



DECLARATION OF COMPLIANCE

Pall-Aquasafe™ Disposable Water Filter 31 Day Use for Protection Against *Legionella* spp. – Tap Application

AQ31L1R - with shower rose outlet

AQ31L1S - with smooth outlet

INTENDED USE

The Pall-Aquasafe Water Filter for 31 day use is supplied sterile and integrity tested. The Supor® membrane within the filter cartridge is validated for the removal of *Legionella* spp. from the water supply. The filter is intended for the purposes of patient protection by providing a barrier against *Legionella* spp. from the water supply. It can be used to provide water for use in topical applications such as personal hygiene, for consumption and the preparation of cold drinks and food*.

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.

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Page: 1 of 3

Carole Durant
Vice President European
Regulatory Affairs

Pall-Aquasafe Disposable Water Filter

- **COMPONENTS**

Components – Fluid pathway

| | |
|--|----------------------------------|
| Filter Media: | Polyethersulphone (Supor) |
| Support/Drainage Layers: | Polyester |
| Core/Cage: | Polypropylene |
| Closed End Cap: | Polyester |
| Inlet Housing (including Quick Connect Inlet Port): | Polyester with TiO ₂ |
| Inlet Port “O” Ring: | Ethylene Polypropylene Elastomer |
| Outlet Housing: | Polyester with TiO ₂ |
| Shower Rose Outlet: (AQ31L1R): | Polyester with TiO ₂ |

- **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 AQ31L1S and AQ31L1R 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 calcium stearate, which is approved as a direct food additive.

- **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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