

**Project Number:** 15/EA/03/41  
**Date received:** 26<sup>th</sup> March 2015  
**Sample Details:** Product contact components used in OVR assembly.  
**Purchase Order:** TV500130210N

# Analysis Certificate

Version: 002

**Client:** Parker Hannifin Manufacturing Ltd  
**Subject:** Compliance testing of product contact materials for Oil Vapour Removal Filter to FDA Title 21 on plastic materials and articles intended to come into contact with food.

## Introduction:

Seven product contact components were received for compliance testing to the following regulations:

1. FDA CFR Title 21 Part 177 "indirect food additives: polymers"

## Methods of Analysis:

1. The infrared spectra of polymeric materials were transmission recorded of cast films or reflectance recorded (ATR) of solid items using FTIR Spectrophotometer to confirm material identification.
2. Thermograms were recorded on thermally conditioned specimens of samples where appropriate using a Differential Scanning Calorimeter (DSC).
3. 21CFR 177 Indirect food additives non volatile residue on extractions.

## Results and Comments

This report covers components used specifically for Oil Vapour Removal systems

### Summary

Sub series	Part	Description	PASS / Fail
A	056030180	O-ring bs249	✓
B	271004735	Round Washer	✓
C	051191060	O-ring 150 ID x 3.0	✓
D	051001640	O-ring B5548	✓
E	276031146	Maxi Plus PC02 Lifting Strap	✓
F	276031206	Maxi PC02 Btm endcap	✓
G	271004270	Porweb	✓

(Reference appendix for test result details.)

All samples met 21CFR 177 Indirect food additives: Polymers test specifications.

**Analyst:**  01/06/2015

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**Pertaining Worksheets:** FTIR Ws10256-10276

CFR Ws10269-10400

Edwards' Analytical contract laboratory has been inspected in accordance with the Medicines Act by the Medicines and Healthcare Regulatory Agency (MHRA) and is considered to comply with the principles of Good Manufacturing Practise as detailed in Directive 2003/94/EC.



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