Roettele Industries, Inc.

Healthcare Grade Silicone
USP Class VI and ISO 10993 Certification

The following testing details pertain to the Grey Silicone used for part 19-0531-1.

ISO 10993 (Studied Performed):

- Cytotoxicity
- Hemolysis
- Pyrogenicity
- Sensitization
- Dermal Irritation
- Implantation (90 Days)

RESULT - The test items showed no relevant biological effects in the studies performance

USP Class VI (Studied Performed):

- Acute Systemic Toxicity (USP)
- Intercutaneous Toxicity (USP)
- Implant Test (USP)

RESULT - The test items showed no relevant biological effects in the studies performance

These typical physical properties are provided for evaluation information only.
It is up to the end-user to determine the appropriate material for the intended application.