



DECLARATION OF COMPLIANCE

Pall QPoint™ Filter Capsule 2 Months (62 Days) - Shower Application

QR22 - Shower Rose Outlet Configuration
QR212 - Shower Rose Outlet Configuration

INTENDED USE

Pall QPoint Filter Capsules are primarily intended to be used to produce water suitable for wound care*, including burn and chronic wounds, in supporting management of the micro-environment of the wound, particularly in immunocompromised and other vulnerable patient groups. To ensure optimal efficacy when the filtered water is used for this purpose, Pall QPoint Filter Capsules are provided as sterile products. The Filter Capsules can also be used to produce water suitable for the rinsing of dental and medical instruments, including endoscopes. 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*.

Pall QPoint Filter Capsules are typically used in the clinical management of severely immunocompromised patients found in high risk areas, such as Bone Marrow Transplant units, Organ Transplant units, Oncological units, Neonatology Care units and Intensive Care Units.

Pall QPoint Filter Capsules are supplied sterile and integrity tested. The sterilising grade Supor® membrane within the filter cartridge is rated and validated at 0.2 µm. The Filter Capsules are indicated to remove bacteria, protozoa, fungi and particles** from the water supply and provide protection to patients and vulnerable users by acting as a barrier to these common waterborne pathogens, and thus reducing the risk of water associated nosocomial infection.

The Filter Capsules are designed to be used for a maximum of 2 months (62 days) following initial connection.

Suspending use does not extend Filter Capsule life.

Do not reprocess.

* Where local practices and regulations allow ** See product literature for performance summary.

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- **COMPONENTS**

Components – Fluid pathway

Filter Pack - membrane:	Polyethersulphone (Supor)
Filter Pack - support layer:	Polyester
Filter Cage:	Polypropylene containing pigment, bacteriostatic additive and opacifier
Inlet Bowl:	Polyester containing pigment, bacteriostatic additive and opacifier
Closed End Cap:	Polyester containing pigment, bacteriostatic additive and opacifier
Inner Shield Protection Device:	Polypropylene containing pigment, bacteriostatic additive and opacifier
Shower Rose Outlet:	Polyester containing pigment, bacteriostatic additive and opacifier

- **EUROPE**

Pall QPoint Filter Capsules 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.

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 Pall QPoint Filter Capsules 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 SYST**

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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