

DECLARATION OF COMPLIANCE SUPRAdisc™ II Backflush Set

Part Number

Backflush Set Part Number	For use with Housing Style	SUPRA-disc II module diameter	Number of SUPRA-disc II modules
GFY0299	VELAdisc	12''	1
GFY0300			2
GFY0301			3
GFY0302			4
20040410		16''	1
20040411			2
20040412			3
20040413			4
GFY0310	WFSZ	12''	1
GFY0311			2
GFY0312			3
GFY0313			4
20041339		16''	1
20041340			2
20041341			3
20041342			4

SUPRA-disc II Backflush Sets are intended to support SUPRA-disc II modules for cold filtration of foodstuffs. These sets may be used to support SUPRA-disc II modules during filtration of non-alcoholic as well as alcoholic beverages.

An initial flush is recommended prior to use.

Issued 3 December 2018
 Revised
 Expires 28 February 2021
 Reference FBDCSDIIBFSETEN
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Mario Basters
 Quality Assurance & Regulatory Affairs Manager
 Pall Filtersystems GmbH

SUPRAdisc II Backflush Set

Components

Hardware:	Polypropylene
Gasket:	Silicone elastomer

Declaration

Europe

The SUPRAdisc II Backflush Set meets the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004 in that:

- 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 (6 % 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 Filtersystems GmbH, Bad Kreuznach, Germany on behalf of Pall International Sàrl.

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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December 2018