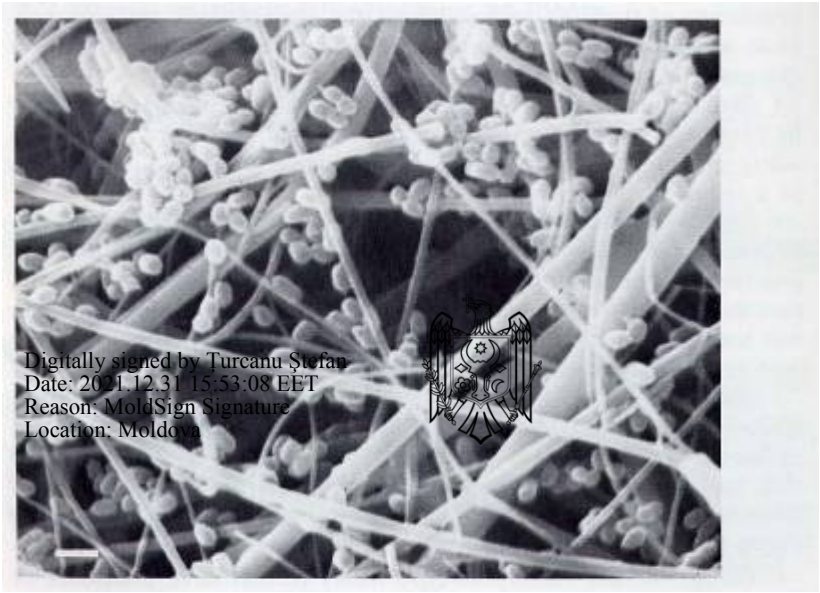
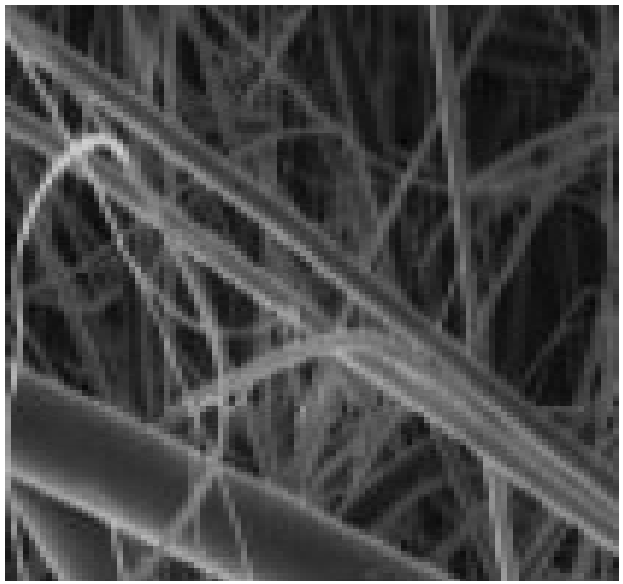
Sterile Air & Gas Filters

Types of Sterile Air & Gas Filters / Retention Mechanisms

→ Sterile Air and Gas Depth Filter



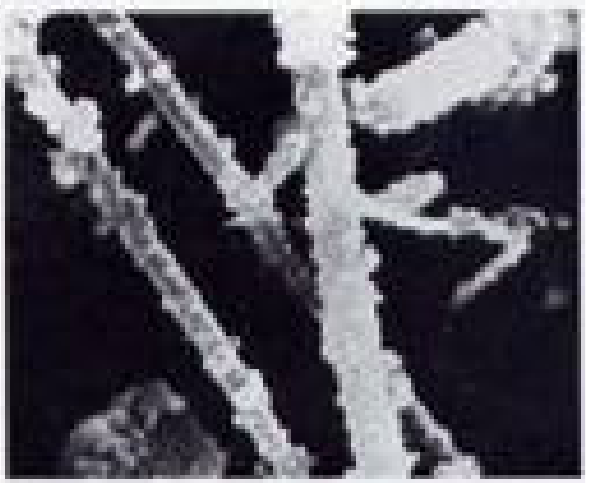


Donaldson
FILTRATION SOLUTIONS

Sterile Air & Gas Filters

Types of Sterile Air & Gas Filters / Retention Mechanisms

→ Sterile Air and Gas Depth Filter: Retention Mechanism



Retention mainly based on:

→ Diffusion (< 0,1µm)
→ Impaction (> / = 1µm)
→ Electrical Attraction (< 1µm)
→ Partly Direct Interception (> 10µm)

Efficiency of filtration depending on:

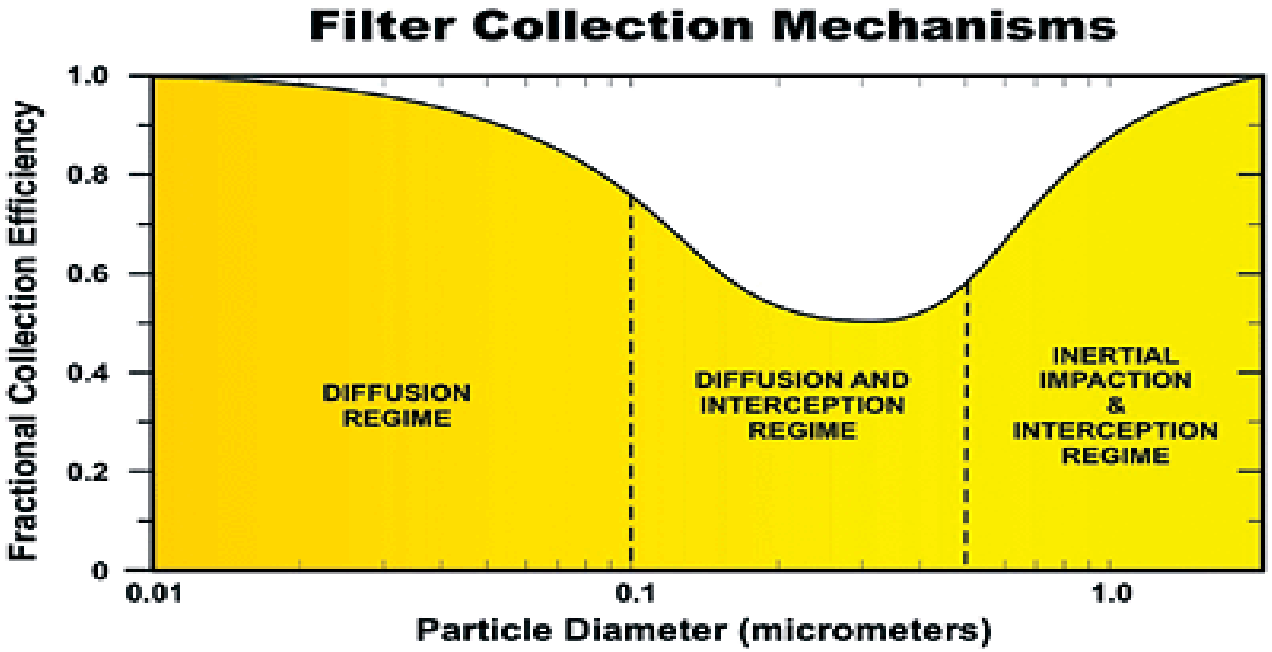
- Effective Length of channels to be flown through
- Thickness and depth of the filter media
- Adsorptive properties of the filter media
- Nature of contaminations to be filtered

Donaldson
FILTRATION SOLUTIONS

Sterile Air & Gas Filters

Types of Sterile Air & Gas Filters / Retention Mechanisms

→ Sterile Air and Gas Depth Filter: Retention Mechanism



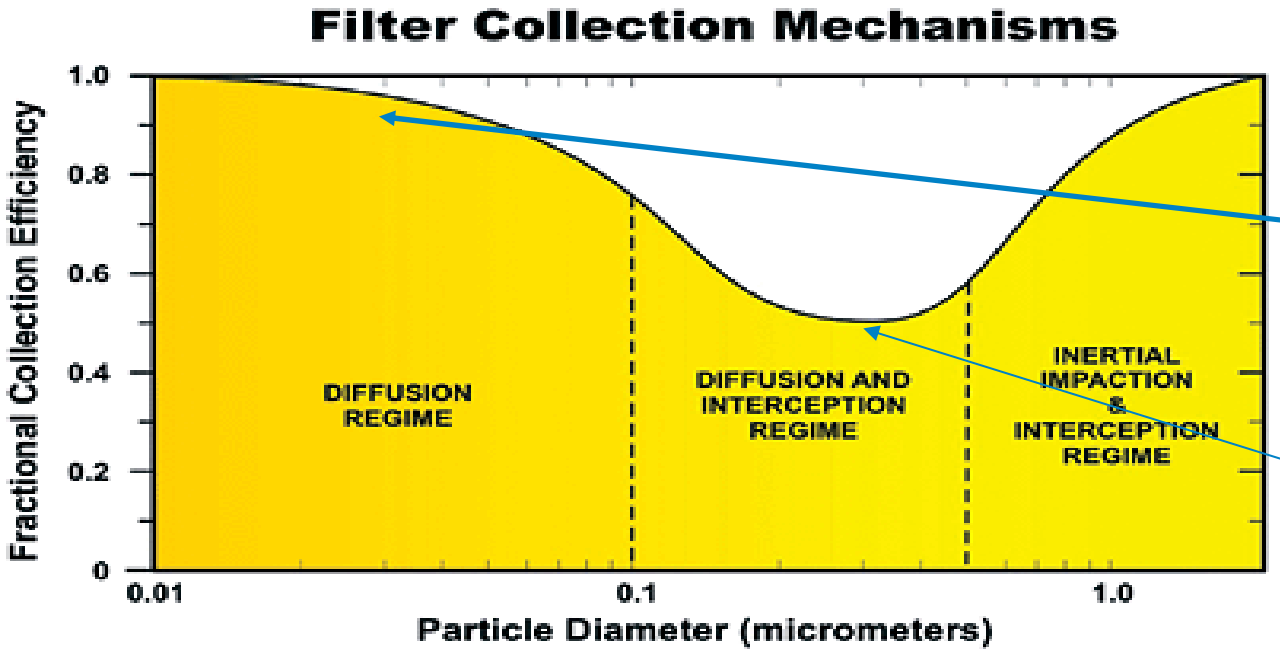
→ Retention Efficiency is lowest between 0,2µm – 0,3µm
→ Area is called MPPS Range (Most Penetrating Pore Size)
→ FDA Definition is based on Retention Efficiency in this range
→ Integrity tests (DOP Test) carried out at 0,2µm – 0,3µm

Donaldson
FILTRATION SOLUTIONS

Sterile Air & Gas Filters

Types of Sterile Air & Gas Filters / Retention Mechanisms

→ Sterile Air and Gas Depth Filter: Retention Mechanism



LRV = 9-10/cm²

LRV >/= 7/cm²

Retention Efficiency: Donaldson P-SRF N:
LRV for Brevundimonas diminuta (0,3µm): >/= 7/cm²
LRV for MS-2 Coliphagae (0,02µm): = 9-10/cm²

Sterile Air & Gas Filters

Relevant Criteria for Sterile Air & Gas Filters

→ FDA Title 21 Compliance and EC/1935/2004 Compliance

L 338/4 EN Official Journal of the European Union 13.11.2004

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 and repealing Directives 80/590/EEC and 89/109/EEC

→ For the territory of the European Union all materials used need to be tested and approved for direct or indirect Food Contact Use. Article 3 of EC/1935/2004:

The principle underlying this Regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.

→ Check the filter for FDA & EC Compliance

Donaldson
FILTRATION SOLUTIONS

Sterile Air & Gas Filters

Relevant Criteria for Sterile Air & Gas Filters

→ Retention Efficiency for Bacteria

According to the FDA definition of a sterilizing grade filter the retention efficiency for the bacterium Brevundimonas diminuta has to be equal to or larger than 99,99999% per sqcm of filtration surface.
This means the LRV >/= 7/cm^2.

Each filter element, which does not fulfill this requirement, is not a sterilizing grade filter and should not be used for applications with sterile requirements.

Very important for:
- Food and Beverage Applications
- Pharmaceutical Applications
- BioTech & Health Care Applications

Donaldson
FILTRATION SOLUTIONS

→ Check the filter for a correct retention rate at 0,2µm – 0,3µm (Brev. diminuta)

Sterile Air & Gas Filters

Relevant Criteria for Sterile Air & Gas Filters

→ Retention Efficiency for Phagae & Virus

Especially for Applications including fermenter ventilation or Lactic Acid Fermentation in the dairy industry any kind of infection with Phagae or Virus is strictly to avoid.
Despite the fact that the average content of Bacteriophagae in one liter air is quite low (3 – 5 / litre), the retention efficiency should be at least 99,9999% per cm^2 (~ LRV >/= 6/cm^2).

The retention rate for virus/phagae (usually 0,01µm – 0,03µm) is not required by the FDA. An indication of this retention efficiency is not enough to qualify a filter element as sterile filter.

Donaldson
FILTRATION SOLUTIONS

→ Check the filter for the retention rate for Virus/Phagae