

Revision: 7 Page 1 of 2 Date: January 26, 2015	Technical Data Sheet <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 biocompatible grade silicone elastomer, offering high clarity combined with excellent physical properties. Reference number of tubing is # 211xxxxx, where xx- identifies different configurations/ sizes of tubing; reference number of silicone formula is # 8205209 or 8203285.

## 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

- a) CE certified
- b) FDA 510(k) # K953864.

## 4 Product range

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

## 5 Physical properties of silicone rubber

No:	Test	Unit	ASTM Std. No.	8205209	8203285
1	Color	-----	-----	Clear	Clear
2	Hardness	Shore "A"	D 2240	55-65	53-63
3	Tensile Strength	N/mm <sup>2</sup>	D 412	8.5	8.5
4	Elongation	%	D 412	500	350
5	Tear Resistance	N/mm	D 624	25	18

## 6 Regulatory overview

6.1. **ISO 10993:** SilClear tubing from 8205209 was tested and found to meet requirements of the following tests:

- a) ISO 10993- 5 : Cytotoxicity
- b) ISO 10993-6 : Implantation Study
- c) ISO 10993-3 : Mutation Study
- d) ISO 10993-10 : Irritation & Sensitization Study
- e) ISO 10993-11 : Acute toxicity

6.2. **USP class VI:** SilClear tubing from 8203285 was tested and found to meet requirements of the following tests:

- a) USP Acute Systemic Toxicity
- b) USP Intracutaneous Toxicity Study
- c) USP 7 day Implantation
- d) USP 30 day Implantation
- e) USP Pyrogen
- f) USP Cytotoxicity
- g) Ames Salmonella Mutagenicity (saline/DSMO)
- h) LAL
- i) Conforming to European Pharmacopoeia
- j) Delayed Contact Sensitization
- k) In Vitro Hemolysis

6.3. **Food contact:** SilClear tubing is in compliance with food grade regulation XV, Silicone of BfR (Germany) and FDA CFR 177.2600 (USA).

6.4. **European Chemical Agency (ECHA) Substances of Concern:** SilClear tubing does not contain any Substances of High Concerns (SVHC) as published by ECHA as of 20<sup>th</sup> July 2013.

6.5. **REACH and RoHS:** None of the substances restricted by REACH regulation and by RoHS Directive 2002/95/EEC are used in the manufacturing of SilClear tubing.

6.6. **Animal origins material: SilClear tubing** are free of any potential TSE (transmissible spongiform encephalopathy) and BSE (Bovine Spongiform Encephalopathy) agents.

6.7. **Absence of certain Substances and Chemicals:** None of the following substances are used in the manufacturing process of SilClear tubing:

- PVC
- Latex
- Polycarbonate
- BPA (Bisphenol A2)
- DEHP
- Benzyl Butyl Phthalate
- Dibutyl Phthalate
- Bis (2-methoxyethyl) Phthalate
- Di-isobutyl Phthalate
- Coltan and its derivative TANTALUM;
- Cassiterite and its derivative TIN;
- Wolframite and its derivative TUNGSTEN,
- Gold
- Lead (Pb ) and Derivatives
- Cadmium ( Cd ) and Derivatives
- Mercury ( Hg ) and Derivatives
- Hexavalent Chromium ( Cr VI ) and Derivatives
  
- Polybromobiphenyl ( PBB )
- Polybromodiphenylether ( PBDE )

**7. Working temperature.**

SilClear tubing may retain its properties at temperature from -40°C up to + 200 °C

**8. Shelf life.**

Shelf life of non-sterile tubing is seven years.  
Shelf life of sterile tubing is five years.

**9. Sterilization**

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

**10. 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.

**11. Storage**

Sterilized tubing will meet specifications for a period of 5 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	30/08/95	I.A.	Originated
2	29/09/97	I.A.	Change of tensile, elongation & tear
3	24/03/05	Omri Mairon	Add 8: Appearance, contamination
4	25/01/09	Zoya Lee	Change in Catalog Numbers
5	1/12/12	Zoya Lee	Change of tensile & tear
6	1/04/13	Zoya Lee	Update of silicone grade
7	26/01/15	Zoya Lee	Addition of 8205209 & Regulatory overview
Signature: 			