM-D Zero-Loss Condensate Drain
6	Refrigerated Dryer
7	DS Oil/Water Separator
8	DF Filter with M-Grade Coalescing Filter
9	Dry Storage Tank
10	Ultrapac 2000 Dryer
11	DF Filter with S-Grade Particulate Filter
12	DF Filter with A-Grade Carbon Adsorption Filter
13	PG-EG Sanitary Housing with P-SRF N Sterile Filter
14	Condensate Trap/Drain
15	P-EG Housing with P-GS 5 µm Steam Filter

Important Notice

This document is not intended as a replacement for careful review of all applicable laws, regulations, and standards. It is the user's responsibility to design, use, and maintain a steam system in accordance with all applicable laws, regulations and standards. Many factors beyond the control of Donaldson can affect the use and performance of Donaldson products in a particular application, including the conditions under which the product is used. Since these factors are uniquely within the user's knowledge and control, it is essential the user evaluate the products to determine whether the product is fit for the particular purpose and suitable for the user's application. All products, specifications, availability and data are subject to change without notice, and may vary by region or country.



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