



Our suppliers state that the monomers and additives of the polypropylenes used to make the hardware components are consistent with Annex I of Commission Regulation (EU) Number 10/2011 and its amendments, relating to plastic materials and articles intended to come into contact with foodstuffs.

Migration testing of the polypropylene hardware components was carried out in after flushing and in flow conditions:

Simulant B (3 % Acetic acid) for 30 minutes at 40 °C (104 °F)

Simulant D1 (50 % Ethanol) for 30 minutes at 40 °C (104 °F)

Note: This product contains Polypropylene that is subject to Specific Migration Limit (SML) requirements. This product contains Calcium Stearate, which is approved as a direct food additive. Our suppliers state that the Silicone Elastomeric seal materials are compliant to the BfR section XV specification for this material.

## USA

The following materials of construction meet the FDA requirements for food contact as detailed in US Code of Federal Regulation 21 CFR 170-199 in that:

- Polypropylene to 21 CFR section 177.1520 (Olefin polymers)
- Silicone Elastomeric seal materials to 21 CFR section 177.2600 (Rubber articles intended for repeated use, excluding milk and edible oils)

## Process Quality System

Site of Manufacture: Pall Moduletechnik GmbH, Bad Kreuznach, Germany supplied by Pall Sàrl. Made in Germany.

The Quality Management System at Pall Filtersystems GmbH, Bad Kreuznach is certified to ISO 9001:2015.

Pall Filtersystems GmbH confirm that the product manufacturing environment, for the above product at our Bad Kreuznach site, is in line with the principles of food contact materials GMP as detailed in Regulation 2023/2006.

## Supplied in Europe by

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Pall Corporation has offices and plants throughout the world. To locate the Pall office or distributor nearest you, visit [www.pall.com/contact](http://www.pall.com/contact).

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.

*IF APPLICABLE* Please contact Pall Corporation to verify that the product conforms to your national legislation and/or regional regulatory requirements for water and food contact use..

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