



## DECLARATION OF COMPLIANCE

### Pall-Aquasafe™ Disposable Water Filter 7 Day Use – Tap Application

AQ7FRN - with shower rose outlet

AQ7FSN - with smooth outlet

#### INTENDED USE

The Pall-Aquasafe Water Filter for 7 day use is supplied sterile and integrity tested. The sterilising grade Nylon 6,6 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 7 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.

**Issued:** 1 March 2010  
**Revised:** 1 October 2011  
**Expires:** 1 October 2012  
**Reference:** 09.3843  
**Page:** 1 of 3

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

## Pall-Aquasafe Disposable Water Filter

- **COMPONENTS**

### *Components – Fluid pathway*

<b>Filter Media:</b>	Polyamide (Nylon 6,6)
<b>Support/Drainage Layers:</b>	Polyester
<b>Core/Cage:</b>	Polypropylene
<b>Closed End Cap:</b>	Polyester
<b>Inlet Housing (including Quick Connect Inlet Port):</b>	Polyester TiO <sub>2</sub>
<b>Inlet Port “O” Ring:</b>	Ethylene Polypropylene Elastomer
<b>Outlet Housing:</b>	Polyester TiO <sub>2</sub>
<b>Shower Rose Outlet: (AQ7FRN):</b>	Polyester 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 AQ7FSN and AQ7FRN 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**

Pall International Sàrl  
Avenue de Tivoli 3  
1700 Fribourg, Switzerland  
  
+41 (0)26 350 53 00 phone  
+41 (0)26 350 53 53 fax  
LifeSciences.EU@pall.com email



Medical

**Pall International Sàrl**

Avenue de Tivoli 3  
1700 Fribourg, Switzerland

+41 (0)26 350 53 00 phone  
+41 (0)26 350 53 53 fax  
LifeSciences.EU@pall.com email

---

**Visit us on the web at [www.pall.com/medical](http://www.pall.com/medical)**

**International Offices**

Pall Corporation has offices and plants throughout the world in locations such as: Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, India, Indonesia, Ireland, Italy, Japan, Korea, Malaysia, Mexico, the Netherlands, New Zealand, Norway, Poland, Puerto Rico, Russia, Singapore, Spain, Sweden, Switzerland, Taiwan, Thailand, the United Kingdom, the United States and Venezuela. Distributors in all major industrial areas of the world.

This document is not for distribution in the USA.

The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly. Part numbers quoted above are protected by the Copyright of Pall Europe Limited.

© 2011 Pall Corporation. Pall,  and Pall-Aquasafe are trademarks of Pall Corporation.

® indicates a trademark registered in the USA and TM indicates a common law trademark.

*Filtration.Separation.Solution.* is a service mark of Pall Corporation.

10/11, PDF, GN11.7404

09.3843