

## DECLARATION OF COMPLIANCE Ultipor® N66 Filter Cartridges Junior Style “W” Code

### Cartridge Part Number

MCY   W H4  
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	Length	Description
1110	32 mm (1.3")	Plug seal adaptor with locating fin and double external O-ring seals
2220	57 mm (2.2")	Plug seal adaptor with locating fin and double O-ring seals
4440	105 mm (4.2")	Plug seal adaptor with locating fin and double external O-ring seals
4463	127 mm (5.3")	Single 116 O-ring Seal and internal plug seal

**Table 2 : Removal Rating**

Code	Description	Membrane Layers
NF	0.2 µm	2
NA	0.2 µm	1
NB	0.45 µm	1

The product comprises of Pall proprietary Ultipor N66 filter medium with integral polyester non-woven support in a disposable filter cartridge using polypropylene and polyester hardware.

For use in water up to 70 °C (158 °F) and in low alcoholic applications at temperatures up to 49 °C (120 °F).

An initial flush is recommended prior to use.

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## Ultipor N66 Filter Cartridges (Junior Style “W” Code)

### Components

Filter Media	Ultipor N66 – nylon with integral polyester non-woven substrate
Support / Drainage	Polyester
Core / Cage	Polypropylene
End Cap	Polyester
O-ring Seal	Silicone Elastomer (H4)

### Declaration

Ultipor N66 Junior style “W” Code filter cartridges comprise of materials that meet regulatory and legislative requirements and guidelines for food contact in that:

#### Europe

The “W” Code Ultipor N66 Junior style 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 Junior Ultipor N66 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 of MCY4463NFWH4 style Ultipor N66 filter cartridges (excluding seals) / materials of construction has been performed as appropriate, in:

Simulant A (10% ethanol),  
Simulant B (3% acetic acid) and  
Simulant C (20% ethanol)

Component testing gave a maximum temperature limit of 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.

- Typical samples of the ‘H4’ and ‘J’ 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 and 50% ethanol, under reflux conditions for 4 hours - repeat use. In respect of the overall migration limit of 10 mg/dm<sup>2</sup>, as given in French requirements for food contact elastomers (Arrêté of November 9th 1994 and published in Journal Officiel de la Republique Française, December 2nd 1994, p17029-17036) the data obtained with the rubber o-rings, under the tested conditions, was well within the limit.
- Our supplier states that the ‘J’ ethylene propylene rubber material employed conforms to BfR XXI Category 4 requirements.
- Our supplier states that the ‘H4’ silicone elastomer material employed conforms to BfR XV requirements.

#### USA

The materials of construction meet the FDA requirements for food contact use, in water up to 70 °C (158 °F), and for bulk alcoholic beverages in low alcoholic applications up to 49 °C (120 °F) as detailed in Code of Federal Regulations, 21 CFR paragraphs 170-199 in that:

- Nylon N66 to 21 CFR section 177.1500 (Nylon resins)
- Polypropylenes to 21 CFR section 177.1520 (Olefin polymers)
- Polyesters to 21 CFR section 177.1630 (Polyethylene phthalate polymers) and 21CFR177.1660 (Polytetramethylene terephthalate)
- Silicone Elastomeric 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: Pall Manufacturing (UK) Ltd., Ilfracombe, UK on behalf of Pall International Sàrl.

The Quality Management System at Pall Manufacturing (UK) Ltd., Ilfracombe is certified to ISO9001:2008  
These products / product packaging carry a lot number / date code to facilitate traceability to suppliers' materials and Pall production records.

## Supplied in Europe by

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