Donaldson
FILTRATION SOLUTIONS

STERILE LIQUID FILTERS
SPECIFICATION GUIDELINE

Process Filtration

This Specification Guideline is designed to assist in the specification of Donaldson sterile liquid filters. As a market leader in compressed air and liquid 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 Class 7 clean room 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 and contain no Substances of Very High Concern (SVHC).

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

PES-WN 0.2 Micron Filter Performance and Operating Specifications		
Filter Specification	**Value**	**Measure**
Retention Efficiency (Liquid)	≥99.99998%	0.2 µm
Bacterial Retention	≥7	LRV of B. diminuta / cm^2 media
Media Air Permeability		$ft^3/(min*ft^2)$ @ 0.5 in. H_2O ΔP
Cumulative Sterilization Time	>/=100	30 min. cycles, 250°F sat. steam
Integrity Test	>/=43.9	psi, water-wetted bubble point
Max Operating Temperature	</=180	Degrees Fahrenheit
Max Pressure Differential	80	lb/in^2 @ 100°F

SECTION 3 – INSTALLATION AND USE SPECIFICATIONS

3.1 Sterile liquid filters are to be installed in sanitary design free-draining housings made of SAE 300 series having an interior surface finish =/<RA 32 microinch. When integrity testing is expected, housing should have vent and drain ports available.

3.2 Sterile liquid filters must be supplied with clean, dry, air pre-treated with coalescing filters.

3.3 Sterile liquid filter assemblies must be sterilized regularly in order to inactivate captured microorganisms.

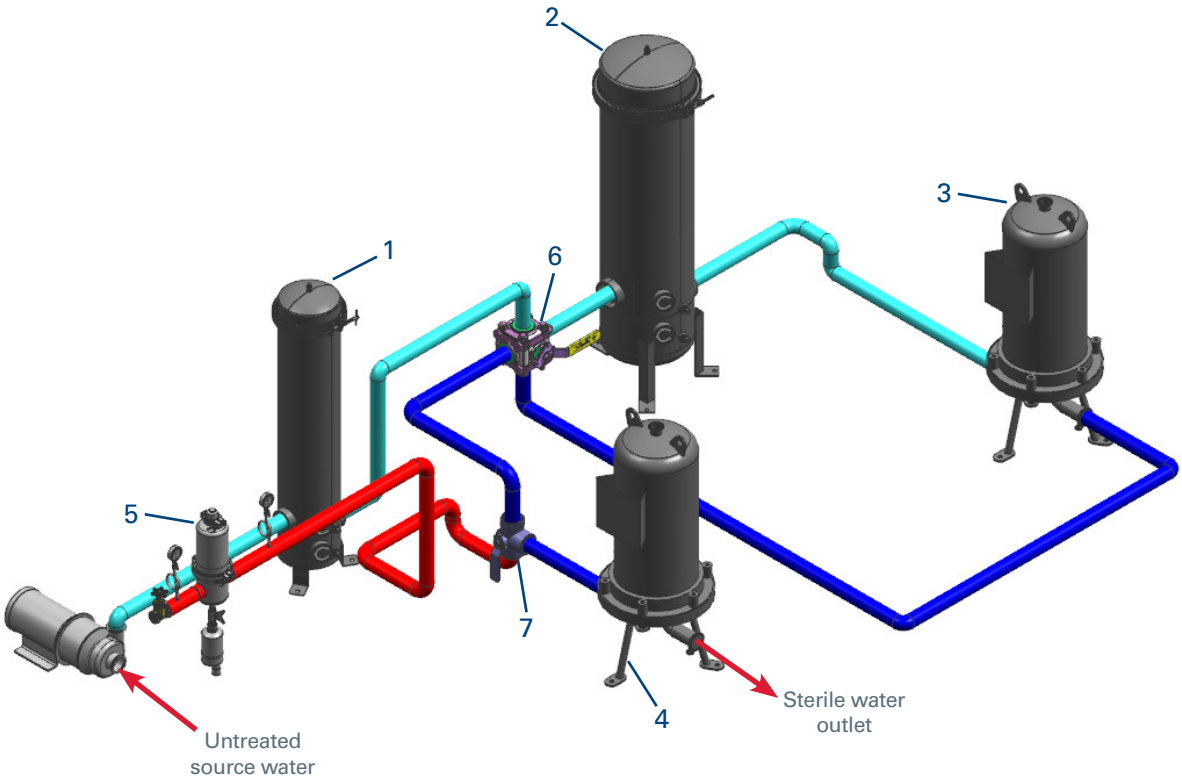
3.4 Sterile liquid filter integrity should be checked on a regular basis, for example after steam sterilization. The integrity test used shall be correlating to an actual bacterial retention test challenge.

3.4.1 Sterile membrane filters should be tested using bubble point, diffusion, and/or water intrusion test methods.

SECTION 4 – MATERIALS SPECIFICATIONS

PES-WN 0.2 Micron Filter Materials of Construction		
Part	**Material**	**CFR Title 21**
Filtering Media	Polyethersulfone	177.2240
Scrim	Polypropylene	177.1520
Cage & Core	Polypropylene	177.1520
End Caps	Polypropylene	177.1520
O-Rings	EPDM	177.2600

RECOMMENDED STERILE LIQUID SYSTEM



No.	Description	Purpose
1	P-FG Housing and PP-TF Element	Coarse water pre-filter removes sediment, rust and sand
2	P-FG Housing and Carbon Block Element	Pre-filter removes unwanted source water treatment chemicals such as chlorines
3	PF-EG Housing and PP100 Element	Membrane pre-filter protects more expensive membrane from fouling
4	PF-EG Housing and PES-WN Element	Final sterilizing membrane filter removes micro-organisms from process stream
5	P-EG Housing and P-GS Element	Steam sterilization of sterile liquid membrane filters PES-WN
6	Four-way Sanitary Valve	Allows for isolation of carbon filter and membrane pre-filter for servicing without interruption of process flow
7	Three-way Sanitary Valve	Allows steam to be introduced to final sterile filter assembly for sterilization

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