

# DECLARATION OF COMPLIANCE

## Fluorodyne® II Filter Cartridges, JSD

### “W” Code

### Cartridge Part Numbers

AB   JSD   WH4  
Table 1                      Table 2

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

**Table 1 : Nominal Length**

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

**Table 2 : Adaptor**

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

\*available in AB3 only

Fluorodyne II filter cartridges (JSD) are intended for use in water and bottled water applications and excludes filtration of fatty foods. The filter medium comprises a hydrophilic PVDF membrane.

An initial flush is recommended prior to use.

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## Fluorodyne II Filter Cartridges (“W” Code)

### Components

Filter Media	Hydrophilic polyvinylidene fluoride (PVDF) membranes
Cage, Core, End Cap and Fin End	Polypropylene
Adaptor	Polypropylene with a stainless steel reinforcing ring as appropriate to the design
O-ring Seal	Silicone Elastomer (H4)

### Declaration

Fluorodyne II “W” Code filter cartridges (JSD) comprise of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

#### Europe

The “W” Code Fluorodyne 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 AB style Fluorodyne II products are made from monomers and additives consistent with Annex I of Commission Regulation (EU) Number 10/2011, relating to plastic materials and articles intended to come into contact with foodstuffs (excluding seals).

OML and SML migration testing of the filter components of the Fluorodyne II filters has been performed, and met migration criteria after flushing and in flow conditions in:

10 % ethanol up to 100 °C (212 °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.

**French requirements for food contact elastomers (Arrêté of 9th November 1994 amended by order of 5th August 2020)** 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, 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.

**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.

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

#### 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:

- Our suppliers state that base polymer materials used by Pall to manufacture the "JSDW" filter membrane and polypropylene components of the above Pall product are listed in 21 CFR 170-199:
- PVDF to 21 CFR section 177.2510 (Polyvinylidene fluoride resins) – excluding hydrophilicity
- Polypropylene to 21 CFR section 177.1520 (Olefin polymers)

- Hydrophilicity -- Membrane was analyzed as per ASTM D2857-95 test methods for conformance to FDA specifications for a food contact substance. The membrane met the specifications for polyvinylidene fluoride resins as described in Title 21 of the U.S. Code of Federal Regulations 177.2510 paragraphs (a), (b), and (c) including acceptable heavy metals content. Additionally, no specified or known adjuvants were detected at a limit of 0.001%.
- Silicone Elastomeric seal materials to 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 supplied by Pall Sàrl. Made in UK.

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

Pall Manufacturing (UK) Ltd., Ilfracombe, confirm that the product manufacturing environment, for the above products at our site, is in-line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

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Pall Corporation has offices and plants throughout the world. To locate the Pall office or distributor nearest you, visit [www.pall.com/contact](http://www.pall.com/contact).

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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