



DICHTOMATIK

Dichtomatik Limited
Donington House Riverside Road Pride Park Derby DE24 8HX

PRESS RELEASE DL023

**PERFORMANCE SEALS FOR USE
WHERE CLEANLINESS IS CRITICAL**

Pharmaceutical and food process lines which are required to operate at the highest hygiene levels, utilise pure, high temperature aggressive water (WFI) systems for their SIP (Steam in Place) and CIP (Clean in Place) processes. The operation of repeated steam recycling, however, places severe demands upon any sealing products incorporated within control valves utilised in the process pipework.

These valves are widely used to control flow, pressure and temperature of fluid media within the system. For example, some of the most critical steps in pharmaceuticals manufacture involve sterilisation with various methods including high temperature saturated steam, strong acidic or basic cleaning solutions and even strong oxidizing media such as ethylene oxide and ozone.

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BFPDA

Dichtomatik Ltd, an official Dupont™ licensee, are able to supply the Kalrez® 6221 perfluorelastomer compound O-rings and other sealing profiles including custom shapes. These products are thermally stable up to 260°C (500°F), and also suitable for stage II sterilisation application processes where other elastomers can lose their sealing capabilities. They have been developed specifically to maintain outstanding reliability while ensuring high level sealing performance in pharmaceutical and food production processes. They maintain the validation of cleanliness-critical operating conditions and overcome degradation difficulties (chemical, thermal and/or mechanical) associated with conventional sealing materials. This FDA compliant product also reduces contamination from extractables to trace levels, has very low swell characteristics or loss of other mechanical properties, even after repeated steam cycling.

Kalrez® 6221 sealing products combine the inert qualities and cleanliness of PTFE, with the outstanding sealing qualities of perfluorelastomer. They have also demonstrated significantly reduced contamination, combined with extended seal life compared to silicone, ethylene propylene diene (EPDM) and fluoroelastomers (FKM). Full manufacturers traceability can be provided, while leakage of process chemicals, or the ultra pure water used in plant cleaning, can be significantly reduced. Because the perfluoroelastomer polymer of the Kalrez® product is fully saturated, it is also well suited for sealing applications involving ozonated deionised water.

Kalrez® 6221 perfluorelastomer (FFKM) parts were developed to meet the unique sealing needs of today's pharmaceutical processes. They are compliant with the United States Food and Drug Administration's regulations and with the United States Pharmacopeia Class VI (USP Class VI). They are successfully used by many customers for steam control valves in the presence of saturated steam at 4 bars pressure and at a temperature of 140°C.

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Further information is available from:

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The production of Dupont™ Kalrez® 6221 sealing products available from Dichtomatik Ltd. These components help maintain highly sterile conditions for the manufacture of pharmaceutical and other food related products.

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