

High Performance Sealing Solutions for the
**FOOD, PHARMACEUTICAL AND
LIFE-SCIENCE INDUSTRIES**



High performance sealing solutions for the food, pharmaceutical and life-science industries

Precision Polymer Engineering (PPE) is a unit of IDEX Sealing Solutions (part of IDEX Corporation). PPE is dedicated to providing sealing solutions for some of the world's most demanding applications and environments. IDEX Sealing Solutions comprises three companies; PPE, FTL Technology and Novotema.

With over 40 years of experience designing and manufacturing sealing components, PPE possess a thorough understanding of food, pharmaceutical and life-science applications. This technical know-how, combined with unique elastomer materials, ensures that the correct sealing solution is delivered to meet legislative and manufacturing performance and standards.

- ▶ High performance elastomer materials
- ▶ Extensive portfolio of products
- ▶ Custom seal design service
- ▶ Certification to major industry standards
- ▶ Industry-leading delivery times
- ▶ Expert technical support, pre and post-sale
- ▶ Comprehensive testing and failure analysis



Your global sealing partner

Precision Polymer Engineering is a leading supplier to the food, pharmaceutical and life-science industries and has a network of direct sales and regional distributors around the world.

PPE works closely with many of the food, pharmaceutical and life-science equipment manufacturers to develop customized sealing solutions that require less maintenance and deliver low cost of ownership.

This is why many of the world's market-leading companies have chosen PPE as their trusted sealing partner.

Reliability and hygiene

Food, pharmaceutical and life-science equipment can involve some demanding sealing applications; a combination of chemical resistance, low and high temperature capability and low permeability for vacuum, plus compliance to a variety of industry standards.

Elastomers used in process equipment, pumps, valves, pipe work, couplings, reaction vessels and bulk containers must be able to cope with a wide range of process media, potent active pharmaceutical ingredients (APIs) and aggressive cleaning and sterilising processes. In addition, seals must be compliant with a growing range of legislative manufacturing regulations and hygiene standards.

PPE helps to overcome these challenges by developing and manufacturing hygienic seals and components that deliver optimum performance and reliability.



Exceeding your expectations

PPE is a leading developer and manufacturer of high quality advanced sealing components offering outstanding performance to the food, pharmaceutical and life-science industries. Through continual innovation, PPE strives to develop the next generation of sealing materials and products. You can be sure that PPE sealing solutions will continue to meet and exceed your expectations.

Below are some examples of the benefits PPE sealing solutions provide in various food, pharmaceutical and life-science applications:-

- ▶ Extended service life of valves, pumps, food processing and pharmaceutical manufacturing equipment, resulting in reduced repair costs.
- ▶ Increased operating periods between maintenance cycles.
- ▶ Industry-leading materials, offering the widest range of universal chemical and temperature resistance.
- ▶ Reduced inventory, stock-holding and control by standardizing on fewer material grades.
- ▶ Reduced risk of contamination, which can lead to product failure/quarantine.
- ▶ Increased reliability and performance, resulting in the prevention of potential damage claims from end users.
- ▶ Engineering support to design non-standard seals and custom components.



Innovative materials & industry standards

PPE offers a broad range of elastomer materials optimized for use in food, pharmaceutical and life-science applications. PPE continues to push the boundaries of elastomer technology and deliver the most technically advanced sealing materials, which are qualified to major industry standards.

PPE provides a comprehensive range of services to assist with material testing, failure analysis and material recommendations.

Food & Drug Administration

The Food & Drug Administration is the US Federal Agency responsible for ensuring that foods are safe, wholesome and sanitary; human and veterinary drugs, biological products and medical devices are safe and effective and cosmetics are safe. CFR21.177.2600 describes the relevant regulations for 'Rubber articles intended for repeated use'. Paragraphs A-D detail the requirements for dry foods, paragraphs E and F detail the requirements for aqueous and fatty foods.

PPE offers an extensive range of FDA-compliant elastomer materials, including NBR, EPDM, Silicone, HNBR, FKM, and FFKM.



3-A Sanitary Standards Inc.

PPE is approved and audited in accordance with 3-A Standard 18-03. This standard defines specifications and best practice for the design, manufacture, installation and use of hygienic equipment. '3-A Sanitary Standard 18-03 for multiple-use rubber and rubber-like materials used in product contact surfaces in dairy equipment' describes requirements for food quality materials that are suitable for steam sterilization, acid and alkali cleaning solutions and chlorine sanitizing agents.

PPE's range of 3-A elastomers are FDA-compliant and include NBR, HNBR, EPDM, Silicone, FKM and FFKM.



WRAS

Materials approved for drinking water applications must satisfy the requirement of BS 6920 for the Water Regulations Advisory Scheme (WRAS) in the United Kingdom.

The testing regime for WRAS approval is different to FDA testing, in that it tests the 'Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of the water'. The test ensures sealing materials do not promote the propagation of bacteria or affect the color, appearance and taste of drinking water.



USP class VI

The United States Pharmacopeia (USP) is the non-government organization that promotes the public health by establishing state-of-the-art standards to ensure the quality of medicines and other health care technologies. Standards are published in the US Pharmacopeia and the National Formulary (USP NF). Testing for compliance involves an assessment of the effects of the material and extractables on tissue. Suffix <87> involves in vitro testing and Suffix <88> involves in vivo testing.

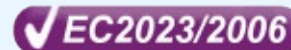
PPE provides a range of elastomers tested and approved to USP Class VI, including EPDM, Silicone, FKM and FFKM.



European Parliament Council

PPE's FDA-compliant products are also compliant with the European regulations laid out in EC1935/2004 and EC2023/2006 in relation to 'Materials and Articles Intended to Come Into Contact With Food', including 'Good Manufacturing Practice' for the same.

The principle of the Directive is that materials should be sufficiently inert to prevent transfer of substances into food in quantities which might be large enough to endanger human health.



ADI-free

All PPE sealing materials are free from Animal Derived Ingredients (ADI) and are therefore BSE / TSE free with respect to source, manufacture and treatment. PPE certifies that its full range of sealing materials are ADI-FREE which avoids the potential risk of BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy) contamination in products that are intended for human consumption.



High performance materials

PPE offers a comprehensive range of high performance sealing materials optimized for food, pharmaceutical and life-science applications:-

- ▶ Compatible with virtually all process media - able to withstand cleaning regimes and sanitization practices including solvents, steams and amines.
- ▶ Operating temperatures in the range of -60°C to +327°C (-76°F to 621°F).
- ▶ Full manufacturing traceability including certification to BS EN ISO 10204.
- ▶ Certification to FDA, USP Class VI and 3-A Sanitary Standards.

Material Types	Temperature Range (°C)	Colors	Certifications
EPDM	-40 to +150	Black, white, blue	FDA, USP, 3-A
NBR	-40 to +121	Black, white, blue	FDA, 3-A
VMQ	-60 to +250	White, blue, translucent, dark grey, red	FDA, USP, 3-A
FKM	-10 to +200	Black, white, blue	FDA, USP, 3-A, WRAS
HNBR	-40 to +180	Black	FDA, 3-A
FFKM	-15 to +327	White	FDA, USP, 3-A

For further information on material grades with certification visit www.prepol.com/material-grades. Material certificates are also available to download at www.prepol.com/material-certs.

Products

PPE offers a portfolio of products used within the food, pharmaceutical and life-science industries.



O-rings

Fully molded O-rings can be manufactured in any size or quantity ranging from 0.8mm to 2.4m (0.030" to 96") internal diameter and 0.8mm to 12mm (0.0302" to 0.4702") cross section, allowing PPE O-rings to be specified in all locations. Standard AS and metric sizes, international and custom non-standard sizes available.



Metal detectable components

PPE's range of metal detectable elastomer compounds are specifically designed for the early detection of contamination from elastomer components. Fragments of **Detectaseal®** as small as 2mm (0.079") can be identified by in-line metal detection and X-ray equipment.



Sanitary gaskets

PPE offers elastomer seal gaskets designed to meet the needs of pipe couplings in food, beverage and pharmaceutical process lines. Sanitary gasket seals can be manufactured to several clamp size standards.



Rubber to metal bonded seals

Customized rubber-to-metal (or rubber-to-plastic) bonded parts can be designed and developed for specific sealing requirements.



Micro components

Micro components are manufactured using PPE's unique production cell, **MicroForm®**. Micro sized elastomer parts for critical applications require the highest level of precision for microfluidics (flow control and dispensing), bio-analytical, industrial automation and lab-on-a-chip applications.



Custom seals

Seals can be designed and manufactured to customer-specific requirements and molded in almost infinite shapes, sizes and profiles. PPE offers a complete component design service to meet the requirements for every type of sealing environment and application.

Services

With state of the art laboratories in the UK and USA, PPE provides a comprehensive range of services for the development, characterization, testing and analysis of polymeric materials.

Testing and analysis

Utilizing the latest equipment and analytical techniques, PPE can provide a complete service including detailed material testing and analysis, failure analysis, chemical compatibility testing, thermo-mechanical evaluation, thermal performance analysis, post-use analysis and problem-solving on any sealing matter.



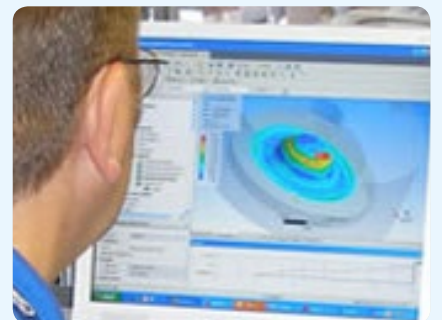
Design service

Seal design is an important factor in hygienic equipment and PPE sets the standard in offering a complete design service to ensure maximum sealing performance. An experienced team of applications engineers and polymer scientists provide a holistic approach to hygienic seal design and complete customized seal designs to meet every type of requirement. Computer simulation helps PPE engineers to predict optimal seal geometry using mathematical and non-linear Finite Element Analysis (FEA). These techniques are utilized in the development of new and unique sealing solutions to maximize service life and reduce maintenance downtime.

Technical support

Customer support and expert technical advice is available on any sealing matter. Engineers can provide a complete consultancy service including support on material selection, compatibility assessment, on-site field assistance and troubleshooting. A collaborative approach towards problem solving ensures successful project completion with regular client interaction throughout.

PPE also offers customized training courses which are tailored to sealing applications experienced within the food, pharmaceutical and life-science industries.



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