

DECLARATION OF COMPLIANCE MEMBRACart XL II Filter Cartridges “W” Code

Cartridge Part Number

419A W P
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 : Microbial Removal Rating

Code	Description
020	0.2 µm
045	0.45 µm
065	0.65 µm

Table 2 : 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 3 : Nominal Length

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

Table 4 : O-ring Seal Material

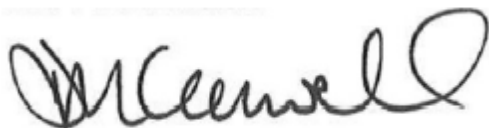
Code	Description
S	Silicone Elastomer
E	Ethylene Propylene Rubber

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 non-alcoholic as well as alcoholic beverages such as water and wine filtration applications at up to 40 °C (104 °F).

An initial flush is recommended prior to use.

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 Reference FBDCMEMBRAENj
 Page 1 of 3



Dawn Cromwell
 Director, QA
 Laboratory, Food & Beverage

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)

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).

Migration testing has been performed on sample filters (excluding seals), 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)

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 Arrete du 25 novembre 1992.

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)
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Process Quality System

Site of Manufacture: Pall Filtersystems GmbH, Bad Kreuznach, Germany on behalf of Pall International Sàrl.

The Quality Management System at Pall Filtersystems GmbH, Bad Kreuznach is certified to ISO 9001:2008. These products / product packaging carry a lot number / date code to facilitate traceability to suppliers’ materials and Pall production records.

Pall Filtersystems GmbH confirm that the product manufacturing environment, for the above product at our Bad Kreuznach site, is in line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

Supplied in Europe by

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