



DECLARATION OF COMPLIANCE

Pall QPoint™ Docking Station - Shower Assembly

QDS

INTENDED USE

The Pall QPoint Docking Station - Shower Assembly is designed for use with Pall QPoint Filter Capsules.

The Pall QPoint Docking Station - Shower Assembly is supplied non-sterile.

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A handwritten signature in blue ink, appearing to read "Sandra Racordon-Pape".

Sandra Racordon-Pape
Director, QA/RA Medical

- **COMPONENTS**

Components – Fluid pathway

Filter Connector:	Glass-filled nylon
Valve Body:	Polyester containing pigment, bacteriostatic additive and opacifier

- **EUROPE**

The Pall QPoint Docking Station meets the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

The polymeric materials of construction of the Pall QPoint Docking Station 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 materials of construction of the Pall QPoint Docking Station 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 9001:2008 and ISO 13485:2003

- **SUPPLIED IN EUROPE BY**

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