Living Up To The Standards

SANITARY AODD PUMPS AND DIAPHRAGMS FROM WILDEN® OFFER THE DESIGN AND OPERATIONAL ADVANTAGES TO MEET THE STRINGENT 1935/2004/EC STANDARDS FOR THE FOOD-PROCESSING INDUSTRY



Strict 1935/2204/EC regulations mean that food processors must take extreme care when selecting the equipment used to create their products. This includes the pumping equipment used extensively throughout the food-production process.

Over the years, a number of standards and compliance requirements have been established for the food-processing industry by different regulatory agencies around the world. For any product going onto grocery store shelves and restaurant menus, food processors must satisfy the "alphabet soup" standards handed down from organizations such as the U.S. Food and Drug Administration (FDA); 3-A Sanitary Standards, Inc., (3-A); and the European Hygienic Engineering and Design Group (EHEDG). In addition, food processors must also comply with standards and regulations imposed by individual countries or governmental entities.

While originally established to protect the public against the distribution of contaminated food that could spread foodborne illness, these regulatory agencies also serve to safeguard food manufacturers. Food product that becomes contaminated during production, but still makes it to market and causes a food-borne illness, can result in a product recall. Product recalls are a food processors worst fear because they can be catastrophic not only in terms of lost product and associated costs, but also in the reparations that must be made to injured parties and the damage to company reputation or brand that can lead to the loss of market share. Furthermore, in the most severe cases, the processor may be forced to cease operations.

European Commission Regulation No. 1935/2004

The European Commission is the executive body of the European Union, a political-economic conglomeration of 28 countries located primarily in Europe. Headquartered in Brussels, Belgium, the European Union was founded in 1993 to provide a standardized legal and economic system for the European community. The European Commission proposes legislation, enforces laws, sets objectives and implements policies for the European Union and its member states.

In 2004, the European Commission adopted Regulation No. 1935/2004, or 1935/2004/EC, that defines a general framework for materials and articles that come into contact with food during the production process. In addition to food-processing and storage equipment, the regulation includes all types of packaging, bottles (glass and plastic), cutlery, and even adhesives and inks for printing labels.

For food processors, the critical provision of 1935/2004/ EC states that the materials and articles coming into contact with food during the production process must not, under any circumstance, transfer substances to the food that can:

- Endanger human health
- Bring about an unacceptable change in the composition of the food
- Bring about a deterioration in the organoleptic characteristics of the food, i.e., they can't affect the appearance, smell or taste of the product

As a result, the strict 1935/2004/EC regulation requires that food or beverage processors ensure that the equipment used in the manufacturing process does not impart any adverse effects at any point in the process. Since pumps are used extensively in food-processing operations, any pump complying with the regulation must:

- Feature product-contact components that are constructed of materials that comply with the regulation and are traceable by heat, batch and lot numbers
- Not allow outside contaminants to enter the production cycle
- Comply with cleaning and sanitation procedures that are designed to meet hygienic requirements

The AODD Pump Solution

One of the primary pump types that has gained acceptance by the food-processing industry as a way to reliably satisfy 1935/2004/EC standards is the air-operated double-diaphragm (AODD) pump. This versatile positive displacement pump was invented in 1955 by Jim Wilden in an effort to create a pump tough enough to handle water, slurry and any other finely divided substances in diverse operating environments. Over the decades, Jim Wilden's company, Wilden® Pump & Engineering, Grand Terrace, CA, USA, a product brand of PSG®, Oakbrook Terrace, IL, USA, a Dover company, has pioneered the evolution of AODD pump technology. Today, Wilden offers AODD pumps that meet a wide range of compliance requirements in diverse industries, including those for sanitary and hygienic applications.

When it comes to selecting AODD pumps for the foodprocessing industry, Wilden Hygienic Series and FDA Series AODD pumps are an ideal choice because of their ability to efficiently pump a wide range of viscosities, solids and shear-sensitive products. Wilden Hygienic Series and FDA Series pumps are also self-priming, dry-run capable, submersible and intrinsically safe while providing superior product containment. To further enhance their operational benefits, Hygienic Series and FDA Series pumps are available with either the energyefficient Pro-Flo® SHIFT, flexible Pro-Flo X™ or durable ProFlo® Air Distribution System (ADS).



EC 1935/2004

While food manufacturers have a number of pump options that meet 1935/2004/EC requirements, Wilden® Hygienic Series and FDA Series AODD pumps provide significant advantages such as enhanced operational efficiency and superior product containment.

Engineered to Meet Stringent Requirements

The design of Wilden Hygienic Series and FDA Series pumps is critical to their compliance with 1935/2004/EC standards. Wilden Hygienic Series and FDA Series pumps cover ports from 13 mm (1/2") to 76 mm (3") with Triclamp™ connections for fast, easy disassembly. Additionally, the pump's hygienic design guarantees effective clean-in-place (CIP) and clean-out-of-place (COP) capabilities due to its various drainage possibilities.

To meet specific end-user needs and applications, Wilden offers two models designed for food applications: FDA Series and Hygienic Series. Wilden FDA Series pumps feature a 316 stainless-steel wetted path that fully complies with FDA CFR 21.177, ATEX, CE and 1935/2004/EC requirements. Wilden Hygienic Series pumps utilize a 316L stainlesssteel wetted path and an interior polish of Ra 0.8 µm (32 µin) for full compliance with an expansive list of certifications, including USP Class VI, 3-A, FDA CFR 21.177, ATEX, CE and 1935/2004/EC requirements.

Largest Selection of Compliant Diaphragms

Wilden also offers a wide selection of diaphragm materials that possess the ability to meet strict 1935/2004/EC standards. This extensive diaphragm selection makes it possible for end-users to choose the right diaphragm for their unique applications. Wilden offers the following diaphragm materials that comply with 1935/2004/EC standards:

Material	Temperature Range
Sanitary Buna-N	-12.2 to +82.2°C (+10 to +180°F)
Sanitary EPDM	-51.1 to +137.8°C (-60 to +280°F)
PTFE[1]	+4.4 to +104.4°C (+40 to +220°F)
Saniflex™	-28.9 to +104.4°C (-20 to +220°F)
Sanitary Wil-Flex™	-40 to +107.2°C (-40 to +225°F)

[1]Maximum temperature range of PTFE is limited by back-up material



The unique design of Pure-Fuse diaphragms from Wilden® help alleviate cleaning labor requirements and contamination concerns by eliminating product-trap areas that can harbor bacteria.

Advanced Diaphragm Technology for Extreme Cleanability

Diaphragm cleanability can also have a major positive impact on overall operations and maintaining a sanitary processing environment. The two primary types of diaphragms in use on AODD pumps that comply with 1935/2004/EC requirements are:

- **Conventional Diaphragms:**
  Conventional diaphragms are comprised of an inner piston, diaphragm and outer piston that secures the diaphragm. Unfortunately, this diaphragm configuration can create a product-trap area between the outer piston and the diaphragm. Bacteria and other contaminants can grow in this trap area and potentially compromise the product and system. To avoid this contamination, pumps with conventional diaphragms need to be disassembled and cleaned manually.

- **Pure-Fuse Full-Stroke Integral Piston Diaphragms:**
  To help alleviate contamination concerns while still allowing for effective automated cleaning, Wilden developed the Pure-Fuse diaphragm. Pure-Fuse combines food-grade plastics and elastomers with a stainless-steel core in a patented design that uses no adhesives or nylon fabric that can contaminate process fluids in the event of a breech. The result is a diaphragm that features an unbroken fluid-contact surface with no product-trap areas. This design also enables CIP capability, which results in lower labor costs, increased efficiency and, most important, reduced contamination risks.

An additional benefit of the Pure-Fuse diaphragm compared to other cleanable diaphragms is the use of a large integral piston and full-stroke shaft that enable greater efficiency. This full-stroke configuration allows the pump to achieve two times the dry vacuum when compared to shorter-stroke CIP-capable diaphragms that are typically constructed of PTFE.

Wilden Pure-Fuse diaphragms are constructed of 1935/2004/EC-compliant food-grade Wil-Flex™ (Santoprene™). This material features wide temperature limits, excellent flex life, high abrasion resistance and outstanding durability, even when handling acids, caustics and other aggressive fluids. As a result, Pure-Fuse diaphragms provide significant production efficiencies while still satisfying 1935/2004/EC requirements.

Conclusion

The 1935/2004/EC regulation sets understandably high standards in food and beverage production that require compliant technology and materials. While a food manufacturer has a number of pump options that meet these stringent requirements, Wilden AODD Hygienic Series and FDA Series pumps provide significant operational advantages. Specifically, FDA and Hygienic Series AODD pumps possess CIP/COP capabilities and the ability to pump products with varying viscosity, solids and shear-sensitivity levels. The Wilden Pure-Fuse diaphragm also enhances cleanability and operational efficiency by eliminating product-trap areas. These features make Wilden Hygienic Series and FDA Series AODD pumps the ideal choice for meeting strict sanitary and hygienic standards in the most energy-efficient and cost-effective manner possible.

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