

# DECLARATION OF COMPLIANCE

## MEMBRACart XL II Filter Cartridges

“W” Code

### Cartridge Part Number

419A 020 W    P

Table 1   Table 2   Table 3

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

**Table 1 : Adaptor**

Code	Description
03	SOE – single open end with flat closed end and external 222 O-rings
07	SOE – single open end with fin end and external 226 O-rings
08	SOE – single open end with fin end and external 222 O-rings
41	SOE – single open end with fin end, 3 locking tabs and external 222 O-rings

**Table 2 : Nominal Length**

Code	Description
1	254 mm (10")
2	508 mm (20")
3	762 mm (30")
4	1016 mm (40")

**Table 3 : O-ring Seal Material**

Code	Description
S	Silicone Elastomer
E	Ethylene Propylene Rubber

MEMBRACart XL II filter cartridges are manufactured from hydrophilic polyethersulfone medium with polypropylene hardware, support and drainage layer.

MEMBRACart XL II filter cartridges are primarily for use in aqueous applications (e.g. water filtration) up to 40 °C (104 °F).

An initial flush is recommended prior to use.

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 Pall S&I and MEA QARA Manager

## MEMBRACart XL II Filter Cartridges (“W” Code)

### Components

Filter Media	Supor® polyethersulfone (hydrophilic) membranes
Support / Drainage	Polypropylene
Cage, Core, End Cap and Fin End	Polypropylene
Adaptor	Polypropylene with a stainless steel reinforcing ring as appropriate to design
O-ring Seal	Silicone Elastomer (S) and Ethylene Propylene Rubber (E)

### Declaration

MEMBRACart XL II filter cartridges comprise of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

#### Europe

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

Our suppliers' information indicates that the polymeric materials used to produce “W” Code MEMBRACart XL II filters are made from monomers and additives consistent with Annex I of Commission Regulation (EU) Number 10/2011 and its amendments, relating to plastic materials and articles intended to come into contact with foodstuffs (excluding seals).

OML and SML migration testing of cartridges (excluding seals) has been performed and met migration criteria after flushing and in flow conditions, in:

- Simulant B (3 % acetic acid) for 30 minutes at 40 °C (104 °F)
- Simulant D1 (50 % ethanol), for 30 minutes at 40 °C (104 °F)
- And water up to 70 °C (158 °F).

Note: This product contains materials that are subject to Specific Migration Limit (SML) requirements. This product contains calcium stearate, which is approved as a direct food additive.

Our supplier states that the ingredients of the silicone elastomeric material employed are in compliance with Recommendation XV of the BfR and Arrêté du 25 novembre 1992.

**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 ‘S’ 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 ‘S’ 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 ‘E’ O-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid and 10 % ethanol. The ‘E’ 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 MEMBRACart XL II 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 4806.11-2016. 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 contact use as detailed in Code of Federal Regulations, 21 CFR paragraphs 170-199 in that:

- Polypropylene to 21 CFR section 177.1520 (Olefin polymers)
- Polyethersulfone to 21 CFR section 177.2440 (Polyethersulfone resins)
- Silicone Elastomeric seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils)
- Ethylene Propylene Rubber seal material to 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils)

### **Process Quality System**

Site of Manufacture: Manufactured in Germany and supplied by Pall Sàrl. Made in Germany

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**

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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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