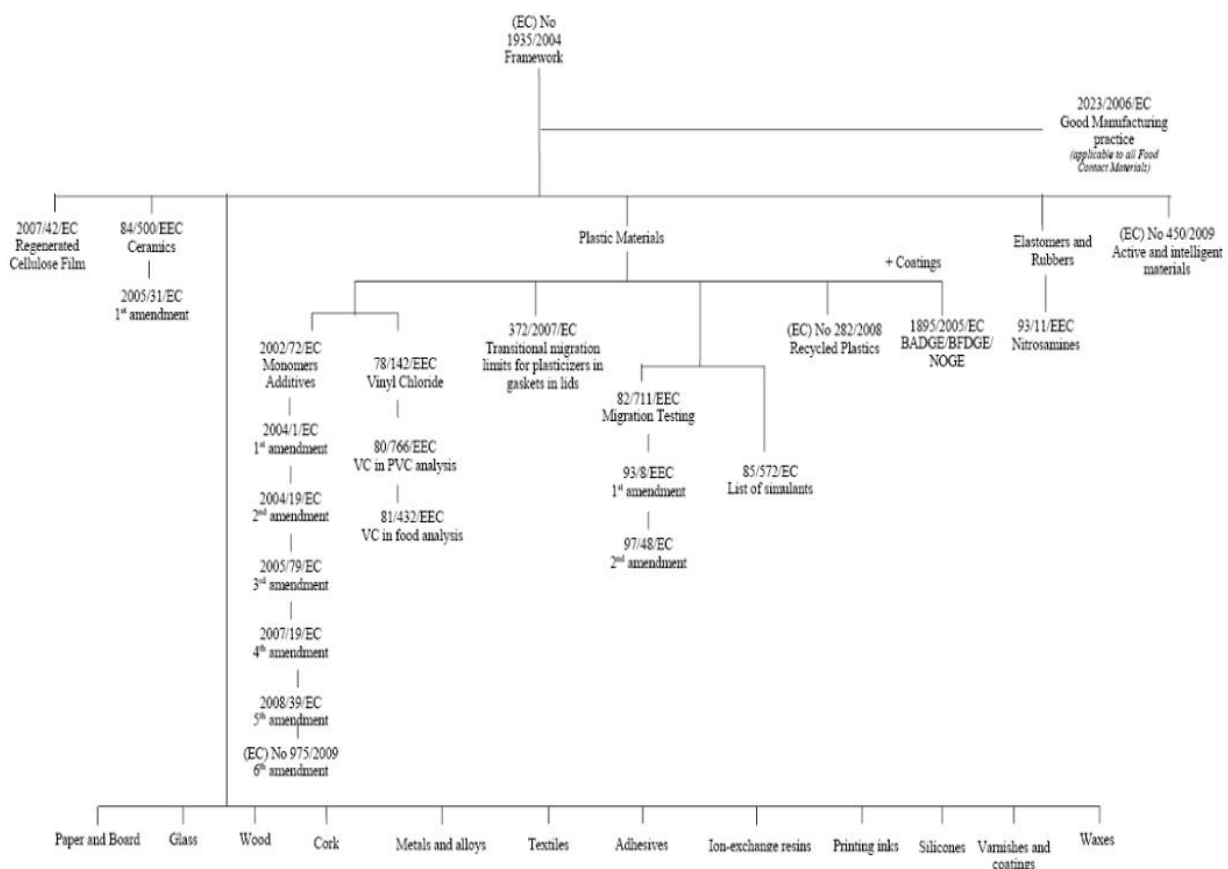


# Business Assurance Standards Working Guidance

## QWGP31-1935/2004 (Cartridge Seals)

EU1935/2004 is the EU regulation on Food Contact Materials and is generally only requested by European end users. The (EC) No 1935/2004 legislation framework cascades down into the different categories of materials and where appropriate, the specific test requirements which they have now legislated for, and which continues to grow. Each listed category then has to comply with varying test criteria. Where a material does not fit within a specific category then 2023/2006 and common sense should rule.

All materials and products have to conform to 2023/2006 EC Good Manufacturing Process (GMP). It is usually acceptable that compliance with this can be ascertained if a Company has ISO 9001.



As such, AESSEAL have reviewed the core materials used in the process seal products with regards how they correspond with the frame work above. The following is a summary of the review.

### Face materials:

Silicon – This is categorised as a Ceramic and therefore must comply with the test requirements outlined in 84/500/EEC. We have had the AESSEAL Silicon tested and have evidence that this complies.

# Business Assurance Standards Working Guidance

## **QWGP31-1935/2004 (Cartridge Seals)**

Ceramic - This is categorised as a Ceramic and therefore must comply with the test requirements outlined in 84/500/EEC. We have had the AESSEAL Ceramic tested and have evidence that this complies.

Chrome Oxide – This is categorised as a Ceramic and therefore must comply with the test requirements outlined in 84/500/EEC. We have had the Chrome Oxide tested and have evidence that this complies.

Carbons – This doesn't fall into any of the categories listed above, so therefore there are no specific test requirements to be met. However, as we're supplying it into Food applications, we need to ensure we comply with GMP. To do this, we utilise FDA compliant materials as this is a fairly stringent regulation that is already in place. Where a grade of carbon is FDA compliant, this number will be listed on certificates of conformity supplied by AESSEAL.

Tungsten Carbide - This doesn't fall into any of the categories listed above, so therefore there are no specific test requirements to be met. However, as we're supplying it into Food applications, we need to ensure we comply with GMP. To do this, we utilise FDA compliant materials as this a fairly stringent regulation. If we don't have a compliance number, the certificate supplied will advise FDA Evidence of Approval retained.

### **Steel:**

Under the EU1935/2004 framework, there is no specific legislation for steel and therefore all certificates issued by AESSEAL will state – No Specific legislation.

### **Elastomers:**

Elastomers supplied by AESSEAL fall into the category of Elastomers and Rubbers however, there is no specific test criteria to meet (this is indicted by the lack of (EC) number), however, they do need to fall within the GMP. To do this, we utilise FDA compliant materials as this is a fairly stringent regulation. Where a grade of elastomer is FDA compliant, this number will be listed on certificates of conformity supplied by AESSEAL.

### **Gaskets:**

Gaskets should comply under the 2002/75/EC – Monomers Additives and therefore only certain grades of gasket material are compliant to EU1935/2004 (typically Gylon 3504) whereas other Gylon may adhere to the GMP (FDA Compliance)they are not directly compliant to EU1935/2004.

### **Adhesive / Glue:**

No specific legislation under EU1935/2004 and contact with the application is incidental. GMP applies -

# Business Assurance Standards Working Guidance

## QWGP31-1935/2004 (Cartridge Seals)

MATERIAL / COMPONENT		STOCK CODE INDICATOR	GRADE	EU1935/2004	COMPLIANT
Stainless Steel	Metalwork	01	316L	N/A	No specific Legislation for steel
Stainless Steel	Metalwork	39	316	N/A	No specific Legislation for steel
Stainless Steel	Metalwork	20	304	N/A	No specific Legislation for steel
Carbon	Face Material	C	FH82Z5	(FDA) 21.CFR 177.2410	GMP2023/2006 EC
Dry Running Carbon	Face Material	F	FH7175 / FH7175H5	FDA Evidence of approval retained	GMP2023/2006 EC
Aluminium Oxide Based Ceramic	Face Material	A	99.5%	84/500EEC Compliant	Yes
Silicon Carbide	Face Material	S	TUFBIDE	84/500EEC Compliant	Yes
Silicon Carbide	Face Material	Z	PUC-SC15	84/500EEC Compliant	Yes
Reaction Bonded Silicon Carbide	Face Material	S	SC-2	84/500EEC Compliant	Yes
Tungsten Carbide	Face Material	T	Nickel Bound	FDA Evidence of approval retained	GMP2023/2006 EC
Viton	Elastomers / 'O' Ring	L	DT 514690	(FDA) 21.CFR.177.2600	GMP2023/2006 EC
EPDM	Elastomers / 'O' Ring	M	DT EP70	(FDA) 21.CFR 177.2600	GMP2023/2006 EC
Kalrez	Elastomers / 'O' Ring	K10 K11 On application	6221 6230 6230A	(FDA) 21.CFR.177.24 (FDA) 21.CFR.177.24 (FDA) 21.CFR.177.24	GMP2023/2006 EC GMP2023/2006 EC GMP2023/2006 EC
Gylon (3504) <i>Non AESSEAL Standard</i>	Gasket	YGB at component level	Grade 3505	2002/75/EC	Yes
Silicone	Grease	YMS35	Molykote 111	21.CFR.178.3570	Yes