

# DECLARATION OF COMPLIANCE

## Profile® II Filter Cartridges

### AB Style “W” Code

### Cartridge Part Number

AB    W

Table 1    Table 2    Table 3                      Table 4

This is a guide to the part numbering structure only. For specific options, please contact Pall.

**Table 1 : Nominal Length**

Code	Description
1	25.4 mm (10")
2	508 mm (20")
3	762 mm (30")
4	1016 mm (40")

**Table 2 : Removal Rating**

Code	Description
Y003	0.3 µm
Y005	0.5 µm
Y010	1 µm
Y030	3 µm
Y050	5 µm
Y100	10 µm

**Table 3 : Adaptor**

Code	Description
3	SOE – single open end with flat closed end and external 222 O-rings
7	SOE – single end with fin end, 2 locking tabs and external 226 O-rings
8	SOE – single open end with fin end and external 222 O-rings
28	SOE – single open end with fin end, 3 locking tabs and external 222 O-rings

**Table 4 : O-ring Seal Material**

Code	Description
H4	Silicone Elastomer
J	Ethylene Propylene Rubber

Pore size variation with the Profile II medium is achieved by varying the fiber diameter while maintaining uniform density. This results in uniform compressibility and high void volume for extended service life.

Profile II polypropylene filter medium does not contain surfactants or binder resins.

AB style Profile II filter cartridges are suitable for use in aqueous-based and low alcohol-based food and beverage products (e.g. wine and beer), excluding fatty food.

An initial flush is recommended prior to use.

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## Profile II Filter Cartridges (AB Style “W” Code)

### Components

Filter Media	Polypropylene
Cage, Core, End Cap and Fin End	Polypropylene
Adaptor	Polypropylene with a stainless steel reinforcing ring as appropriate to the design*
O-ring Seal	Ethylene Propylene Rubber (J) and Silicone Elastomer (H4)

\*For applications requiring autoclaving or steam sterilization, Pall recommends the use of Code 2 or Code 7 adaptors to ensure filter sealing after cooling. Cartridges should be cooled to system operating temperature prior to use.

### Declaration

AB style Profile II “W” Code filter cartridges are comprised of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

#### Europe

The “W” Code AB style Profile II polypropylene filter cartridges meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

- Our suppliers state that the polypropylene materials used to produce 'W' option AB style Profile II products are made from monomers and additives consistent with Annex 1 of Commission Regulation (EU) Number 10/2011 relating to plastic materials and articles intended to come into contact with foodstuffs and subsequent amendments (excluding seals).
- OML and SML migration testing of AB style Profile II filters was performed, and met migration criteria after flushing and in flow conditions in:
  - Simulant A (10% ethanol) for 2 hours at 100 °C (212 °F)
  - Simulant B (3% acetic acid) for 2 hours at reflux
  - Simulant C (20% ethanol),
 at minimum flow of 0.03 kg/hr per 10" filter length.

In addition, OML and SML migration testing of Profile II filter medium tested as an E604Y400MW filter (manufactured at Pall Ilfracombe) was carried out in:  
Simulant B (3% acetic acid) for 4 hrs at reflux

Note: This product contains calcium stearate, which is approved as a direct food additive.

- Typical samples of the 'H4' seal material formulations specified for 'W' code Profile II filters have been tested as 226 size seals for volatiles and found to be within the specifications of the BfR requirements of 0.5% after heating at 200 °C (392 °F) for 4 hours.

In addition, typical samples of the 'H4' and 'J' seal material formulations specified for 'W' code Profile II filters have been tested as 226 size seals for overall migration. Testing was conducted in distilled water, 3% acetic acid, 20% ethanol and 50% ethanol, under reflux conditions for 4 hours - repeat use. In respect of the overall migration limit for food contact elastomers according to the French requirements (given in Arrete of November 9th 1994 and published in Journal Officiel de la Republique Francaise, December 2nd 1994, p17029-17036) is 10 mg/dm<sup>2</sup>, data obtained with the rubber o-rings under the tested conditions was well within this limit. The seal materials are suitable for repeated use in aqueous based foods.

The volatile levels from samples of the silicone elastomer (H4) formulation, after heating at 200 °C (392 °F) for 4 hours, was found to be within the BfR section XV specification for this material.

Our supplier states that the EPR (J) seal formulation is suitable for food contact use under BfR XXI category 4.

Users should satisfy themselves that these materials are suitable for use in their specific food application.

## USA

The materials of construction meet the FDA requirements for food contact use as detailed in *Code of Federal Regulations*, 21 CFR paragraphs 170-199 in that:

- Polypropylenes to section 177.1520 (olefin polymers) and section 178.2010 (antioxidants and/or stabilizers for polymers).
- Ethylene Propylene Rubber and Silicone elastomeric seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils).

In addition, typical samples of the “H4” seal material formulations specified for “W” code Profile filters have been tested as 226 size seals for overall migration. Testing was conducted in n-hexane and found to be within the specifications of the FDA regulations for materials intended for repeated use in fatty type foods.

## Process Quality System

Site of Manufacture: Pall Manufacturing (UK) Ltd., Ilfracombe, UK on behalf of Pall International Sàrl.

The Quality Management System at Pall Manufacturing (UK) Ltd., Ilfracombe, is certified to ISO 9001:2015.

These products / product packaging carry a lot number / date code to facilitate traceability to suppliers' materials and Pall production records.

Pall Manufacturing (UK) Ltd. confirms that the product is manufactured in line with the principles of food contact materials GMP as detailed in Regulation 2023/2006

## Supplied in Europe by

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