



DECLARATION OF COMPLIANCE

Pall-Aquasafe™ Disposable Water Filter 31 Day Use – In Line Application

AQIN - with quick connect inlet and outlet port

AQIN2 - with quick connect inlet and outlet port

INTENDED USE

The Pall-Aquasafe Water Filter for in-line 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 for in-line applications such as water intake lines of ice making machines, endoscope rinsing or other similar uses and is intended for the purposes of patient protection by providing a barrier to 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.

* See product literature for performance summary.

Issued: 1 March 2010
Revised: 1 October 2011
Expires: 1 October 2012
Reference: 09.3857
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 and Outlet Port “O” Rings:	Ethylene Polypropylene Elastomer
Outlet Housing, (including Quick Connect Outlet Port):	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 AQIN and AQIN2 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

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, , Pall-Aquasafe, and Supor 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, GN 11.7406

09.3857