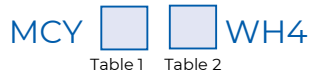


# DECLARATION OF COMPLIANCE

## Profile® Star Filter Cartridges

### MCY Junior Style “W” Code

#### Cartridge Part Numbers



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

**Table 1 : Nominal Length**

Code	Length	Description
4440*	105 mm (4.1")	Plug seal adaptor with locating fin and double external O-ring seals
4463	136 mm (5.3")	Single 116 O-ring and internal plug seal

\*Available in A010 grade only

**Table 2 : Removal Rating**

Code	Description
A010	1 µm
A030	3 µm
A100	10 µm

Profile Star Junior style pleated depth filter cartridges are manufactured using all polypropylene materials. They are designed for particle and gel removal in general food and beverage applications (aqueous, low alcohol beverages, fatty food or oil) and air/gas particle removal in food and beverage applications.

An initial flush is recommended prior to use in liquids.

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 Page         1 of 3



Andrew Betts  
 Quality Manager  
 Pall Manufacturing (UK) Ltd., Ilfracombe

## Profile Star Filter Cartridges (“W” Code)

### Components

Filter Media pack	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 (H4)

### Declaration

Profile Star “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 Profile Star filter cartridges meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

Our suppliers’ state that the polymeric materials used to produce “W” Code AB style Profile Star products 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 the filters and components of the Profile Star filters has been 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 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.

#### 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. 02/12 y
- aditivos para materiales plásticos destinados a la elaboración de envases y equipamientos in contacto con alimentos, Mercosur/GMC/Res. No 39/19.

## 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:

- Polypropylene to 21 CFR section 177.1520 (Olefin polymers)
- 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.

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, 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.

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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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