



Medical

DECLARATION OF COMPLIANCE

EC Regulation EC/1935/2004 and
Commission Directive 2002/72/EC Plastic materials
and articles intended to come into contact with food stuffs

Pall-Aquasafe™ Disposable Water Filter 14 Day Use – Shower Head Application

AQF3

INTENDED USE

The Pall-Aquasafe Water Filter for 14 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 14 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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Pall-Aquasafe Disposable Water Filter

- **COMPONENTS**

Components – Fluid pathway

Filter Media:	Polyethersulphone (Supor)
Support/Drainage Layers:	Polyester
Filter Element/Cage:	Polyester
Closed End Cap:	Polyester
Open End Cap;	Polyester
Inlet Port “O” Ring:	Silicone Rubber
Handle Assembly:	Polyester
Shower Rose:	Polyester

- **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 EU Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs (excluding seals).

These articles are intended for indirect food use in filtration of water for food preparation, therefore migration testing is not applicable.

Note: This product contains materials that are subject to Specific Migration Limit (SML) requirements.

- **PROCESS QUALITY SYSTEM**

Site of Manufacture: Pall Newquay
a Division of Pall Europe Ltd

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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