



DECLARATION OF COMPLIANCE

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

AQIN - with quick connect inlet and outlet port

INTENDED USE

Pall-Aquasafe Water Filters are considered general hospital equipment and are typically used in areas such as Bone Marrow Transplant Units, Organ Transplant Units, Oncological Units, Neonatology Care Units and Intensive Care Units. They can also be used in other healthcare settings or the public and home environment.

The water filters can be used to produce water suitable for applications such as the rinsing of dental and medical instruments, including endoscopes. They are indicated to remove bacteria, protozoa, fungi and particles* from the water supply by acting as a physical barrier to common waterborne pathogens. To ensure optimal efficacy when the filtered water is used for this purpose, the water filters are provided as sterile products, sterilised by irradiation. 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**.

The Pall-Aquasafe Water Filter for 31 day use contain double layer sterilising grade Supor® membrane which is rated and validated at 0.2µm* and are individually integrity tested during manufacture. The water filters are disposable and may be used for up to 31 days following initial connection. Do not re-sterilise or reprocess.

* See product literature for performance summary.

** Where local practices and regulations allow.

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Director, QA/RA Medical

- **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 TiO ₂
Inlet and Outlet Port “O” Ring:	Ethylene Polypropylene Elastomer
Outlet Housing, (including Quick Connect Outlet Port):	Polyester TiO ₂

- **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 AQIN 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 Sàrl

The Quality Management System at Pall Newquay is certified to ISO 9001:2015 and ISO 13485:2016

- **SUPPLIED IN EUROPE BY**

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