

NEWMAN

SANITARY GASKET COMPANY

Products of integrity...from people of integrity.

PHARMACEUTICAL CLASS VI



www.newmangasket.com





Class VI Certification Means Substantial Savings for You

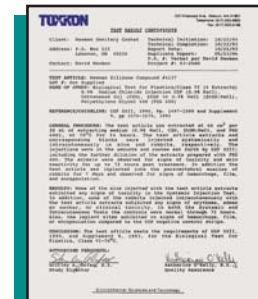
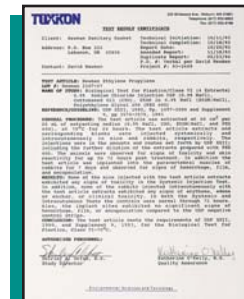
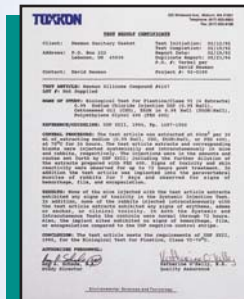
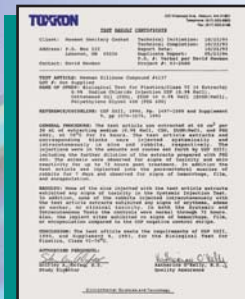
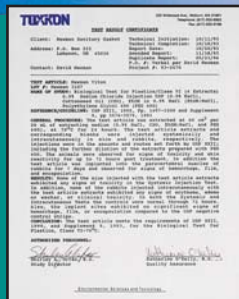
Established in 1973 David Newman set out to create the only company in the country dedicated to manufacturing FDA gaskets, "O"-rings and custom molded parts. Today, Newman continues to serve every element of the sanitary processing industries. Along with rubber-based compounds, we also produce Teflon® and Silicone components. With a 23,000 sq. ft. production facility, Newman has a full line of manufacturing equipment from transfer and compression presses, LIM injection molding and vertical injection presses, complete cleaning and finishing stations, inspection and shipping all under one roof for maximum efficiency.

Meet Standards of Excellence in Every Way

Newman parts are traceable through our process and meet the standards of the FDA Code of Federal Regulations, Title 21, Paragraph 177.2600, all classes of the 3-A Sanitary Standards, USP Class VI criteria and are accepted by the USDA. Our compounds are specifically formulated for companies requiring the highest sanitary standards and chemical purity. So you can be assured of the quality of each product's compound formulations. Our minimum standard has always been FDA specifications. Now the Company's goal for perfection brings USP Class VI certification to Newman's impressive portfolio of compounds. Newman has five compounds that have received Class VI Certification from Toxicon Laboratory in Woburn, Massachusetts, a federally bonded independent laboratory. These five compounds were found to be in compliance with the criteria of the U.S. Pharmacopeia, Class VI, Section <88> Biological Reactivity Test, in Vivo.

Meeting both FDA and USP criteria guarantees that the elastomer is acceptable for sanitary process applications and the elastomers, or extracts from the elastomers, will not be harmful to human health. Providing FDA conformance with new, or replacement components is an imperative minimum requirement.

Newman Sanitary Gasket Company offers you the experience and dedication of personnel committed to the integrity of their products. Newman is prepared to meet all standard and custom rubber compound requirements of the pharmaceutical and biotech industries.



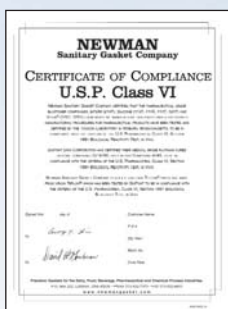
Quality Assurance and Product Development

All Newman Class VI components are shipped with a Class VI certificate and are packaged and identified with a batch number and a cure date, making them 100% traceable. All parts are inspected and carefully packaged to assure you the highest quality part in the industry today. For sanitary process applications, it is also important that elastomers conform to FDA requirements and meet testing specifications of USP Class VI. Without these conditions, validation of the processing system and product would be in jeopardy. Engineers have a good understanding of metals, particularly stainless steel, which has a long history in sanitary processing. Most biotechnology, pharmaceuticals, food and beverage products that go from process to packaging run through stainless steel tubing and pipe. To ensure that the trip down these paths occurs lead-free, fittings, valves and pumps have specialized elastomer seals or gaskets. These special sealing devices have all been selected to perform under the process conditions, along with the characteristics of the process media and the effects of cleaning-in-place and sterilization clearly in mind.

The critical role played by elastomer components tends to be overlooked despite the risks of plant stoppages, or worse, product contamination, when seals are improperly specified. Elastomers are included in the wetted components of most process systems, which means they come directly into contact with line media. The same level of crucial consideration given to specifying appropriate piping material should also be applied to seals and gaskets. In fact, the ultimate safety, applicability and reliability of the total plant process system depend on the understanding of elastomers.



Our laboratory is solely dedicated to the development of the ultimate in elastomers that meet the criteria of the FDA, USDA, 3-A Sanitary Standards, and USP Class VI.



Elastomer Use in Sanitary Process Applications

Material	Common Applications
Silicone	High purity. Temperatures service range to 450° F
Viton®	Resistant to chlorine cleaning agents, solvents and strong acids. Temperature service range to 400° F
EPDM	Pure waters, salts in water, dilute acids and alkalis low temp steam. Ozone resistant.





Platinum Cured Silicone Class VI "O"-Rings

Newman's USP Class VI Platinum Cured Silicone "O"-Rings are complimented with our Class VI EPDM (black or white/peroxide cured) and Viton® (black or white/bisphenol cured). Each "O"-Ring is identified with a batch number and a cure date, making them 100% traceable and come packaged in heat-sealed bags.

Silicone material is known for its standard of purity and non-leaching characteristics. Its ability to withstand many chemicals and combination of chemicals is the reason it is so popular with the pharmaceutical industry. Silicone has excellent low temperature flexibility. Available in clear and red Silicone. Rated -80°F to 400°F.



USP Class VI Extrusions & Cord

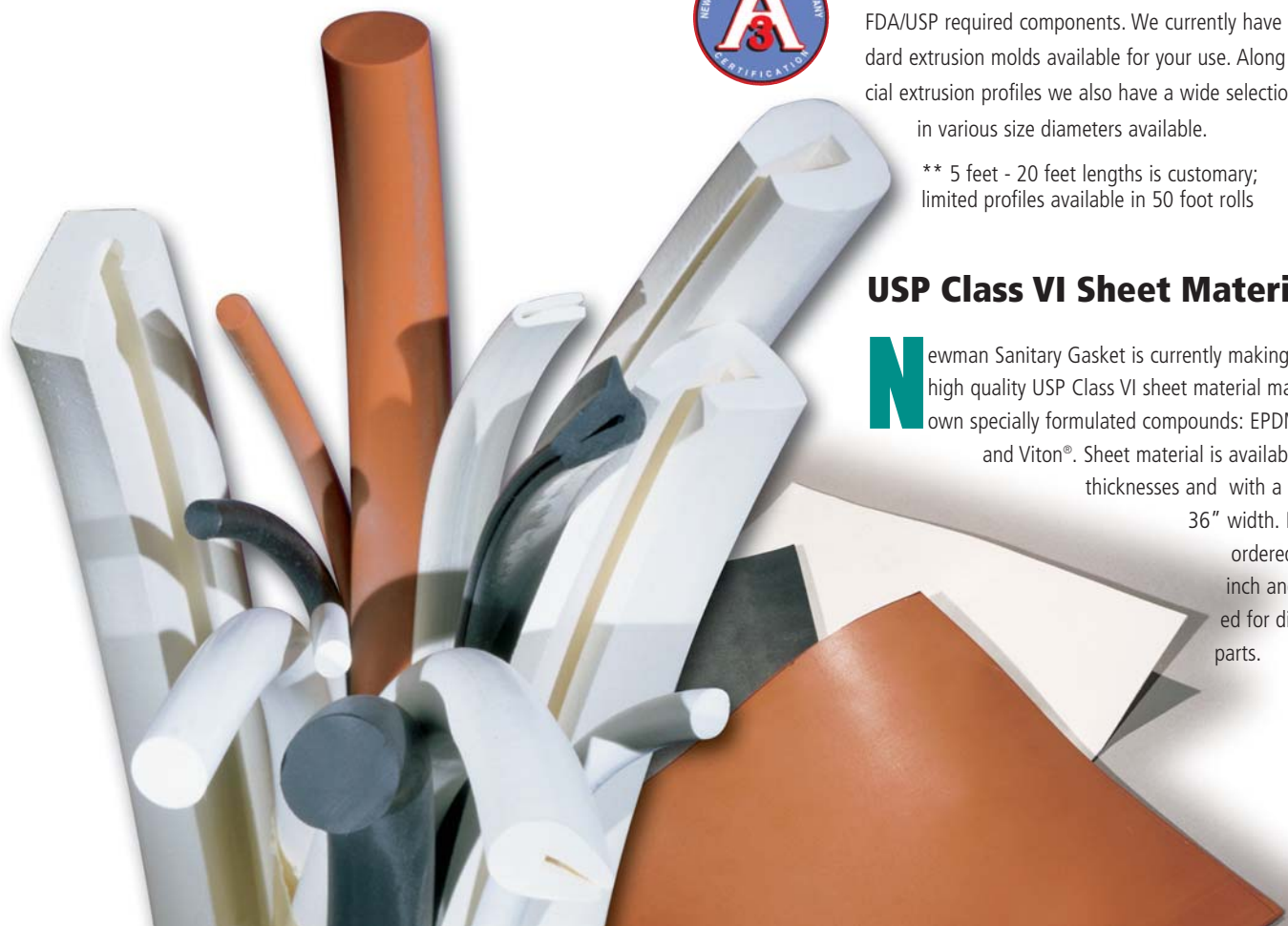
Newman's extrusion capabilities are available in straight lengths or in bonded shapes to form an endless component. Newman can extrude a custom profile (limited to 1" in diameter) from 2 feet to 50 feet** in length from our Silicone, Viton®, or EPDM compounds.

Custom extrusions can be made to your specifications in compounds that meet FDA, USDA, 3-A Sanitary Standards and USP Class VI certifications. Our specially formulated compounds make Newman your number one source for these superior FDA/USP required components. We currently have several standard extrusion molds available for your use. Along with our special extrusion profiles we also have a wide selection of cord stock in various size diameters available.

** 5 feet - 20 feet lengths is customary;
limited profiles available in 50 foot rolls

USP Class VI Sheet Material

Newman Sanitary Gasket is currently making available our high quality USP Class VI sheet material made from our own specially formulated compounds: EPDM, red Silicone and Viton®. Sheet material is available in various thicknesses and with a standard of 36" width. Material is ordered by the linear inch and is most suited for die cutting parts.



Custom Molding

Newman's custom molding group is able to develop and produce a broad range of products...products designed not only for the industries it now serves, but also for other sanitary applications.

Much of the custom molded work applies to processing systems and the manufacture of processing equipment. The materials used are much the same as the standard products which are Buna-N, Viton®, Silicon, EPDM and Teflon®.

All items are made to the customer's specifications by working closely with the customer to ensure proper fit and quality. Custom molding can vary from a small non-standard "O"-ring to a highly sophisticated rubber compound bonded to stainless steel, or a specific item needing just the right amount of resiliency to work efficiently on a given piece of equipment. Processing equipment manufacturers rely on Newman for their original and replacement rubber parts for countless uses in the pharmaceutical industry.

Each custom molded part is developed with your time-table in mind. With the highly skilled design engineer and the most efficient tooling costs, along with Newman's processing equipment experience working with FDA material where sanitary conditions are essential, the customer is assured the highest quality custom molded part in the industry today. Most importantly, it is provided at much less than the cost of other custom molders.

Class VI Compounds for Custom Molders

Newman will provide its Class VI compounds to qualified custom molders so you may upgrade to the highest standard of rubber compounds for your pharmaceutical customers and/or prospects. This is especially beneficial for pharmaceutical manufacturers already committed with tooling and who have long-standing business relationships with current suppliers.



Class VI "O"-Ring Kit for Glatt Nozzles

Newman "O"-Ring Kits for Glatt Nozzles are made from our exclusive U.S. Pharmaceutical Class VI certified, EPDM or Viton® elastomers. Each "O"-Ring is hand finished and inspected to assure the finest in quality. Each "O"-Ring kit is identified with a batch number and a cure date, making them 100% traceable.

Newman has more than 30 years of expertise in the Pharmaceutical/Medical rubber-manufacturing field. We will satisfy your most rigid requirements and deliver a high quality "O"-Ring kit to you at substantial savings.

Doing business with Newman means:

- Dependable delivery
- Blanket order "always stocked" inventory
- "Just in time" delivery reduces your inventory expenses
- Inventory for all standard sizes
- Custom packaging
- Sterile packaging available
- 100% inspection, flash-free parts guaranteed
- Customer tooling to meet your requirements
- Longevity of product life
- Custom molded products designed to position parting lines out of conflict with product contact areas
- Traceability through each product being labeled with batch number, compound, and cure date listed on every Newman package
- USP Class VI, FDA, USDA, and 3-A Sanitary Standard certification can accompany every order.



Certificate # 3Y401-1

NEW PRODUCTS



USP Class VI Silicone Dust Covers

Eliminates pill dust from escaping into the plant atmosphere making it a safer place for your employees.

- meets USP Class VI certification
- money saving



Teflon® Encapsulated Gaskets

Standard Tri-Clamp style gaskets can now be Teflon® encapsulated for special hygienic applications.

- available in EPDM, Viton® and Platinum Cured Silicone
- higher heat resistant
- perfect for every application
- meet USP Class VI certification



The I.D. TAG Identification System

ID Tag System for process piping maintenance programs.

- ideal for maintenance schedules
- marked with batch and cure information with in-service date
- tear resistant Tyvek® material
- color coded - available in yellow, red, white, blue and green



The WEDGE

Eliminates over torqued clamps and intrusion of the gasket in the ID of the tubing without special clamps or torque wrenches.

- eliminates over tightening
- reduces maintenance downtime
- saves time and money with longer production runs
- superior cleaning capabilities
- meets the criteria of the FDA, USDA and 3-A

Join the many companies already using Newman products in pharmaceutical applications requiring USP Class VI certification.

NEWMAN

SANITARY GASKET COMPANY

P.O. Box 222, Lebanon, Ohio 45036 • Telephone 513-932-7379 • FAX 513-932-4493
www.newmangasket.com • e-mail: customer@newmangasket.com