



## ***Roettele Industries, Inc.***

### **Sterilization Compatibility & BSE/TSE Statement Silicone Discs, 19-0226-2 (D1000) & 19-0531-1 (D1100)**

May 4, 2026

Roettele Industries, Inc. hereby provides the following information regarding **silicone materials** used in the manufacture of **Silicone Discs, 19-0226-2 (D1000) & 19-0531-1 (D1100)**. This declaration is based on supplier certifications, material specifications, and industry-recognized performance characteristics of silicone elastomers.

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#### **Sterilization Compatibility**

Silicone elastomers are widely recognized for their excellent stability under sterilization conditions. Based on material characteristics, the following guidance is provided:

- **Gamma Irradiation:**  
Silicone materials are **compatible with gamma irradiation** and typically maintain functional performance under standard sterilization doses. Minor cosmetic changes (e.g., slight discoloration) may occur without affecting performance.
- **Autoclaving (Steam Sterilization):**  
Silicone materials are **highly resistant to repeated autoclave cycles** (typically 121°C–134°C) and are commonly used in applications requiring steam sterilization.
- **Ethylene Oxide (EtO):**  
Silicone materials are **compatible with ethylene oxide sterilization**. Adequate aeration is required to ensure removal of residual EtO per applicable standards.

**Note:** Final sterilization validation remains the responsibility of the end user based on application-specific conditions and regulatory requirements.

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*Manufacturer of Precision Non-metallic Gaskets & Washers*

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## ***Roettele Industries, Inc.***

### **BSE / TSE (Animal Origin) Statement**

Roettele Industries, Inc. confirms that the silicone materials used:

- Are **synthetic and inorganic in composition**
  - Do **not contain animal-derived ingredients**
  - Do **not contain bovine or porcine-derived substances**
  - Present **no risk related to Transmissible Spongiform Encephalopathy (TSE) or Bovine Spongiform Encephalopathy (BSE)**
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### **Regulatory Compliance**

Based on supplier documentation and internal compliance review, silicone materials supplied by Roettele Industries meet the following regulatory requirements:

- **RoHS (Directive 2011/65/EU & (EU) 2015/863):**  
Compliant; no restricted substances above allowable limits.
- **REACH (Regulation (EC) No. 1907/2006):**  
Compliant; Substances of Very High Concern (SVHC) are **not present above 0.1% w/w**.
- **California Proposition 65:**  
Does not intentionally contain listed substances above applicable Safe Harbor limits under normal conditions of use.
- **FDA Food Contact Compliance:**  
Complies with applicable sections of **U.S. FDA 21 CFR** for food-contact materials, where applicable.
- **USP Class VI:**  
Silicone materials meet **USP Class VI biological reactivity requirements**, suitable for use in medical and pharmaceutical applications.

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This declaration is provided in good faith based on information available at the time of issuance. Roettele Industries, Inc. will notify customers should material composition change in a manner that may affect regulatory compliance.

If additional documentation or product-specific declarations are required, please advise.

Sincerely,

Lance Roettele  
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