

# Group Documentation: Standards

## EU Regulation 1935/2004 - Food Safe Component Seal Materials

Component Seal materials in accordance with EU 1935/2004 will only be available in the following materials.

### Compliant Process Seal Materials

#### **Materials of construction**

- SS 304/316 (FDA EOAR)

#### **Face Materials**

- Carbon – FH82Z5 / FH71Z5 (FDA EOAR)
- Sic – Sintered and Reaction Bonded (FDA EOAR)
- TC – Nickel bound - AESSEAL standard Supply (FDA EOAR)
- Chrome Oxide – (84/500EEC Compliant – SGS Certificate NBMLC101200084)
- Chrome Oxide – (84/500EEC Compliant - BLR/R(FCM)/13/001471)
- Ceramic – (84/500EEC Compliant – SGS Certificate NBMLC101000035)
- Ceramic 99% – (84/500EEC Compliant – A002T130508041-1R01)
- Ceramic 99.5% – (84/500EEC Compliant – A002T130508041-2R01)

#### **'O'Rings/Elastomers – No specific legislation**

- Epdm – Specific FDA Grade (CFR177.2600)
- Viton – ESP V680-70 or PPE V70H (CFR177.2600)
- Kalrez – Kalrez 6221, 6230 & 6230A (CFR177.1550)
- Nitrile – Specific Grade (CFR177.2600)
- AES Elast – Standard Grade (CFR177.2600)

#### **FEP O'Rings**

- Specific Grade Compliant with EU No 10/2011

#### **Grease**

- Molykote 111 – (FDA EOAR)

#### **Adhesives – No specific legislation**

- Loctite 290 – NSF 61 tested and approved  
(Additional information - only incidental contact takes place).

These materials will be compliant to the relevant categories within regulation 1935/2004 and any associated legislation. In the absence of specific legislation materials acceptable under FDA guidelines will be used in line with our own risk analysis.

FDA EOAR – (FDA Evidence of acceptability retained).

### Traceability

- Batch traceability on all 1935/2004 seals will be maintained via L500. See AESSEAL Q-SEAL Quality procedure QGP31 - Certification.
- Quality systems certified to ISO 9001 ensure adherence with EU 2023-2006 GMP.
- NB this list will be reviewed in line with any regulation / Directive updates.