TECHNICAL PAPER

Why seal traceability is important

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What is seal traceability?

Traceability is the capability to track and trace every aspect of a product. In the case of hygienic seals and gaskets it gives complete transparency on all the processes involved in the creation and distribution of that component. From the procurement of the raw materials to the testing, production and distribution of the seals. It means distributors and customers can clearly understand how, when and where the item was produced.

Why is seal traceability important in Food & Pharma applications?

The biggest benefit of traceability is that it helps ensure the safety of your manufactured products. This is especially important in the Food and Pharmaceutical industries where seal traceability reduces the risk of contamination in the production line.

If for example, a batch of food or medicine was contaminated in the production process, how would you be able to identify the root cause of the issue and fix it without being able to trace your components?

In a case like this, the lack of traceability would make it almost impossible to effectively recall a defective or contaminated product.

In the heavily regulated Food and Pharma sectors, there are strict requirements for cleanliness in production processes. You can ensure the safety of your manufactured seals by finding out their origin. This will also help you avoid the risk posed by counterfeit materials.



Figure 1 — Hygienic gaskets within pipe couplings used in yogurt dispensing application

The growing problem of counterfeit materials in Food & Pharma

Counterfeit materials entering the supply chain is a growing problem with more products being counterfeited across all industries including Food and Pharmaceuticals. The European Intellectual Property Office (EUIPO) found in its <u>report on</u> <u>counterfeiting in the pharmaceutical industry</u>, that counterfeiters largely succeed by exploiting weaknesses in the supply chain.

What are counterfeit materials?

Counterfeits are low-quality products designed to replace genuine components. Counterfeit products can come in various forms, including low-quality materials or components at the end of their lifecycle which are portrayed and sold as legitimate items.

Counterfeit materials are often very hard to identify visually as they can be made to pass early levels of testing, appearing functional for all intents and purposes.

Precision Polymer Engineering (PPE), a leading manufacturer of seals and gaskets, has first-hand experience of companies trying to pass off counterfeits as their own products and materials. From unauthorized use of images and trademarks (Fig. 2) to completely doctoring of material datasheets. None of these companies had any rights to use these in any way and swift action was taken against them.





Perlast Perfluoroelastomer Ffkm ... walleseals.en.made-in-china.com

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Figure 2 — Examples of a Chinese company unlawfully using PPE images and tradename

More recently, the dedicated R&D team at Precision Polymer Engineering conducted mystery shopper research, purchasing 1", 1½" and 2" hygienic gaskets from various online retailers and testing critical features such as finish quality; inner diameter, outer dimeter and bulb height against international sanitary standards. The results were incredibly revealing.

Visually, it was clear that certain retailers were supplying seals with an inconsistent finish. Further testing revealed that inner and outer diameter dimensions deviated from expected standards by anything between -4.6% and +6.7%. Some of the 1" gaskets had an inner diameter of 20.8mm, much smaller than either the British (BS) or German (DIN) standards (22.8mm and 22.3mm respectively). As a result, these gaskets will protrude into the pipeline and reduce the flow of media. Although 1.5mm seems like a small difference to the inner diameter, this would represent a 16.5% blockage. It was a similar result for the 1.5" gasket (8.8% blockage) and 2" gasket (4.5% blockage).



Figure 3 — Four 1" gaskets (left) and four 1.5" gaskets (right) purchased online

The bulb height on the silicone gaskets (Fig. 3) purchased online should be 5.5mm as stated in the BS and DIN standards. Just by stacking the two sets of gaskets side-by-side, it's clear to see that 4×1.5 " gaskets on the right are visibly lower than the 4×1 " gaskets on the left. They should be the same height.

On measuring the gaskets, the bulb height on the 1" samples averaged 4.8mm and the 1.5" and 2" gaskets averaged 4.0mm height. Being undersized will affect the location of the seal in the ferrule, it could move when closing the clamp and end up incorrectly aligned, causing it to protrude into the pipeline obstructing the flow of media.



Figure 4 — Two 2" silicone gaskets supplied damaged from online retailer



Figure 5 — Close up of damage to unused 2" silicone gasket (as supplied from the retailer)



Figure 6 — Close up of damage to another unused 2" silicone gasket (as supplied from the retailer)

In these 2" samples (Fig. 5 & 6) there is obvious damage to the parts. This could be caused by how they were removed from the moulding tool during manufacturing.



Figure 7 — Close up of internal surface defects on unused 2" silicone gasket (as supplied from the retailer)



Figure 8 — Close up of internal surface defects on another unused 2" silicone gasket (as supplied from the retailer)

On close inspection these gaskets have cuts and scratches on the internal surfaces. There is also flash remaining, all of these issues could present a contamination risk. Another batch of green FKM sanitary gaskets purchased online clearly show the poor quality and inconsistent finish (Fig. 9 to 11).



Figure 9 — FKM gasket with poor surface finish sourced from online retailer



Figure 10 — Poor quality FKM gasket with uneven edges sourced from online retailer



Figure 11 — Another poor quality FKM gasket with uneven edges sourced from online retailer

What are the risks associated with counterfeit materials entering your supply chain?

Above all else, counterfeit materials can compromise the safety of your products, which in Food & Pharmaceutical applications can have extremely serious health & safety consequences. In 2006, cough medicine manufactured in Panama using counterfeit materials resulted in over 78 deaths.

Beyond this, utilising counterfeit materials can result in loss of revenue and damage to your brand reputation.

In our mystery shopper research, it was apparent that using counterfeit seals greatly increases the risk of process contamination as evidenced by the images below (Fig. 12 & 13) of a third batch of new, unused gaskets.



Figure 12 — New unused silicone gasket with surface contamination as supplied from the online retailer



Figure 13 — New unused silicone gasket with surface contamination as supplied from the online retailer

How traceability can protect against counterfeit seals

Due to being hard to detect, the best and most cost-effective method for combating counterfeit materials entering your supply chain is to avoid them in the first place. This is where traceability comes into play. Having clear visibility of your supply chain and being able to track and trace your seals greatly reduces the risk of counterfeiters being able to exploit any weaknesses.

Seal manufacturers must maintain accurate records of all aspects of the design, materials, manufacturing process and tests performed on their seal products. Therefore genuine seal manufacturers will be able to provide you with a complete history of that product, demonstrating traceability and compliance with government and industry standards.

Consider asking your seal and gasket manufacturer for a 3.1 certificate.

A 3.1 inspection certificate is a document in which the manufacturer declares that the delivered products are in accordance with the buyer's order. The declaration of compliance contains test results from a specific inspection on the products supplied. Tests are performed in accordance with official or technical regulations provided in the product specification.

The 3.1 certificate provides full details of the manufacturing batch, ensuring complete supply chain traceability. The test results also give buyer's proof that they are getting exactly what they ordered and the ability to identify any batch to batch variability.

In addition, if a seal manufacturer claims to be compliant with industry regulations such as FDA, 3A 18-03, EC 1935-2004, etc, they should be able to provide you with a certificate of conformity which will include a name, reference, batch and delivery number enabling you to identify the raw material.

Precision Polymer Engineering's elastomer seals meet various international sanitary standards and approvals including: -

- FDA
- USP Class VI
- 3A 18-03
- EC 1935-2004
- EC 2023-2006
- GB 4806.11-2016
- WRAS

Traceability is an essential consideration when specifying seals, providing you with reduced variation in production processes and mitigating the risk of allowing counterfeit materials into your supply chain.

Conclusions

The growing issue of counterfeit sealing materials is having major implications for the safety and reliability of food and pharmaceutical process lines. These seals are typically of poor quality, frequently damaged, and often well outside the international standards on inner and outer dimensions. While they can appear functional at first glance, these counterfeit materials are extremely susceptible to failure, resulting in operational downtime, equipment damage and carrying significant financial and reputational cost to the operator, but most importantly, health risk to end consumers. Operators can manage this risk by ensuring that their seal and gasket manufacturers supply 3.1 certification, providing full supply chain traceability.

Precision Polymer Engineering (PPE) manufactures sealing components which meet customer requirements, as well as all statutory and regulatory requirements. From standard O-rings to HyClamp[™] hygienic gaskets for food and pharmaceutical pipe couplings, every sealing component from PPE has been manufactured to the highest quality standards, with full traceability and 3.1 certification if required - protecting the reliability of your operations, and the safety of vour end consumers. For further information about PPE sealing products, or advice on protecting your business from counterfeit materials, visit www.prepol.com or call +44 (0)1254 295400.

Watch video: <u>https://www.prepol.com/video-</u> webinar-library/hygienic-elastomer-sealtraceability

HyClamp[™] is a trademark of Precision Polymer Engineering



PPE's HyClamp™ gaskets are available with full manufacturing traceability.



Hygienic gaskets are important sealing components for pipe couplings in food and pharmaceutical applications

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TP00131-23



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