



## DECLARATION OF COMPLIANCE

### Pall-Aquasafe™ Disposable Water Filter 31 Day Use – Shower Head Application

AQF4

AQF42

#### INTENDED USE

The Pall-Aquasafe Water Filter for 31 day use is supplied sterile and integrity tested. The sterilising grade Supor® membrane within the filter cartridge is rated and validated at 0.2 µm. The filter is indicated for the removal of bacteria, protozoa, fungi and particles\* from the water supply and is intended for the purposes of patient protection by providing a barrier to infection. It can be used to provide water for use in topical applications such as wound care\*\*, personal hygiene, for consumption and the preparation of cold drinks and food\*\* and for rinsing medical instruments.

The filter is designed to be used for a maximum of 31 days following initial connection.

Suspending use does not extend filter life.

Do not reprocess.

\* See product literature for performance summary.

\*\* Where local practices and regulations allow.

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**Carole Durant**  
**Vice President European**  
**Regulatory Affairs**

- **COMPONENTS**

*Components – Fluid pathway*

<b>Filter Media:</b>	Polyethersulphone (Supor)
<b>Support/Drainage Layers:</b>	Polyester
<b>Filter Element/Cage:</b>	Polyester
<b>Closed End Cap:</b>	Polyester
<b>Open End Cap:</b>	Polyester with TiO <sub>2</sub>
<b>Inlet Port “O” Ring:</b>	Silicone Rubber
<b>Handle Assembly:</b>	Polyester with TiO <sub>2</sub>
<b>Shower Rose:</b>	Polyester with TiO <sub>2</sub>

- **EUROPE**

The Pall-Aquasafe Disposable Water Filters meet the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

The polymeric materials of construction of these filters are made from monomers and additives listed in Annex I of Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with foodstuffs (excluding seals).

These articles are intended for direct food use in filtration of water for food preparation, therefore migration testing is applicable.

Migration testing has been performed on the components of AQF4 and AQF42 in simulant A (10% ethanol) and met migration requirements after total immersion for 4 hours at 85 °C.

Note:

These products contain materials that are subject to Specific Migration Limit (SML) requirements.

These products do not contain any dual use additives.

- **PROCESS QUALITY SYSTEM**

**Site of Manufacture:** Pall Newquay, UK on behalf of Pall International Sàrl

The Quality Management System at Pall Newquay is certified to ISO 9001:2008 and ISO 13485:2003

- **SUPPLIED IN EUROPE BY**

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