



## DECLARATION OF COMPLIANCE

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

AQF4  
AQF42

#### INTENDED USE

Pall-Aquasafe Water Filters are primarily intended to be used to produce water suitable for wound care\*, including burn and chronic wounds, in supporting management of the microenvironment of the wound, particularly in immunocompromised and other vulnerable patient groups. To ensure optimal efficacy when the filtered water is used for this purpose Pall-Aquasafe Water Filters are provided as sterile products. The filters can also be used to produce water suitable for the rinsing of dental and medical instruments, including endoscopes. In addition, the filtered water is suitable for topical applications such as showering and washing, personal hygiene procedures such as tooth brushing and mouth rinsing, for consumption and the preparation of cold drinks and food\*.

Pall-Aquasafe Water Filters are typically used in the clinical management of severely immunocompromised patients found in high risk areas, such as Bone Marrow Transplant units, Organ Transplant units, Oncology units, Neonatology Care units and Intensive Care Units.

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 to remove bacteria, protozoa, fungi and particles\*\* from the water supply and provide protection to patients and vulnerable users by acting as a barrier to these common waterborne pathogens, and thus reducing the risk of water associated nosocomial infection.

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.

\* Where local practices and regulations allow. \*\* See product literature for performance summary.

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- **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**

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 contain substances which are approved as direct food additives. For current information consult your local Pall distributor or contact Pall directly.

- **PROCESS QUALITY SYSTEM**

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

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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