



ElastaPro Silicone Sheeting

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HEALTHCARE GRADE SILICONE SHEETING

USP Class VI and ISO 10993 Certification

DESCRIPTION:

The following details testing as it pertains to ElastaPro Silicone Sheeting's, Healthcare Elastomers with the following part numbers, including suffixes COLOR-P and COLOR-L:

- ESS10HC
- ESS20HC
- ESS30HC
- ESS40HC
- ESS45HC
- ESS50HC
- ESS55HC
- ESS60HC
- ESS70HC

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)
- Intracutaneous Toxicity (USP)
- Implant Test (USP)

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

**NOTE: 4hr/400F post cure requirement for compliance for Peroxide Catalyzed Formulas (part numbers ending in -L).*

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.