



## DECLARATION OF COMPLIANCE

### Pall QPoint® Docking Station - Shower

**QDS - Pall QPoint Docking Station - Shower - Chrome**  
**QDSW - Pall QPoint Docking Station- Shower - White**

#### **INTENDED USE**

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

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

**Issued:** 1 March 2016  
**Revised:** 1 March 2020  
**Expires:** 1 March 2021  
**Reference:** 16.6429  
**Page:** 1 of 3

A handwritten signature in black ink, appearing to read "SR", written over a horizontal line.

Sandra Racordon-Pape  
Director, QA/RA Medical

- **COMPONENTS - Fluid pathway**

**QDS**

**Docking station body:** Polymer (Chrome plated)

**Filter Connector:** Glass-filled nylon

**Filter Connector Gasket Seal and O-ring:** Ethylene Propylene Diene Monomer (EPDM)

**Shower Hose Gasket:** Ethylene Propylene Diene Monomer (EPDM)

**Valve Body:** Polyester containing pigment, bacteriostatic additive and opacifier

**Valve Spring:** Stainless Steel

**Valve O-ring:** Ethylene Propylene Diene Monomer (EPDM)

**QDSW**

**Shower Handle:** Polyester containing bacteriostatic additive

**Hose Connector:** Polyester containing bacteriostatic additive

**Release Button:** Polyester containing bacteriostatic additive

**Filter Connector:** Polyester containing bacteriostatic additive

**Inlet Valve Body:** Polyester

**O-ring:** Ethylene Propylene Diene Monomer (EPDM)

**O-ring:** Silicone

**Filter Connector Gasket:** Ethylene Propylene Diene Monomer (EPDM)

**Pipe Gasket:** Ethylene Propylene Diene Monomer (EPDM)

- **EUROPE**

The Pall QPoint Docking Stations - Shower meet 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 Stations - Shower 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 Stations - Shower in simulant A (10% ethanol) and met migration requirements.

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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