

# DECLARATION OF COMPLIANCE

## Nexis® T Filter Cartridges

### “W” Code

### Cartridge Part Number

NXT   U  W  480

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 : Removal Rating**

Code	Description
3	3 µm
5	5 µm
10	10 µm
20	20 µm
30	30 µm
40	40 µm
50	50 µm
75	75 µm
100	100 µm
150	150 µm
200	200 µm

**Table 2 : Nominal Length**

Code	Description
<b>DOE Style Only</b>	
4	102 mm (4")
5	127 mm (5")
975	248 mm (9.75")
9875	251 mm (9.875")
10	254 mm (10")
195	495 mm (19.5")
20	508 mm (20")
2925	753 mm (29.25")
295	748 mm (29.5")
30	762 mm (30")
39	991 mm (39")
395	1003 mm (39.5")
40	1016 mm (40")
<b>SOE Style only</b>	
10	254 mm (10")
20	508 mm (20")
30	762 mm (30")
40	1016 mm (40")

**Table 3 : Adaptor**

Code	Description
Blank	DOE - double open end with no End Caps
M3	SOE - single open end with flat closed end and external 222 O-rings
M7	SOE - single open end with fin end, 2 locking tabs and external 226 O-rings
M8	SOE - single open end with fin end and external 222 O-rings

**Table 4 : O-ring Seal Material\***

Code	Description
S	Silicone Elastomer
E**	Ethylene Propylene Rubber


\* For M3, M7 and M8 configurations only  
 \*\*Not suitable for use in fatty foods

Nexis T depth filter cartridges are constructed using an advanced, microprocessor controlled CoLD Melt™ production process that permits the creation of multiple filtration zones within a single filter cartridge.

Nexis T filter cartridges are intended for general food and beverage application use.

An initial flush is recommended prior to use.

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## Nexis T Series Filter Cartridges (“W” Code)

### Components

Filter Media	Polypropylene
Core, End Cap and Fin End	Polypropylene
Adaptor	Polypropylene
O-ring Seal	Silicone Elastomer (S) or Ethylene Propylene Rubber (E)

### Declaration

Nexis T Series “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 Nexis T Series 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 Nexis T Series filter cartridges 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, and met migration criteria after flushing and in flow conditions in:

Simulant B (3% acetic acid) 2 hours at reflux,  
Simulant D1 (50% ethanol) 2 hours at reflux,  
Simulant D2 (Sunflower oil) 48 hours at 40 °C,

And water up to 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 5<sup>th</sup> August 2020)  
Typical samples of the ‘S’ (Silicone) and ‘E’ (EPDM) 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, 50 % ethanol, and 95 % ethanol under reflux conditions for 4 hours - repeat use. The data obtained with the ‘S’ o-rings, under the test conditions, were well within the limit for all migration fluids tested. The data obtained with the ‘E’ o-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid, 20 % ethanol and 50 % ethanol. The ‘E’ orings are not suitable for use in fatty foods.

German requirements for food contact elastomers (BfR XV Silicones)

Typical samples of the ‘S’ (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 ‘S’ o-rings, under the test conditions, were well within the limit for all migration fluids tested.

German requirements for food contact elastomers (BfR XXI Natural and Synthetic Rubber Category 1)

Typical samples of the ‘E’ (EPDM) 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 ‘E’ o-rings, under the test conditions, were well within the limit for distilled water, 3 % acetic acid and 10 % ethanol. The ‘E’ orings are not suitable for use in high alcohol or fatty foods.

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. 30/19.

## 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:

- Polypropylene to 21 CFR sections 177.1520 (Olefin polymers)
- Ethylene Propylene Rubber seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use with aqueous foods, excluding fatty foods (e.g. milk and edible oils)) based on confirmatory testing as detailed in section (e).
- Silicone Elastomer seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use, with aqueous and fatty foods (e.g. milk and edible oils)) based on confirmatory testing as detailed in sections (e, f).

## Process Quality System

Site of Manufacture: Pall Timonium, USA

The Quality Management System at Pall Timonium 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 Timonium confirm that this product is manufactured in line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

## Supplied in Europe

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