

## DECLARATION OF COMPLIANCE Emflon® PFRW Filter Capsules Kleenpak™ W Code

### Capsule Part Number

K A  PFR W 1

Table 1

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

**Table 1 : Nominal Size**

Code	Description		
	Length (mm) <sup>1</sup>	Diameter (mm) <sup>2</sup>	Diameter (mm) <sup>3</sup>
1	117	61	94
2	158	61	94
3	174	76	110

<sup>1</sup> Length including 38 mm sanitary connections

<sup>2</sup> Excluding valves

<sup>3</sup> Including valves

"W" Code Emflon PFRW Kleenpak style filter capsules are designed for sterile gas filtration in the food and beverage industry.

'Sterile air' is defined as that filtered using a 0.2 µm liquid rated filter (capable of removing 10<sup>7</sup> of *Brevundimonas diminuta* per cm<sup>2</sup> of effective filtration area, in laboratory tests).

Please note this product is not supplied pre-sterilized.

The key feature of this product is the inclusion of two layers of hydrophobic, 0.2 µm microbially-rated Emflon PTFE medium in a polypropylene hardware filter capsule construction.

Issued	18 April 2016
Revision	28 February 2017
Expires	28 February 2019
Reference	FBDCKPKPFRENa
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## Emflon PFRW Filter Capsules (Kleenpak "W" Code)

### Components

Filter Membrane	PTFE
Support/Drainage	Polypropylene
Core, Cage, End Caps	Polypropylene
Outer Shell	Polypropylene
O-Ring Seals (Vent/Drain Valves)	Ethylene Propylene Rubber

### Declaration

W" Code Emflon PFRW Kleenpak style filter capsules comprise materials that meet regulatory and legislative requirements and guidelines for food contact in that:

### Europe

"W" Code Emflon PFRW Kleenpak style filter capsules meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

- Our suppliers state that the monomers and additives employed in the polymeric components of the construction are consistent with Annex I of European Regulation (EU) number 10/2011 and subsequent amendments relating to plastic materials and articles intended to come into contact with foodstuffs (excluding seals).
- These articles are intended for indirect food use in filtration of gases, therefore migration testing is not applicable.

### USA

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

- PTFE to 21 CFR section 177.1550 (Perfluorocarbon resins)
- Polypropylene to 21 CFR section 177.1520 (Olefin polymers)
- Ethylene Propylene Rubber seal material is listed in 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils)

### Process Quality System

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

These products are manufactured under a Quality Management System certified to ISO9001:2008.

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

Pall Manufacturing (UK) Ltd., Ilfracombe, UK confirm that the product manufacturing environment, for the above product at our 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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