

# Group Quality Procedures – Quality

## QGP31.FDA Compliant Materials: Component Seals (-F)

### **Scope:**

This procedure outlines the requirements for the use of FDA Compliant material in component seals within the AES Group.

### **Responsibility:**

The Group Business Assurance Manager and the Director responsible for Health and Safety will review and develop this procedure. It is the responsibility of all managers and employees to ensure that this procedure is adhered to and complied with.

### **Procedure:**

ALL WETTED MATERIALS MUST BE CONSIDERED.

FDA COMPLIANT (OR EOAR) MATERIALS ARE ONLY  
AVAILABLE FOR F- COMPONENT SEALS

#### **Carbon**

- Specific FDA grade
- Listed FDA 21 CFR 177.2410

#### **Silicon Carbide, Tungsten Carbide & Alumina Ceramic**

- Sintered and reaction bonded SiC (AESSEAL standard supply).
- Tungsten Carbide Nickel bonded (AESSEAL standard supply).
- Alumina Ceramic 99.5% Purity (AESSEAL standard supply).
- These materials conform to FDA requirements applied to materials in contact with foodstuffs.

#### **PTFE / Teflon**

- Virgin PTFE (EOAR\*).

#### **EPDM 'O' rings**

- Specific FDA grade (certified).
- Listed FDA 21 CFR 177.2600

#### **Viton 'O' rings**

- Specific FDA grade (certified).
- Listed FDA 21 CFR 177.2600

#### **Kalrez 'O' rings**

- Specific FDA grade (certified). Kalrez® 6221, 6230 & 6230A
- Listed FDA 21 CFR 177.2400

#### **Nitrile 'O' rings:**

- Specific FDA grade (certified).
- Listed FDA 21 CFR 177.2600

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### **FEP ‘O’ rings**

- Standard AESSEAL supply FEP O-rings.
- Listed FDA 21 CFR 177.1550

### **AES Elast:**

- Standard grade (certified).
- Listed FDA 21 CFR 177.2600

### **Silicone-70 O’Rings (Red)**

- Listed FDA 21 CFR 177.2600

### **304/316 Stainless Steel:**

- These materials conform to FDA requirements for applied to materials in contact with foodstuffs.

\* EOAR = Evidence of Acceptability Retained