

STATEMENT OF COMPLIANCE

REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004

This is to confirm that the below noted Chesterton products equipped with the noted manufactured components and sealing materials; governed by EC 1935/2004 and are intended to come into food contact, are compliant with REGULATION (EC) No 1935/2004 and manufactured in accordance to Chesterton internal control procedure “Certified Order Process for Pharma/FDA/Sanitary Products”.

Compliant Components, Packing & Seal Materials

Metal components: 316SS, Alloy 20, Hastelloy C-276, 304SS - (GRAS)

Seal rings:

SSC	(FDA compliant grades) / GRAS
RSC	(FDA compliant grades) / GRAS
Carbon	(FDA compliant grades) / GRAS
Ceramic	(FDA compliant grades) / GRAS

Elastomers:

EP	(FDA compliant grades) / GRAS
FKM	(FDA compliant grades) / GRAS
Kalrez	(FDA compliant grades) / GRAS
Isolast	(FDA compliant grades) / GRAS
Chemlast	(FDA compliant grades) / GRAS
Gasket material	(FDA compliant grades) / GRAS

O-ring lubricant: (FDA compliant grades) / GRAS

Packing Materials:

Style 425	(FDA compliant grades) / GRAS
Style 184/185	(FDA compliant grades) / GRAS
Style ECS-T	(FDA compliant grades) / GRAS

Style 800 Gold End Tape: (FDA compliant grades) / GRAS

Polymers:

AWC-510	(FDA compliant grades) / GRAS
AWC-615	(FDA compliant grades) / GRAS
AWC-630	(FDA compliant grades) / GRAS

Ceramic materials shall be Generally Considered As Safe (GRAS) as demonstrated under FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30. Rubbers shall be approved conform FDA 21 CFR 177.2600

Traceability per Article 17 of REGULATION (EC) No 1935/2004 is assured via compliance with the requirements of AWC Groveland Business management System Revision H, dated 5/5/11 and control procedure “Certified Order Process for Pharma/FDA/Sanitary Products”.



Quality Manager – Operations
A.W. Chesterton Company