

# DECLARATION OF COMPLIANCE

## Profile® II Filter Cartridges

### AB Style “W” Code

#### Cartridge Part Number



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). Additionally, some grades may be utilized for fatty food or oil applications.

An initial flush is recommended prior to use.

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Syed Sirajuddin  
Pall Sàrl and MEA QARA Manager

## 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 I and II 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 was performed and met migration criteria after flushing and in flow conditions in:

- Simulant B (3% acetic acid) for 2 hours at reflux
- Simulant D1 (65% ethanol) for 2 hours at reflux
- Simulant D2 (sunflower oil) for 2 hours at 40 °C (104 °F)
- Distilled water for 2 hours at 70 °C (158 °F)

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

**French requirements for food contact elastomers (Arrêté of 9th November 1994 amended by order of 5th August 2020)** Typical samples of the ‘H4’ (Silicone) and ‘J’ (EPDM) seal material formulations have been tested as BS3601-226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid, 20 % ethanol, 50 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the ‘H4’ O-rings, under the test conditions, were well within the limit for all migration fluids tested. The data obtained with the ‘J’ O-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid, 20 % ethanol and 50 % ethanol. The ‘J’ O-rings are not suitable for use in fatty foods.

**German requirements for food contact elastomers (BfR XV Silicones)** Typical samples of the ‘H4’ (Silicone) seal material formulation have been tested as BS3601-226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid, 10 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the ‘H4’ O-rings, under the test conditions, were well within the limit for all migration fluids tested.

**German requirements for food contact elastomers (BfR XXI Natural and Synthetic Rubber Category 1)** Typical samples of the ‘J’ (EPDM) seal material formulation have been tested as BS3601-226 size seals for overall migration. Testing was conducted in distilled water, 3 % acetic acid, 10 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the ‘J’ O-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid and 10 % ethanol. The ‘J’ O-rings are not suitable for use in high alcohol or fatty foods. Additionally, our supplier states that this O-ring 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.

### **Mercosur**

The materials of construction meet the requirements for food contact as detailed in Reglamento Técnico Mercosur sobre materiales lista positiva de

- monómeros, otras sustancias de partida y polímeros autorizado para la elaboración de envases y equipamientos plásticos in contacto con alimentos, Mercosur/GMC/Res. No. 19/21 y
- aditivos para materiales plásticos destinados a la elaboración de envases y equipamientos in contacto con alimentos, Mercosur/GMC/Res. No 56/92.

### **People's Republic of China**

The “W” Code Claris filter cartridges meet requirements for food contact materials as detailed in GB 4806.1-2016. These filters meet the requirements detailed in Chinese standard Numbers GB 46806.7-2023 and GB 4806.11-2023. OML and SML migration testing of cartridges (excluding seals) has been performed and met migration criteria after flushing and in flow meeting the requirements for use.

### **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: Manufactured in the UK and supplied by Pall Sàrl. Made in the UK.

The Quality Management System at the manufacturing site 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 Sàrl confirms that this product is manufactured in line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

**Supplied in Europe by**

Pall Sàrl  
Av. de Tivoli 3  
Fribourg  
Switzerland  
CH-1700



+1-866-905-7255 **Food and Beverage toll free**  
foodandbeverage@pall.com

**Corporate Headquarters**

Port Washington, NY, USA  
+1-800-717-7255 toll free (USA)  
+1-516-484-5400 phone

**European Headquarters**

Fribourg, Switzerland  
+41 (0)26 350 53 00 phone

**Asia-Pacific Headquarters**


Singapore  
+65 6389 6500 phone

**Visit us on the Web at [www.pall.com/foodandbev](http://www.pall.com/foodandbev)**

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The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

*IF APPLICABLE* Please contact Pall Corporation to verify that the product conforms to your national legislation and/or regional regulatory requirements for water and food contact use..

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