



**S.I.F.R.A. EST S.P.A.**  
 QUALITY CONTROL DEPARTMENT  
 APPROVED LABORATORY FOR APPLIED RESEARCH  
 (Reg. Aut. F.V.G. decr. 150/art. 10/250)

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**TECHNICAL DATA SHEET**

**SIFLEX<sup>®</sup> Medical Grade PVC Granulate**  
 Product code: SE0068EG

**NOTE:** Small color differences depend only on the color tone of the PVC resin.  
 This technical information consists of typical product data and should not be used as a specification.

**CHEMICAL SPECIFICATIONS**

Eur. Ph. Ed. in force

**FORMULATION**

- Not less than 55% of poly(vinyl chloride)
- Not more than 40% of di(2-ethylhexyl)phthalate
- Not more than 1% of zin octanoate (zinc 2-ethylhexanoate)
- Not more than 1% of calcium stearate or zinc stearate or 1% of a mixture of the two
- Not more than 1% of *N,N'* diacylethylenediamines (in this context acyl means in particular palmitoyl and stearoyl)
- Not more than 10% of one the following epoxidised oils or 10% or a mixture of the two
- Epoxidised soya oil of which the oxiran oxygen content is 6% to 8% and the iodine value is not greater than 6
- Epoxidised linseed oil of which the oxiran oxygen content is not greater than 10% and the iodine value is not greater than 7

**TEST**

- Alkalinity
- Acidity
- UV absorption
- Reducing Substances
- Residue on Evaporation
- Cadmiun
- Heavy Metals
- Appearance
- Tin
- Zinc
- Vinychloride
- Barium
- Calcium

**Limit Value**

- 1,0 ml HCl 0.01 M
- 1,5 ml NaOH 0.01 M
- 0,25 250/370nm
- 2,0 ml Na<sub>2</sub>S<sub>2</sub>O<sub>3</sub> 0.01 M
- 0,3 %
- 0,6 ppm
- 50,0 ppm
- Clear, colourless
- 20,0 ppm
- 0,2 %
- 1,0 ppm
- 5,0 ppm
- 0,0 %

**BIOLOGICAL REACTIVITY**

USP XXIV

**TEST**

- Test for Cytotoxicity
- Implantation Test in the Rabbit
- Hemolysis test
- Bacterial Endotoxins Test (LAL Test)

**VALUE**

- In Conformity
- In Conformity
- In Conformity
- In Conformity

**PHYSICAL PROPERTIES**

**TEST**

- Tensile strength at break
- Elongation at break
- Break at low temperature
- Shore "A" durometer hardness
- Density
- Water vapour trans. rate
- Oxygen permeability

**UNIT MEASURES**

- MPa
- %
- °C
- SH"A" (15"/23°C)
- gr/cm<sup>3</sup>
- gr/(mq\*day\*bar)
- cm<sup>3</sup>/(mq\*day\*bar)

**VALUE**

- 19
- 390
- 25° C
- 84 ± 2
- 1,23 ± 0.02
- 4,9 to 23°C
- 440 to 23°C

**PROCEDURE**

- ISO 527
- ISO 527
- ISO 458
- MAL 1-002
- MAL 1-001
- ASTM F-1249
- ASTM D-3985

Date: 20/10/2009 – revision: 10  
 Date of issued: 20/10/09  
 Signature:

Date of verification: 20/10/09  
 Signature:

Date of approval: 20/10/09  
 Signature:

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