

# Degania Silicone

Revision: 3 Page 1 of 2 Date: March 24, 2005	SPECIFICATION FOR <b>SilClear™ Tubing</b>	Degania Silicone Ltd. Degania Bet 15130, Israel Tel: 972-4-6750533 Fax: 972-4-6709182
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## 1 Description

Silclear tubing is made of a medical grade peroxide cured silicone elastomer, offering high clarity combined with excellent physical properties.

## 2 Intended use

Silclear tubing can be used in a wide variety of applications. These include use within peristaltic pumps, including dialysis machines, blood and fluid handling equipment and feed lines.

## 3 Regulatory status

- 3.1 MDD 93/42/EEC Class I and IIa, CE 0473 certificate No. 065CE.
- 3.2 USA FDA 510(k) number K953864.

## 4 Product range

There are many standard sizes of Silclear tubing and custom sizes are available to order.

## 5 Physical properties

No:	Test	Unit	ASTM Std. No.	Die	Requirement	Tolerance
0	Color	-----	-----	----	Clear	-----
1	Hardness	Shore "A"	D 2240	----	58	+ - 5
2	Tensile Strength	N/mm <sup>2</sup>	D 412	C	9.0	Minimum
3	Elongation	%	D 412	----	350	Minimum
4	Tear Resistance	N/mm	D 624	C	19	Minimum
5	Modulus 50%	N/mm <sup>2</sup>	D 412	----	1.15	Minimum
6	Modulus 300%	N/mm <sup>2</sup>	D 412	----	4.7	Minimum

## 6 Biocompatibility

The materials used in the formulation of Silclear tubing were tested and approved to USP Class VI, ISO 10993 and the European Pharmacopoeia 3.1.9. The tubing is suitable for applications requiring constant contact with body tissue for up to 29 days.

## 7 Sterilization

Silclear tubing is usually supplied non-sterile. It is suitable for sterilization by Ethylene Oxide, Gamma radiation and Autoclave.

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## 8 Appearance, contamination

Silclear tubing is manufactured in an environmentally controlled clean area class 100,000. Refer to TAPPI chart for determining defects size:

Air bubbles greater than 1.0 mm<sup>2</sup> – no more than one per meter of tubing.

Surface blemishes greater than 2.0 mm<sup>2</sup> – no more than one per meter of tubing.

Embedded particles greater than 0.15 mm<sup>2</sup> - no more than one per meter of tubing.

## 9 Storage

The tubing will meet specifications for a period of 7 years from manufacturing date.

Product should be stored in ambient temperature, between 5-40°C and up to 80% relative humidity.

Rev.	Date	Approved By:	Description
1	30.8.95	I.A.	
2	29.9.97	I.A.	Change of tensile, elongation & tear
3	24.3.05	Omri Mairon	Add 8: Appearance, contamination
Signature:		<i>Omri Mairon</i>	<i>8.9.09</i>

Degania Silicone Ltd.  
Degania Bet 1518\*

# Degania Silicone

Degania Bet, 15130, Israel

Phone:+972-4675-0533

Fax:+972-4655-155

Website: [www.ds-il.com](http://www.ds-il.com)

Date: December 24, 2007

Re: **SilClear Tubing** part number 21108005

## Food contact approval

The above mentioned silicone rubber product is manufactured from medical grade raw material that complies to the FDA food grade regulation, CFR 177.2600.



Reuven Yunger  
QA / RA Manager  
Degania Silicone Ltd.