



RENOLIT SOLMED

TECHNICAL DATA

COMPOUND	:	4301
PRODUCT	:	RENOLIT SOLMED GRANUFLEX
POLYMER	:	PE
MAIN APPLICATION AREAS	:	Injection molding, biotechnology systems

PHYSICAL PROPERTY*	DIMENSION	VALUE	PROCEDURE
Elastic Modulus	MPa	175	ASTM D-882
Density	g/cm ³	0.92	ASTM D-792
Melt flow rate	g/10 min.	22 (230°C, 2.16 kg)	ISO 1133
Shore-D hardness	-	45	ISO 868

Recommended sealing method	:	Heat
Recommended sterilization method	:	Gamma, ETO
Recommended maximum dose	:	25-40 kGy
Formulation characteristics	:	No animal derived components

Pharmacopoeia compliancy and biocompatibility	:	ISO 10993-4 Hemolysis ISO 10993-5 Cytotoxicity ISO 10993-6 Implantation test ISO 10993-10 Irritation and Sensitization tests ISO 10993-11 Acute Systemic Toxicity test USP <85> Bacterial Endotoxins – LAL test USP <88> Biological reactivity testing, in vivo, class VI USP <661> Plastic Containers European Pharmacopoeia tests, Ch. 3.1.5. Copies of the test reports are available upon request.
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2011/11

This technical information consists of typical product data and should not be used as a specification. All **RENOLIT SOLMED** film, tubing and compound materials can be stored for two years indoors under controlled environmental conditions and in the original closed containers. The ideal storage condition is 23 °C (73 °F) and 50% relative humidity in a well ventilated and dry facility. When ideal controlled environmental storage conditions are not possible, **RENOLIT SOLMED** materials should be stored in their original closed containers at temperatures between 0 - 40 °C (32 – 104 °F), relative humidity between 20 – 80% and protected from direct heat and sunlight (UV). Prior to the use of product exceeding 2 years in storage, it should be tested to confirm its usefulness for the intended application.

The data contained in this document are provided in good faith for the sake of general information. It is deemed to be accurate at the time of going into press. The purchaser or user is required to verify with our technical services whether any specific application is appropriate. Freedom of possession, use or marketing under intellectual rights or legal provisions or regulations, whether national or local, must be duly considered before use. Under no circumstances should any **RENOLIT SOLMED** film, tubing or compound be used in any cosmetic, reconstructive or any other temporary or permanent bodily implant application.