
Declaration of Compliance for Materials and Articles in Contact With Food

Description of Product: PolymidPure Series Cartridges

Validation Service Center: 2202, No. 1759 North Zhongshan Road, Shanghai 200061 Date of

Declaration: Jan 5th, 2024

This letter is the declaration of compliance within the meaning of Article 16(1) of Regulation (EC) No. 1935/2004.

The product(s) listed above comply with the requirements of Regulation (EC) No. 1935/2004 in that:

- ⊕ The product(s) are manufactured at an ISO 9001:2015 certified facility in accordance with good manufacturing practice as required by Regulation (EC) No.2023/2006.
- ⊕ The product(s) have fully documented traceability throughout the manufacturing process that is identifiable by the means of a lot number printed on the product label or quality documentation supplied with the product.
- ⊕ The product(s) are manufactured from materials that are suitable for contact with foodstuffs according to the following European specific measures or other recognized standards where specific measures have yet to be defined;

Plastic Parts

The plastic components of the product meet the requirements of Regulation (EU) 10/2011 and (EU) 2023/1442 amendments.

- ⊕ All starting monomers, substances and additives are listed in the annexes of Regulation (EU) 10/2011.
- ⊕ Migration testing in accordance with Directives 82/711/EEC and 85/572/EEC in simulants B and D1 (50% ethanol) has shown that the measured total migration is below the limit of 10mg/dm² (60mg/kg)
- ⊕ The product contains components that are subject to a specific migration limit (SML). Specific migration testing in simulants B and D1 (50% Ethanol) and calculation has shown that SMLs will not be exceeded under normal conditions of use. If required the identity of these components may be disclosed under the cover of a confidentiality agreement.
- ⊕ The product contains calcium stearate which is defined as a dual use additive.

Rubber O-Rings

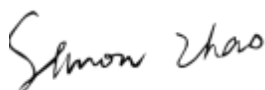
- ⊕ All starting monomers, substances and additives are listed in the annexes of Regulation (EU) 10/2011
- ⊕ The product contains components that are subject to a specific migration limit (SML). Specific migration testing in simulants B and D1 (50% Ethanol) and calculation has shown that SMLs will not be exceeded under normal conditions of use. If required the identity of these components may be disclosed under the cover of a confidentiality agreement.
- ⊕ Silicone, Fluorocarbon, Nitrile and Ethylene Propylene Rubber O-rings are made from materials listed in FDA CFR Title 21 177.2600 and are safe for food contact.

Metal Support Ring

The optional metal support ring is made from food grade Type 316/EN 1.4401 stainless steel which is compliant with the French order of January 13, 1976.

In preparing this declaration PU has relied in part on information provided by PU suppliers.

Signed:



Validation Manger,